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I

(Acts whose publication is obligatory)

COUNCIL REGULATION (EEC) No 2377/90

of 26 June 1990

laying down a Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 43 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 the use of veterinary medicinal products in food-producing animals may result in the presence of residues of foodstuffs obtained from treated animals;

Whereas as a result of scientific and technical progress it is possible to detect the presence of residues of veterinary medicines in foodstuffs at ever lower levels; whereas it is therefore necessary to establish maximum residue limits for pharmacologically active substances which are used in veterinary medicinal products in respect of all the various foodstuffs of animal origin, including meat, fish, milk, eggs and honey;

Whereas in order to protect public health, maximum residue limits must be established in accordance with generally recognized principles of safety assessment, taking into account any other scientific assessment of the safety of the substances concerned which may have been undertaken by international organizations, in particular the Codex Alimentarius or, where such substances are used for other purposes, by other scientific committees established within the Community;

Whereas the use of veterinary medicinal products plays an important part in agricultural production; whereas the establishment of maximum residue levels will facilitate the marketing of foodstuffs of animal origin;

Whereas the establishment of different maximum residue levels by Member States may hinder the free movement of foodstuffs and of veterinary medicinal products themselves;

Whereas it is therefore necessary to lay down a procedure for the establishment of maximum residue levels of veterinary medicinal products by the Community, following a single scientific assessment of the highest possible quality;

Whereas the need for the establishment of maximum residue levels throughout the Community is recognized in the Community rules relating to trade in foodstuffs of animal origin;

Whereas provisions must be adopted with a view to the systematic establishment of maximum residue levels for new substances capable of pharmacological action intended for administration to food-producing animals;

Whereas arrangements must also be made for the establishment of maximum residue levels for substances which are currently used in veterinary medicines administered to food-producing animals; whereas, however, in view of the complexity of this matter and the large number of substances involved, long transitional arrangements are required;

Whereas, after scientific assessment by the Committee for Veterinary Medicinal Products, maximum residue levels must be adopted by a rapid procedure which ensures close cooperation between the Commission and the Member States through the Committee set up under Council Directive 81/852/EEC of 28 September 1981 on the approximation of the laws of the Member States relating to analytical, pharmaco-toxicological and clinical standards and protocols in respect of the testing of veterinary medicinal products (4), as last amended by Directive 87/20/EEC (5); whereas an urgent procedure is also required to ensure the swift review of any tolerance which might prove insufficient to protect public health;

(1) OJ No C 61, 10. 3. 1989. p. 5.
(2) OJ No C 96, 17. 4. 1990, p. 273.
(3) OJ No C 201, 17. 8. 1989, p. 1.
(4) OJ No L 317, 6. 11. 1981, p. 16.
(5) OJ No L 15, 17. 1. 1987, p. 34.

Whereas medicinally induced immunological responses are usually indistinguishable from those which arise naturally, and do not affect consumers of food of animal origin;

Whereas the information necessary to assess the safety of residues should be presented in accordance with the principles laid down by Directive 81/852/EEC,

HAS ADOPTED THIS REGULATION:

Article 1

1. For the purposes of this Regulation, the following definitions shall apply:

(a) 'residues of veterinary medicinal products': means all pharmacologically active substances, whether active principles, excipients or degradation products, and their metabolites which remain in foodstuffs obtained from animals to which the veterinary medicinal product in question has been administered;

(b) 'maximum residue limit': means the maximum concentration of residue resulting from the use of a veterinary medicinal product (expressed in mg/kg or µg/kg on a fresh weight basis) which may be accepted by the Community to be legally permitted or recognized as acceptable in or on a food.

It is based on the type and amount of residue considered to be without any toxicological hazard for human health as expressed by the acceptable daily intake (ADI), or on the basis of a temporary ADI that utilizes an additional safety factor. It also takes into account other relevant public health risks as well as food technology aspects.

When establishing a maximum residue limit (MRL), consideration is also given to residues that occur in food of plant origin and/or come from the environment. Furthermore, the MRL may be reduced to be consistent with good practices in the use of veterinary drugs and to the extent that practical analytical methods are available.

2. This Regulation shall not apply to active principles of biological origin intended to produce active or passive immunity or to diagnose a state of immunity used in immunological veterinary medicinal products.

Article 2

The list of pharmacologically active substances used in veterinary medicinal products in respect of which maximum residue limits have been established shall be contained in Annex I, which shall be adopted in accordance with the procedure laid down in Article 8. Except as provided for in Article 9, any amendments to Annex I shall be adopted in accordance with the same procedure.

Article 3

Where, following an evaluation of a pharmacologically active substance used in veterinary medicinal products, it appears that it is not necessary for the protection of public health to establish a maximum residue limit, that substance shall be included in a list in Annex II, which shall be adopted in accordance with the procedure laid down in Article 8. Except as provided for in Article 9, any amendments to Annex II shall be adopted in accordance with the same procedure.

Article 4

A provisional maximum residue limit may be established for a pharmacologically active substance used in veterinary medicinal products on the date of entry into force of this Regulation, provided that there are no grounds for supposing that residues of the substance concerned at the level proposed present a hazard for the health of the consumer. A provisional maximum residue limit shall apply for a defined period of time, which shall not exceed five years. That period may be extended once only in exceptional cases for a period not in excess of two years if that proves expedient for the completion of scientific studies in progress.

In exceptional circumstances, a provisional maximum residue limit may also be established for a pharmacologically active substance not previously used in veterinary medicinal products on the date of entry into force of this Regulation provided that there are no grounds for supposing that residues of the substance concerned at the limit proposed present a hazard for the health of the consumer.

The list of pharmacologically active substances used in veterinary medicinal products in respect of which provisional maximum residue limits have been established shall be contained in Annex III, which shall be adopted in accordance with the procedure laid down in Article 8. Except as provided for in Article 9, any amendments to Annex III shall be adopted in accordance with the same procedure.

Article 5

Where it appears that a maximum residue limit cannot be established in respect of a pharmacologically active substance used in veterinary medicinal products because residues of the substances concerned, at whatever limit, in foodstuffs of animal origin constitute a hazard to the health of the consumer, that substance shall be included in a list in Annex IV, which shall be adopted in accordance with the procedure laid down in Article 8. Except as provided for in Article 9, any amendments to Annex IV shall be adopted in accordance with the same procedure.

The administration of the substances listed in Annex IV to food-producing animals shall be prohibited throughout the Community.

Article 6

1. In order to obtain the inclusion in Annex I, II, or III of a new pharmacologically active substance which is:

— intended for use in veterinary medicinal products for administration to food-producing animals, and

— intended to be placed on the market of one or more Member States which have not previously authorized the use of the substance concerned in food-producing animals,

the person responsible for marketing shall submit an application to the Commission. The application shall contain the information and particulars referred to in Annex V and shall comply with the principles laid down in Directive 81/852/EEC.

2. After verifying within a period of 30 days that the application is submitted in correct form, the Commission shall forthwith submit the application for examination by the Committee for Veterinary Medicinal Products set up under Article 16 of Directive 81/851/EEC. The Committee shall appoint one of its members to act as rapporteur and to undertake an initial evaluation of the application.

3. Within 120 days of referral of the application to the Committee for Veterinary Medicinal Products, and having regard to the observations formulated by the members of the Committee, the Commission shall prepare a draft of the measures to be taken. If the information submitted by the person responsible for marketing is insufficient to enable such a draft to be prepared, that person will be requested to provide the Committee with additional information for examination. The rapporteur shall update the evaluation report to take account of the additional information received.

4. Within 90 days of receipt of the additional information referred to in paragraph 3, the Commission shall prepare a draft of the measures to be taken, which shall forthwith be communicated to the Member States and the person responsible for marketing. Within a further 60 days, the person responsible for marketing may, at his request, provide oral or written explanations for consideration by the Committee for Veterinary Medicinal Products. The Commission may, at the request of the applicant, extend this time limit.

5. Within a further 60 days the Commission shall submit the draft measures to the Committee for the Adaptation to Technical Progress of the Directives on the Removal of Technical Barriers to Trade in the Veterinary Medicinal Products Sector, set up under Article 2b of Directive 81/852/EEC, for the application of the procedure laid down in Article 8.

Article 7

1. Paragraphs 2 to 6 shall apply in respect of pharmacologically active substances which are authorized for use in veterinary medicinal products on the date of entry into force of this Regulation.

2. After consulting the Committee on Veterinary Medicinal Products, the Commission shall publish a timetable for the consideration of these substances, including time limits for submission of the information referred to in Annex V.

The persons responsible for marketing the veterinary medicinal products concerned shall ensure that all relevant information is submitted to the Commission in accordance with the requirements of Annex V and in conformity with the principles laid down in Directive 81/852/EEC before expiry of the relevant time limits. The competent authorities of the Member States shall bring any other relevant information to the attention of the Commission.

3. After verifying within 30 days that the information is submitted in correct form, the Commission shall forthwith submit the information for examination to the Committee for Veterinary Medicinal Products, which shall deliver its opinion within a renewable period of 120 days. That Committee shall appoint one of its members to act as rapporteur and to undertake an evaluation of the information.

4. Having regard to the observations formulated by the members of the Committee for Veterinary Medicinal Products, the Commission shall prepare, within a maximum period of 30 days, a draft of the measures to be taken. If the information submitted by the person responsible for marketing is insufficient to enable such a draft to be prepared, that person will be requested to provide additional information, within a specified period, for examination by the Committee. The rapporteur shall update the evaluation report to take account of the additional information received.

5. The draft of the measures to be taken shall be communicated forthwith by the Commission to the Member States and those persons responsible for marketing who have submitted information to the Commission before expiry of the time limit established in accordance with paragraph 2. These persons may, at their request, provide oral or written explanations to the Committee for Veterinary Medicinal Products.

6. The Commission shall forthwith submit the draft measures to the Committee for Adaptation to Technical Progress of the Directives on Veterinary Medicinal Products for the application of the procedure laid down in Article 8.

Article 8

1. Where the procedure laid down in this Article is to be followed, the chairman shall, without delay, refer the matter to the Committee for Adaptation to Technical Progress of the Directives on Veterinary Medicinal Products either on his own initiative or at the request of a representative of a Member State.

2. The representative of the Commission shall submit a draft of the measures to be adopted to the Committee for Adaptation to Technical Progress. The Committee shall deliver its opinion on the draft within a time limit set by the chairman, having regard to the urgency of the matter. It shall act by a qualified majority, the votes of the Member States being weighted as provided for 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 opinion of the Committee.

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

(c) If, after a period of three months of the proposal being referred to it, the Council has not acted, the proposed measures shall be adopted by the Commission, unless the Council has voted against them by a simple majority.

Article 9

1. Where a Member State, as a result of new information or a reassessment of existing information, considers that the urgent amendment of a provision contained in Annexes I to IV is necessary in order to protect human or animal health, and therefore requires swift action to be taken, that Member State may temporarily suspend the operation of the provision concerned in its own territory. In that case, it shall immediately notify the other Member States and the Commission of the measures, attaching a statement of the reasons therefor.

2. The Commission shall as soon as possible examine the grounds given by the Member State concerned and, after consulting the Member States within the Committee for Veterinary Medicinal Products, it shall then deliver its opinion forthwith and take appropriate measures; the person responsible for marketing may be requested to provide the Committee with oral or written explanations. The Commission shall immediately notify the Council and the Member States of any measures taken. Any Member State may refer the Commission's measures to the Council within 15 days of such notification. The Council, acting by a qualified majority, may take a different decision within 30 days of the date on which the matter was referred to it.

3. If the Commission considers that it is necessary to amend the provision of Annex I to IV concerned in order to resolve the difficulties referred to in paragraph 1 and to ensure the protection of human health, it shall initiate the procedure laid down in Article 10 with a view to adopting those amendments; the Member State which has taken measures under paragraph 1 may maintain them until the Council or the Commission has taken a decision in accordance with the abovementioned procedure.

Article 10

1. Where the procedure laid down in this Article is to be followed, the chairman shall, without delay, refer the matter to the Committee for Adaptation to Technical Progress of the Directives on Veterinary Medicinal Products either on his own initiative or at the request of a representative of a Member State.

2. The representative of the Commission 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, having regard to the urgency of the matter. It shall act by a qualified majority, the votes of the Member States being weighted as provided for 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 opinion of the Committee.

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

(c) If within 15 days of the proposals being submitted to it, the Council has not acted, the proposed measures shall be adopted by the Commission.

Article 11

Any changes which are necessary to adapt Annex V to take account of scientific and technical progress shall be adopted in accordance with the procedure laid down in Article 2c of Directive 81/852/EEC.

Article 12

As soon as possible after the amendment of Annexes I, II, III or IV, the Commission shall publish a summary of the assessment of the safety of the substances concerned by the Committee for Veterinary Medicinal Products. The confidential nature of any proprietary data shall be respected.

Article 13

Member States may not prohibit or impede the putting into circulation within their territories of foodstuffs of animal origin originating in other Member States on the grounds that they contain residues of veterinary medicinal products if the quantity of residue does not exceed the maximum residue limit provided for in Annex I or III, or if the substance concerned is listed in Annex II.

Article 14

With effect from 1 January 1997, the administration to food-producing animals of veterinary medicinal products containing pharmacologically active substances which are not mentioned in Annexes I, II or III shall be prohibited within the Community, except in the case of clinical trials

accepted by the competent authorities following notification or authorization in accordance with the legislation in force and which do not cause foodstuffs obtained from livestock participating in such trials to contain residues which constitute a hazard to human health.

Article 15

This Regulation shall in no way prejudice the application of Community legislation prohibiting the use in livestock farming of certain substances having a hormonal action.

Nothing in this Regulation shall prejudice the measures taken by Member States to prevent the unauthorized use of veterinary medicinal products.

Article 16

This Regulation shall enter into force on 1 January 1992.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Luxembourg, 26 June 1990.

For the Council
The President
M. O'KENNEDY

ANNEX I

List of pharmacologically active substances for which maximum residue levels have been fixed

(List to be established in accordance with the procedure laid down in Article 8)

ANNEX II

List of substances not subject to maximum residue levels

(List to be established in accordance with the procedure laid down in Article 8)

ANNEX III

List of pharmacologically active substances used in veterinary medicinal products for which maximum residue levels have been fixed

(List to be established in accordance with the procedure laid down in Article 8)

ANNEX IV

Lists of pharmacologically active substances for which no maximum levels can be fixed

(List to be established in accordance with the procedure laid down in Article 8)

ANNEX V

Information and particulars to be included in an application for the establishment of a maximum residue limit for a pharmacologically active substance used in veterinary medicinal products

1. *Administrative particulars*

1.1. Name or corporate name and permanent address of the person responsible for placing the veterinary medicinal product(s) on the market.

1.2. Name of the veterinary medicinal product(s).

1.3. Qualitative and quantitative composition in terms of active principles, with mention of the international non-proprietary name recommended by the World Health Organization, where such name exists.

1.4. Manufacturing authorization, if any.

1.5. Marketing authorizations, if any.

1.6. Summary of the characteristics of the veterinary medicinal product(s) prepared in accordance with Article 5a of Directive 81/851/EEC.

2. *Identity of substance*

2.1. International non-proprietary name.

2.2. International Union of Pure and Applied Chemistry (IUPAC) name.

2.3. Chemical Abstract Service (CAS) name.

2.4. Classification:
- therapeutic
- pharmacological.

2.5. Synonyms and abbreviations.

2.6. Structural formula.

2.7. Molecular formula.

2.8. Molecular weight.

2.9. Degree of impurity.

2.10. Qualitative and quantitative composition of impurities.

2.11. Description of physical properties:
- fusion point
- boiling point
- vapour pressure
- solubility in water and organic solvents expressed in g/l, with indication of temperature
- density
- spectra of refraction, rotation, etc.

3. *Toxicological studies*

3.1. Short-term toxicological studies.

3.2. Long-term toxicological studies.

3.3. Studies on reproduction.

3.4. Studies on teratogenicity.

3.5. Studies on mutagenicity.

3.6. Studies for carcinogenicity.

3.7. Studies of immunological effects.

3.8. Studies of microbiological effects.

3.9. Observations in humans.

3.10. Other biological effects.

4. *Metabolic and residue studies*

4.1. Absorption, distribution, excretion and biotransformations.

4.2. Determination of residues, including methods of residue analysis.

4.3. Existing maximum permitted residue levels.

5. *Conclusions*

5.1. Level causing no toxicological effect.

5.2. Estimate of temporary acceptable daily intake for man.

5.3. Estimate of maximum residue levels in food with the specification of the residue concerned.

5.4. Methods of routine analysis that may be used by the competent authorities for the detection of residues.

5.5. Further work or information:
— required
— desirable.

6. *References*

7. *Experts report*

II

(Acts whose publication is not obligatory)

COUNCIL

COUNCIL DIRECTIVE

of 26 June 1990

amending Directive 64/432/EEC as regards enzootic bovine leukosis

(90/422/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 43 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 Directive 88/406/EEC (4), which amends Directive 64/432/EEC of 26 June 1964 on animal health problems affecting intra-Community trade in bovine animals and swine (5), as last amended by Directive 89/662/EEC (6), lays down common health guarantees regarding enzootic bovine leukosis as applicable to certain categories of bovine animals intended for intra-Community trade which will apply from 1 July 1990;

Whereas Article 4 of Directive 88/406/EEC requires that proposals be made to lay down the criteria permitting a Member State or part of the territory of a Member State to be recognized as being free from enzootic bovine leukosis, the conditions to be implemented to guarantee the maintenance of such status and the rules applicable to trade conducted from such regions;

Whereas, from surveys carried out to date, it would appear that certain Member States and regions are free from enzootic bovine leukosis whereas it is necessary to define, on a Community basis, how these areas shall be defined and the conditions under which they shall be maintained as being free from enzootic bovine leukosis and the conditions in relation to trade;

Whereas it appears necessary that Member States be granted an additional period of time in order to conform to the requirements of Directive 64/432/EEC as thus amended,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Directive 64/432/EEC is hereby amended as follows:

1. Article 2 (s) is replaced by the following:

   '(s) "Enzootic bovine leukosis free herd" shall mean a herd which satisfies the conditions laid down in Annex G, Chapter I, section A.'

2. The following is added to Article 2:

   '(t) "enzootic bovine leukosis free Member State or region" shall mean a region or Member State which meets the requirements laid down in Annex G, Chapter I, section B.'

3. Article 3 (3) (e) is replaced by the following:

   '(e) in addition to the condition under (d), where they are over 12 months of age and come from a region or Member State which does not have enzootic bovine leukosis free status, have reacted negatively to an individual test carried out in accordance with Annex G, Chapter II, during the 30 days before they were loaded;'

(1) OJ No C 17, 24. 1. 1990, p. 11.
(2) OJ No C 113, 7. 5. 1990, p. 205.
(3) OJ No C 112, 7. 5. 1990, p. 31.
(4) OJ No L 194, 22. 7. 1988, p. 1.
(5) OJ No 121, 29. 7. 1964, p. 1977/64.
(6) OJ No L 395, 30. 12. 1989, p. 13.

4. The following paragraph is added to Article 3:

'15. By way of derogation from the requirements laid down in Annex G, Chapter I, section B (2), a Member State or region of a Member State declared enzootic bovine leukosis free within the meaning of Article 2 (t) may be authorized, in accordance with the procedure laid down in Article 12, to lower the inspection level in respect of animals more than two years of age provided that tests have shown that the following requirements are met:

— no case of enzootic bovine leukosis has been recorded in a proportion of one herd out of 10 000 for at least three years,

— all cattle which have reacted positively to an immuno-diffusion test have been slaughtered and the herd has remained subject to restrictions until re-establishment of its status pursuant to Annex G, Chapter I, C (1) or (2),

— all cattle slaughtered within the territory of that Member State or region have been submitted to a post mortem examination by an official veterinarian who must issue notification of all tumours with a view to laboratory examination.

If one of the conditions provided for in the first subparagraph ceases to be fulfilled — especially in the case provided for in Annex G, Chapter I, section C (3) — the Commission, after assessing the circumstances of the recrudescence of enzootic bovine leukosis, and if its assessment gives grounds for so doing, shall adopt a decision in accordance with the same procedure to rescind the derogation decision taken in respect of that Member State or region(s) of that Member State.'

5. In Article 8 (2), the second sentence of the second subparagraph is replaced by the following:

'However, such guarantees shall not be required upon the introduction of animals from an enzootic bovine leukosis free Member State, region or holding.'

6. The following subparagraph is added to Article 8a (1) (b):

'This test shall not be required in respect of animals from an enzootic bovine leukosis free Member State or region or holding.'

7. The present wording of Annex G becomes Chapter II of the said Annex; section A (2) (j) of Chapter II is replaced by the following:

'(j) Spain: Subdirrección general de sanidad animal. Laboratorio de sanidad y producción animal ALGETE (Madrid);'

8. The Annex to this Directive is incorporated as Chapter I of Annex G.

Article 2

In Articles 2 and 5 of Directive 88/406/EEC, '1 July 1990' is replaced by '1 July 1991'.

However, from 1 July 1990 to 30 June 1991, Member States which have thus qualified all or part of their herds are authorized — in order to maintain that qualification — to make introduction into enzootic bovine leukosis free herds subject, in respect of animals of the bovine species other than slaughter animals, to the following conditions:

(a) the animals must come from an enzootic bovine leukosis free herd; or

(b) the animals must have been born and raised in a herd in which all the bovine animals over 24 months of age at the time of the test and forming part of the bovine herd from which the animals come have reacted negatively during the last 12 months to a test carried out pursuant to Annex G.

Article 3

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive not later than 1 July 1990 as far as Article 2 is concerned and not later than 1 October 1990 as concerns the other provisions. They shall forthwith inform the Commission thereof.

Article 4

This Directive is addressed to the Member States.

Done at Luxembourg, 26 June 1990.

For the Council

The President

M. O'KENNEDY

ANNEX

'CHAPTER I

ENZOOTIC BOVINE LEUKOSIS FREE HERDS, MEMBER STATES AND REGIONS

A. **"Enzootic bovine leukosis free herd" means:**

1. a herd in which:

   (i) there is no evidence, either clinical or as a result of a test carried out in accordance with Chapter II, of any case of enzootic bovine leukosis and in which no such case has been confirmed in the previous two years, and

   (ii) all animals over 24 months of age have previously reacted negatively during the preceding 12 months to two tests carried out in accordance with this Annex, at intervals of at least four months, and

   (iii) following the tests referred to in (ii), there are only animals born in the herd, or which have come from an enzootic bovine leukosis free herd

   and in which, after qualification, the animals over 24 months of age have continued to react negatively to one of the tests carried out in accordance with Chapter II at intervals of three years and the conditions provided for in (i) and (iii) continue to be fulfilled;

2. a herd situated in an enzootic bovine leukosis free Member State or region.

B. **"Enzootic bovine leukosis free Member State or region" means:**

A Member State or a region, within the meaning of Article 2 (o), of that Member State

1. in which:

   (a) at least 99,8 % of the bovine herds are enzootic bovine leukosis free herds within the meaning of subparagraph (s),

   or

   (b) on the one hand, no case of enzootic bovine leukosis has been notified or confirmed in any way whatever in the five years preceding the date of notification of this Directive or in the last three years after that date, and, on the other hand, in the last two years:

      (i) random checks on a national scale carried out in accordance with Chapter II have been conducted over a period of two years on all the animals over 24 months of age in at least 10 % of herds, with negative results, and

      (ii) all animals over 24 months of age have undergone a test as provided for in Chapter II at least once, with negative results;

2. in which, having satisfied the conditions provided for in 1,

   (i) every year either a random sample with a confidence rating of 99 % has established that less than 0,2 % of the herds were infected or not less than 20 % of bovine animals over two years of age have reacted negatively to a test carried out in accordance with Chapter II, and

   (ii) the conditions set in A (1) continue to be fulfilled.

C. **Suspension of leukosis free status after an outbreak of the disease**

1. If an animal in an enzootic bovine leukosis free herd has reacted positively to one of the tests referred to in (ii), the enzootic bovine leukosis free status of the herd shall be suspended until the following measures have been taken:

   (i) the animal which has reacted positively, and, in the case of a cow, any calf it may have produced, must have left the herd for slaughter under the supervision of the veterinary authorities;

   (ii) the remaining animals have reacted negatively to a serological test carried out in accordance with Chapter II three months at least after elimination of the positive animal and any possible progeny thereof;

(iii) an epidemiological enquiry must be conducted and the herds linked epidemiologically to the infected herd must be subjected to the measures laid down in (ii);

However, the competent authority may grant a derogation from the obligation to slaughter the calf of an infected cow where it was separated from its mother after calving. In this case, the calf must be made subject to the requirements provided for in 2 (ii).

2. Where more than one animal from an enzootic bovine leukosis free herd has reacted positively, the leukosis free status of the herd shall be suspended until the following measures have been taken:

(i) the infected animals and, in the case of an infected cow, except in the event of a derogation granted by the competent authority pursuant to the second subparagraph of 1 (iii), their calves must be removed for slaughter under the supervision of the veterinary authorities;

(ii) the remaining animals — including, where such is the case, the calves of infected animals — of less than six months of age must, after identification, remain on the holding until they have satisfied the tests referred to in A (1) (ii);

(iii) the herd must remain under official supervision until the conditions provided for under A (1) (ii) and (iii) are again fulfilled;

(iv) an epidemiological enquiry must be conducted, and the herds linked epidemiologically to the infected herd must be subjected to the measures laid down in A (1) (ii);

3. If enzootic bovine leukosis is detected and confirmed in more than 0,2 % of herds in the region or Member State, leukosis free status of that region or Member State shall be suspended and, in addition to the measures provided for in paragraph 1 or 2, 20 % of the other herds in the region or Member State must, within the time limits stipulated in A (1) (ii), undergo one of the tests referred to in Chapter II.

Leukosis free status shall be re-established if, on completion of the measures provided for in the preceding points, the tests provided for therein have proved negative.'

COUNCIL DIRECTIVE

of 26 June 1990

amending Directive 85/511/EEC introducing Community measures for the control of foot-and-mouth disease, Directive 64/432/EEC on animal health problems affecting intra-Community trade in bovine animals and swine and Directive 72/462/EEC on health and veterinary inspection problems upon importation of bovine animals and swine and fresh meat or meat products from third countries

(90/423/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 43 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 Directive 85/511/EEC (4) introduced Community measures for the control of foot-and-mouth disease;

Whereas, in view of the completion of the internal market for 1 January 1993, it is necessary to amend the measures already taken at Community level to control foot-and-mouth disease in the entire Community; whereas it is essential that a uniform policy should be implemented throughout the Community;

Whereas a Commission study on control of foot-and-mouth disease has shown that the adoption of a non-vaccination policy for the Community as a whole would be preferable to a vaccination policy; whereas it has been concluded that a risk exists in the manipulation of virus in laboratories due to the possibility of escape to local susceptible animals and in the use of vaccine if inactivation procedures do not ensure its safety;

Whereas the Commission's study as regards a vaccination policy for the future has clearly shown that an official withdrawal of vaccination against the disease should be implemented from a given date and that such withdrawal should be accompanied by a policy of total slaughter and destruction (stamping out) of infected animals;

Whereas Commission Decision 88/379/EEC of 12 July 1988 coordinating rules laid down by Member States in application of Article 6 of Council Directive 85/511/EEC (5) has already provided for a minimum set of rules to be applied in all Member States when granting exceptions from total slaughter on an infected holding;

Whereas, in extreme situations where an epizootic disease threatens to become extensive, it may be necessary to have recourse to emergency vaccination; whereas it is necessary to lay down conditions under which this vaccination may be carried out;

Whereas the adoption of a uniform Community policy in the campaign against foot-and-mouth disease involves an adjustment of the rules governing intra-Community trade in live animals and the import, from third countries, of live animals and certain animal products;

Whereas financial support to Member States concerning slaughter, destruction and other emergency actions should be laid down in separate measures;

Whereas the functioning of the new measures must be kept under the review of the Commission, which shall report to the Council annually on their implementation,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Directive 85/511/EEC is hereby amended as follows:

1. Article 1 is replaced by the following:

   'Article 1

   This Directive defines the Community control measures to be applied in the event of outbreaks of foot-and-mouth disease, whatever the type of virus concerned.'

2. In Article 5:

   (a) in point 2, '(a) in Member States or regions where vaccination is prohibited' and the whole of point (b) are deleted;

   (b) in point 3 'shall not apply' is replaced by 'need not apply'.

(1) OJ No C 327, 30. 12. 1989, p. 84.
(2) OJ No C 113, 7. 5. 1990, p. 179.
(3) OJ No C 62, 12. 3. 1990, p. 44.
(4) OJ No L 315, 26. 11. 1985, p. 11.
(5) OJ No L 189, 20. 7. 1988, p. 25.

3. In Article 6:

(a) in the first subparagraph of paragraph 1, 'Article 5 (2) (a), first and second indents and (2) (b) (i)' is replaced by 'Article 5 (2), first and second indents';

(b) in the second subparagraph of paragraph 1, '(a)' is deleted;

(c) paragraph 2 is replaced by the following:

'2. When recourse is had to paragraph 1, Member States shall apply the measures specified in Commission Decision 88/397/EEC (*).

(*) OJ No L 189, 20. 7. 1988, p. 25.'

4. In Article 9:

(a) the last sentence of paragraph 1 is replaced by the following:

'The definition of zones shall take account of natural boundaries, supervision facilities and technological progress which make it possible to foresee the possible dispersion of the virus by air or any other means and will have to be reviewed, if necessary, in the light of such elements.'

(b) in paragraph 2 (a), the first indent is replaced by the two following indents:

'— a census of all the holdings with animals of susceptible species must be carried out,

— holdings which are the subject of such a census must periodically undergo a veterinary inspection,'.

5. In Article 11 (1), first and second indents, 'Annex' and 'Annex I' are replaced each time by 'Annex B'.

6. Article 13 is replaced by the following:

'Article 13

1. Member States shall ensure that:

— the use of foot-and-mouth vaccines is prohibited,

— the manipulation of foot-and-mouth virus for research, diagnosis and/or manufacture of vaccines shall be carried out only in approved establishments and laboratories listed in Annex A and B,

— the storage, supply, distribution and sale of foot-and-mouth vaccines on the territory of the Community are carried out under official control,

— the establishments and laboratories referred to in the second indent shall be approved only if they fulfil the minimum standards recommended by the FAO for laboratories working on foot-and-mouth viruses *in vitro* and *in vivo*.

2. Veterinary experts from the Commission, in collaboration with the competent authorities of the Member States, shall carry out spot-checks to ascertain whether the security systems applied in the establishments and laboratories referred to in Annexes A and B comply with the FAO's minimum standards.

The Commission shall carry out these checks at least once a year, the first of these checks being due before 1 January 1992, and shall submit, also before that date, an initial report to the Standing Veterinary Committee. The list of establishments and laboratories in Annexes A and B may be reviewed in the light of these checks by the Commission, in accordance with the procedure referred to in Article 17, by 31 December 1991. The list will be regularly updated in accordance with the same procedure.

In accordance with the same procedure, a decision may be taken to adopt a uniform code of good conduct for the security systems applied in the establishments and laboratories listed in Annexes A and B.

3. Notwithstanding the provisions of paragraph 1 concerning the use of foot-and-mouth disease vaccine, it may be decided, when foot-and-mouth disease has been confirmed and threatens to become extensive, that emergency vaccination using technical procedures guaranteeing the animals' total immunity may be introduced. In this case, the measures to be taken shall include:

— the extent of the geographical area in which emergency vaccination is to be carried out,

— the species and the age of the animals to be vaccinated,

— the duration of the vaccination campaign,

— a specific standstill of vaccinated animals and their products,

— the special identification and special registration of the vaccinated animals,

— other matters appropriate to the emergency situation.

The decision to introduce emergency vaccination shall be taken by the Commission in collaboration with the Member State concerned, acting in accordance with the procedure laid down in Article 16. This decision shall have particular regard to the degree of concentration of animals in certain regions and the need to protect special breeds.

However, by way of derogation from the first subparagraph, the decision to introduce emergency vaccination around the outbreak may be taken by the Member State concerned following notification to the Commission, provided that basic Community interests are not endangered. This decision shall be immediately reviewed in the Standing Veterinary Committee in accordance with the procedure laid down in Article 16.'

7. Article 14 is replaced by the following:

'Article 14

1. Pending the setting up of Community reserves of foot-and-mouth disease vaccine, Member States shall

be authorized to retain reserves of antigens in one of the establishments referred to in the Annexes.

For the purposes of the first subparagraph, contracts between the Commission and those responsible in the establishments designated by the Member States shall be concluded; the contracts will in particular specify the quantities of antigen doses necessary, taking account of the requirements estimated in the context of the plans referred to in Article 5 (1) of Directive 90/423/EEC (*), for a maximum of 10 serotypes.

After this transitional period, Member States shall be authorized under Community supervision to retain establishments for the packaging and storage of ready-to-use vaccines for emergency vaccination.

2. Before 1 April 1991, the Council, acting by a qualfied majority on a proposal from the Commission, shall designate a specialized institute for vaccine and cross-immunity checks and shall determine its powers.

3. Before 1 April 1991, the Commission shall submit to the Council a report accompanied, where appropriate, by proposals on the rules relating to the packaging, production, distribution and state of the stocks of anti-foot-and-mouth disease vaccines in the Community, together with proposals on the setting up of at least two Community reserves of anti-foot-and-mouth disease vaccines.'

(*) OJ No L 224, 18. 8. 1990, p. 13.

8. Article 15 is deleted.

9. Article 18 is replaced by the following:

'Article 18

On the basis of a report from the Commission on the experience gained in the application of this Directive, accompanied by proposals where appropriate, the Council shall review the situation within two years of the adoption of Directive 90/423/EEC (*).

(*) OJ No L 224, 18. 8. 1990, p. 13.'

10. An Annex, which shall be known as 'Annex A' and which appears in the Annex to this Directive, shall be added. The present Annex, entitled 'National Laboratories dealing with Foot-and-Mouth Disease', becomes Annex B.

Article 2

Article 4a of Directive 64/432/EEC (1), as last amended by Directive 89/662/EEC (2), is hereby amended as follows:

1. In the first subparagraph, in point 1:

(i) line 3 reads: '. . . which have not practised vaccination for at least 12 months and . . .';

(ii) B is replaced by the following:

'B. where the animal comes from a Member State which has, during the previous 12 months, practised prophylactic vaccination or has had recourse, in exceptional cases, to emergency vaccination on its territory';

(iii) the following subparagraph is added at the end of B and at the end of the first subparagraph of point 2:

'In this case, the aforementioned guarantees may be required for a period of 12 months after completion of the emergency vaccination operations.'

2. In the first subparagraph, in point 2, the introductory words are replaced by the following:

'2. Member States having recourse, in exceptional cases, to emergency vaccination on the whole of their territory and allowing vaccinated animals on to their territory shall make the introduction into their territory of live cattle subject to the following conditions:'

3. The following subparagraph is inserted before the last subparagraph:

'Where a Member State is authorized, in accordance with Article 13 (3) of Directive 85/511/EEC (*), as last amended by Directive 90/423/EEC (**), to have recourse to emergency vaccination on a limited part of its territory, the status of the remainder of the territory shall not be affected, providing that the immobilization measures for the vaccinated animals are effective during a period of 12 months following the end of the vaccination operations.

(*) OJ No L 315, 26. 11. 1985, p. 11.
(**) OJ No L 224, 18. 8. 1990, p. 13.'

Article 3

Directive 72/462/EEC (3), as last amended by Directive 89/662/EEC (4), is hereby amended as follows:

1. Article 6 is replaced by the following:

'Article 6

1. Without prejudice to Article 3 (1), Member States shall not authorize importation of animals covered by this Directive unless they come from third countries:

(a) which have been free of those diseases to which the animals are susceptible:

— for the previous 12 months, in respect of cattle plague, contagious pleuro-pneumonia, blue-tongue, African swine fever and contagious porcine paralysis (Teschen disease),

— for the previous six months, in respect of contagious vesicular stomatitis;

(b) in which, during the preceding 12 months, vaccination against the diseases referred to in the first indent of (a) to which these animals are susceptible has not been carried out.

(1) OJ No 121, 29. 7. 1964, p. 1977/64.
(2) OJ No L 395, 30. 12. 1989, p. 13.
(3) OJ No L 302, 31. 12. 1972, p. 28.
(4) OJ No L 395, 30. 12. 1989, p. 13.

2. Member States shall make the introduction into their territory of animals which are of a species susceptible to foot-and-mouth disease from the territory of a third country subject to the following conditions:

1. where the animals come from a third country which has been free of foot-and-mouth disease for at least two years, which has not practised vaccination for at least 12 months and which does not allow on to its territory animals which have been vaccinated less than one year previously, a guarantee that they have not been vaccinated against foot-and-mouth disease;
2. where the animals come from a third country which has been free of foot-and-mouth disease for at least two years, which practises vaccination and which allows vaccinated animals on to its territory:
   (a) a guarantee that the animals have not been vaccinated against foot-and-mouth disease;
   (b) a guarantee that the cattle have reacted negatively to a foot-and-mouth virus test carried out by the laryngo pharyngeal scrape method (probang test);
   (c) a guarantee that the animals have reacted negatively to a serological test carried out to detect the presence of foot-and-mouth antibodies;
   (d) a guarantee that the animals have been isolated in the exporting country at a quarantine station for 14 days under the surveillance of an official veterinarian. In this connection, no animal located at the quarantine station shall have been vaccinated against foot-and-mouth disease during the 21 days preceding exportation and no animal, other than those forming part of the consignment, shall have been introduced to the quarantine station during that same period;
   (e) placing in quarantine for a period of 21 days.
3. where the animals come from a third country which has not been free of foot-and-mouth disease for at least two years:
   (a) the guarantees referred to in point 2;
   (b) further guarantees to be decided on in accordance with the procedure laid down in Article 30.

For the purposes of this paragraph, a third country may continue to be considered as having been free of foot-and-mouth disease for at least two years, even if a limited number of outbreaks of the disease have been recorded on a limited part of its territory, on condition that such outbreaks were stamped out within a period of less than three months.

3. In accordance with the procedure laid down in Article 29:

(a) without prejudice to Article 3 (1), a list shall be adopted of the third countries which are authorized to export animals to the Community and which satisfy the requirements of paragraph 2;

(b) a list shall be adopted of the quarantine stations from which those countries may export animals to the Community; and

(c) a decision shall be taken on any further guarantees in relation to each such country.'

2. Article 14 is hereby amended as follows:

1. In paragraph 2 (a) the words 'exotic foot-and-mouth disease' are deleted.

2. The following paragraph is added:

'3. Without prejudice to Article 3 (1):

(a) the import of fresh meat from third countries in which:
   — foot-and-mouth disease (strains A, O, C) is endemic,
   — systematic slaughtering is not carried out where an outbreak of foot-and-mouth disease occurs,
   — vaccination is practised,

shall be permitted only under the following conditions:
   (i) the third country or a region within the third country is approved under the procedure laid down in Article 29;
   (ii) the meat is matured, its pH controlled, deboned and the major lymphatic glands removed.

The import of offals for human consumption shall be restricted, taking into account expert scientific opinion. Special conditions may be possible for offals for the pharmaceutical and petfood industry. These restrictions and conditions shall be adopted according to the procedure laid down in Article 29.

(b) The import of fresh meat from third countries in which vaccination against foot-and-mouth disease strains SAT or ASIA 1 is used shall be permitted only under the following conditions:
   (i) the third country has regions where vaccination is not permitted and no foot-and-mouth disease has occured for 12 months; the regions shall be approved under the procedure laid down in Article 29;
   (ii) the meat is matured, deboned, and the major lymphatic glands have been removed, and is not imported until 3 weeks after slaughter;
   (iii) the importation of offal from these countries is not permitted.

(c) the import of fresh meat from third countries
   — in which vaccination is practised, and
   — which have been free of foot-and-mouth disease for 12 months

shall be permitted in accordance with conditions established under the procedure laid down in Article 29.

(d) the import of fresh meat from third countries in which:

— routine vaccination is not carried out, and

— freedom from foot-and-mouth disease has been established

shall be permitted under the procedure laid down in Article 29 and in accordance with the rules governing intra-Community trade.

Additional rules which may apply to the countries referred to in (a) and (b) of the first subparagraph shall be established in accordance with the procedure laid down in Article 29.'

Article 4

1. Member States which practise prophylactic vaccination in the whole or part of their territory shall forego vaccination by 1 January 1992 at the latest and shall prohibit, from the date on which they stop vaccination, vaccinated animals from being introduced into their territory.

2. However, paragraph 1 shall take effect on the date of the application of the decisions referred to in Article 14 (3) of Directive 85/511/EEC and Article 23 (1) of Directive 90/425/EEC in respect of live animals and animal products which are susceptible to foot-and-mouth disease.

3. If the decisions referred to in paragraph 2 have not been adopted by 30 June 1991, the Commission will make the necessary proposals.

Article 5

1. Each Member State shall draw up a plan of warning, specifying the national measures to be implemented in the event of an outbreak of foot-and-mouth disease.

This plan should allow access to the plant, equipment, personnel and all other appropriate materials necessary for the rapid and efficient eradication of the outbreak. It must give a precise indication of the vaccine requirements which each Member State concerned considers it needs in the event of the reinstatement of emergency vaccination.

2. The Commission shall, in accordance with the procedure in Article 16 of Directive 85/511/EEC, lay down by 31 December 1990 the criteria to be applied for drawing up plans.

3. Plans drawn up in accordance with the criteria provided for in paragraph 2 shall be submitted to the Commission by 31 December 1991.

4. The Commission shall examine the plans in order to determine whether they permit the desired objective to be attained and shall suggest to the Member State concerned any amendments required in particular to ensure that they are compatible with those of the other Member States.

The Commission shall approve the plans, if necessary amended, in accordance with the procedure laid down in Article 16 of Directive 85/511/EEC.

The plans may subsequently be amended or supplemented, in accordance with the same procedure, to take into account developments in the situation.

5. The Commission may, in accordance with the procedure laid down in Article 6 of Directive 82/894/EEC, establish, by way of derogation from Article 3 (1) thereof, an early warning system for informing the Commission and the other Member States of outbreaks of foot-and-mouth-disease.

Article 6

In order to take account of possible difficulties, in particular when recourse is had to Article 13 (3) of Directive 85/511/EEC, which might result from the transition from the arrangements which existed before the application of this Directive in one or more Member States to the arrangements established by this Directive, or where implementation of the plans provided for in Article 5 makes it necessary, the Commission may, in accordance with the procedure provided for in Article 16 of Directive 85/511/EEC, adopt appropriate measures for a maximum period of two years. In particular, without prejudice to Article 4 (a) of Directive 64/432/EEC, measures shall be adopted before 1 January 1991 in respect of the movement of animals not vaccinated during the course of the last 12 months.

Article 7

Before 1 January 1992, the Commission shall submit a report on the structure of the veterinary services in the Community.

Article 8

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive before 1 January 1992. They shall forthwith inform the Commission thereof.

Article 9

This Directive is addressed to the Member States.

Done at Luxembourg, 26 June 1990.

For the Council

The President

M. O'KENNEDY

ANNEX

'ANNEX A

Member State	Establishments	
	Public	Private
Belgium	Uccle	—
Denmark	Lindholm	—
Germany	—	Cooper Behringwerke Bayer
Greece	Athens	—
France	LCRV Alfort	Rhône-Merieux
Ireland	—	—
Italy	Brescia Padua Perugia	—
Luxembourg	—	—
Netherlands	Lelystad	—
Portugal	—	—
Spain	Madrid	Cooper Hipra Sabrino
United Kingdom	—	Cooper'

COUNCIL DECISION

of 26 June 1990

on expenditure in the veterinary field

(90/424/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 43 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 live animals and products of animal origin appear on the list in Annex II to the Treaty; whereas livestock farming and the placing on the market of products of animal origin constitute a source of income for a large part of the agricultural population;

Whereas the rational development of this sector and an improvement in its productivity may be achieved by the initiation of veterinary measures aimed at protecting and raising the level of public and animal health in the Community;

Whereas the pursuit of that objective necessitates the provision of Community aid for actions undertaken or intended to be undertaken;

Whereas the Community is to adopt measures designed to establish the internal market progressively over a period expiring on 31 December 1992;

Whereas, within that framework, the Community should make a financial contribution towards the eradication, as quickly as possible, of any outbreak of a serious infectious disease;

Whereas it is also necessary to prevent and reduce, by appropriate control measures, the appearance of zoonoses which pose a threat to human health;

Whereas the new control strategy postulates the suppression of internal frontier controls and the harmonization of the control system for products coming from third countries; whereas it seems appropriate to facilitate the implementation of that strategy by providing for a financial contribution by the Community towards the initiation and the development of the new strategy;

Whereas the harmonization of essential requirements concerning the protection of public health, the protection of animal health and the protection of animals presupposes the designation of Community liaison and reference laboratories and the undertaking of technical and scientific actions; whereas it seems appropriate to provide for a Community financial contribution; whereas, in the field of animal protection in particular, it is desirable to create a database to gather, store and disseminate any information necessary;

Whereas Community measures for the eradication of certain animal diseases already qualify for financial aid from the Community; whereas the provisions concerned include those adopted by way of Council Directive 77/391/EEC of 17 May 1977 introducing Community measures for the eradication of brucellosis, tuberculosis and leucosis in cattle (4), as last amended by Regulation (EEC) No 3768/85 (5), Council Directive 82/400/EEC of 14 June 1982 amending Directive 77/391/EEC and introducing a supplementary Community measure for the eradication of brucellosis, tuberculosis and leucosis in cattle (6), as last amended by Regulation (EEC) No 3768/85, Council Decision 89/145/EEC of 20 February 1989 introducing a Community financial measure for the eradication of contagious bovine pleuropneumonia (CBPP) in Portugal (7), Council Decision 80/1096/EEC of 11 November 1980 introducing Community financial measures for the eradication of classical swine fever (8), as last amended by Decision 87/488/EEC (9), Council Decision 86/649/EEC of 16 December 1986 introducing a Community financial measure for the eradication of African swine fever in Portugal (10), as last amended by Decision 89/577/EEC (11), Council Decision 86/650/EEC of 16 December 1986 introducing a Community financial mesure for the eradication of African swine fever in Spain (12), Council Decision 89/455/EEC of 24 July 1989 introducing Community measures to set up pilot projects for the control of rabies with a view to its eradication or prevention (13); whereas it is advisable that financial contributions from the Community which are intended for the eradication of the diseases referred to above continue to be governed by the Decision relating thereto; whereas, nevertheless, as concerns the additional measure for the eradication of brucellosis, tuberculosis and leucosis in cattle, as provided for in Decision 87/58/EEC (14), there would appear to be justification, in the interests of consistency, for providing for the possibility

(1) OJ No C 84, 2. 4. 1990, p. 1.
(2) OJ No C 149, 18. 6. 1990.
(3) OJ No C 168, 10. 7. 1990, p. 5.
(4) OJ No L 145, 13. 6. 1977, p. 14.
(5) OJ No L 362, 31. 12. 1985, p. 9.
(6) OJ No L 173, 19. 6. 1982, p. 18.
(7) OJ No L 53, 25. 2. 1989, p. 55.
(8) OJ No L 325, 1. 12. 1980, p. 5.
(9) OJ No L 280, 3. 10. 1987, p. 26.
(10) OJ No L 382, 31. 12. 1986, p. 5.
(11) OJ No L 322, 7. 11. 1989, p. 21.
(12) OJ No L 382, 31. 12. 1986, p. 9.
(13) OJ No L 223, 2. 8. 1989, p. 19.
(14) OJ No L 24, 27. 1. 1987, p. 51.

of increasing the level of the Community's financial contribution up to 50 % of the costs incurred by Member States for the slaughter of cattle;

Whereas provision should be made for a Community financial measure for the eradication and monitoring of certain animal diseases; whereas all Community financial measures for the eradication and monitoring of animal diseases which involve compulsory Community budget expenditure should be brought together under one head;

Whereas it is appropriate to confer upon the Commission the task of taking the necessary applicatory measures,

HAS ADOPTED THIS DECISION:

Article 1

This Decision lays down the procedures governing the Community's financial contribution towards:

— specific veterinary measures,

— inspection measures in the veterinary field,

— programmes for the eradication and monitoring of animal diseases.

This Decision shall not affect the option enjoyed by certain Member States of being eligible for a financial contribution by the Community of more than 50 % under Council Regulation (EEC) No 2052/88 of 24 June 1988 on the Tasks of the Structural Funds and their effectiveness and on coordination of their activities between themselves and with the operations of the European Investment Bank and the other existing instruments (1).

TITLE 1

SPECIFIC VETERINARY MEASURES

Article 2

Specific veterinary measures shall include:

— emergency measures;

— the campaign against foot-and-mouth disease,

— measures for the protection of animals,

— contribution to national schemes for the eradication of certain diseases,

— technical and scientific measures.

(1) OJ No L 185, 15. 7. 1988, p. 9.

Chapter 1

Emergency measures

Article 3

1. The provisions of this Article shall apply in the event of the occurrence of one of the following diseases in the territory of a Member State:

— rinderpest cattle plague,

— sheep and goat plague,

— swine vesicular disease,

— blue tongue,

— Teschen disease,

— avian plague,

— sheep pox or goat pox,

— Rift Valley fever,

— lumpy skin disease,

— African horse sickness,

— vesicular stomatitis,

— Venezuelan equine viral encephalomyelitis.

2. The Member State concerned shall obtain a financial contribution from the Community for the eradication of the disease, on condition that the measures applied immediately comprise at least the isolation of the holding from the time of suspicion and, following official confirmation of the disease:

— the slaughter of animals of susceptible species which are affected or contaminated or suspected of being affected or contaminated, and their destruction, and, in the case of avian plague, destruction of the eggs,

— the destruction of contaminated feedingstuffs and contaminated equipment, where the latter cannot be disinfected in accordance with the third indent,

— the cleaning, disinsectization and disinfection of the holdings and of the equipment on the holdings,

— the establishment of protection zones,

— the imposition of suitable measures to prevent the risk of the spread of infection,

— the establishment of a waiting period to be observed after slaughter before re-stocking of the holding,

— swift and adequate compensation of the livestock farmers.

3. The Member State concerned shall, without delay, inform the Commision and the other Member States of the measures applied in accordance with Community legislation on notification and eradication and the results thereof. The situation shall be examined as soon as possible within the Standing Veterinary Committee, hereinafter referred to as the 'Committee', set up by Decision 68/361/EEC (2). The specific financial contribution by the Community shall be decided in accordance with the procedure laid down in

(2) OJ No L 255, 18. 10. 1968. p. 23.

Article 41, without prejudice to the measures provided for in the context of the common organization of markets concerned.

4. If, in view of the development of the situation in the Community, it proves necessary to continue the measures provided for in paragraph 2, a new decision concerning the financial contribution by the Community, which might exceed the figure of 50 % laid down in the first indent of paragraph 5, may be adopted in accordance with the procedure laid down in Article 40. When this decision is adopted, any measures which the Member State concerned must take in order to ensure the success of the action may be laid down, and in particular measures other than those mentioned in paragraph 2.

5. Without prejudice to market support measures to be taken as part of the common organization of markets, the financial contribution by the Community, divided if necessary into several tranches, must be:

— 50 % of the costs incurred by the Member State in compensating owners for the slaughter, destruction of animals and, where appropriate, their products, for the cleaning, disinsectization and disinfection of holdings and equipment and for the destruction of the contaminated feedingstuffs and contaminated equipment referred to in the second indent of paragraph 2,

— where vaccination has been decided upon in accordance with paragraph 4, 100 % of the cost of supply of the vaccine and 50 % of the costs incurred in carrying out that vaccination.

Article 4

1. Article 3 shall apply in the event of the occurrence of African swine fever or contagious bovine pleuropneumonia in the territory, or part of the territory, of a Member State which is not subject to an eradication plan for that disease in accordance with Community provisions.

2. In the event of the occurrence of Newcastle disease in the territory of a Member State, Article 3 shall apply.

However, except where the Commission takes a decision in accordance with the procedure provided for in Article 41, authorizing, on certain conditions and for a limited period and a limited area, recourse to vaccination, no financial contribution by the Community will be granted for the supply of the vaccine or the carrying out of the vaccination.

Article 5

1. In accordance with the procedure laid down in Article 41, the Commission, at the request of a Member State, shall add to the list in Article 3 (1) an exotic disease for which declaration is mandatory and which is likely to constitute a danger for the Community.

2. In accordance with the procedure laid down in Article 41, the list in Article 3 (1) may be supplemented in line with developments in the situation, to include diseases which must be notified in accordance with Directive 82/894/EEC and diseases which can be transmitted to fish, or amended or shortened, to take account of progress made with the measures decided at Community level to control certain diseases, classical swine fever in particular.

3. Article 3 (2) may be supplemented or amended in accordance with the procedure laid down in Article 41, in particular to take account of the inclusion of new diseases in the list in Article 3 (1), of experience acquired or of the adoption of Community provisions concerning disease control.

Article 6

1. Where a Member State is directly threatened by the occurrence or the development, in the territory of an adjacent third country or Member State, of one of the diseases referred to in Article 3 (1), 4 (1) and (2) or 11 (1), it shall inform the Commission and the other Member States of the measures which it intends to adopt for its protection.

2. As soon as possible, the situation shall be examined within the Committee referred to in Article 41. In accordance with the procedure laid down in that Article, it may be decided to adopt any measures appropriate to the situation including, in particular, the establishment of a vaccination buffer zone, and to grant a financial contribution by the Community towards the measures deemed particularly necessary for the success of the action undertaken.

3. The decision referred to in paragraph 2 shall set out the eligible costs and the level of the financial contribution by the Community.

Article 7

1. The Community may decide, at the request of a Member State, that the Member States should establish stocks of biological products intended for the control of the diseases referred to in Article 3 (1), Article 4 (1) (vaccines, standardized virus serotypes, diagnostic sera) and, without prejudice to the decision provided for in Article 14 (2) of Directive 85/511/EEC, Article 11 (1) of this Decision.

2. The action referred to in paragraph 1, and the rules for its implementation, particularly concerning the choice, production, storage, transport and use of such stocks, and the level of financial contribution by the Community, shall be decided in accordance with the procedure laid down in Article 41.

Article 8

1. If the occurrence or the development in a third country of one of the diseases referred to in Article 3 (1), 4 (1), 5 (1) or 11 (1) may constitute a danger to the Community, the Community may give its support to control measures against that disease by supplying vaccine or by financing the acquisition of vaccine.

2. The action referred to in paragraph 1, the rules for its implementation, the conditions to which it may be subject and the level of financial contribution by the Community shall be decided in accordance with the procedure laid down in Article 41.

Article 9

1. The Commission shall carry out, with the cooperation of the national competent authorities, on-the-spot checks to ensure, from a veterinary point of view, that the measures adopted have been applied.

2. Member States shall take all necessary steps to facilitate these checks, and shall, in particular, ensure that the experts have access to all information and documents necessary for assessing whether the measures have been carried out.

3. General rules for the application of this Article, particularly concerning the frequency and methods of carrying out the checks referred to in paragraph 1, the appointment of veterinary experts and the procedure which they must follow in drawing up their report, shall be adopted in accordance with the procedure laid down in Article 41.

Article 10

The appropriations required for measures as referred to in this chapter shall be decided each year as part of the budgetary procedure.

Chapter 2

The campaign against foot-and-mouth disease

Article 11

1. The provisions of this Article shall apply in the event of the occurrence of foot-and-mouth disease in the territory of a Member State.

2. The Member State concerned shall obtain a financial contribution from the Community for the eradication of foot-and-mouth disease, on condition that the measures provided for in Article 3 (2) and the appropriate provisions of Council Directive 85/511/EEC of 18 November 1985 introducing Community measures for the control of foot-and-mouth disease [1], as amended by Directive 90/423/EEC [2], are applied immediately.

3. Article 3 (3) shall apply.

4. Without prejudice to the measures to be taken in the context of the common organization of the market to support the market, the specific financial contribution under this Decision shall be equal to 60 % of the costs incurred by the Member State in:

(a) compensating owners for:
  (i) the slaughter and destruction of animals,
  (ii) the destruction of milk,
  (iii) the cleaning and disinfection of holdings,
  (iv) the destruction of contaminated feedingstuffs and, where it cannot be disinfected, contaminated equipment,
  (v) losses incurred by farmers as a result of restrictions imposed on the marketing of livestock and pasture-fattened animals as a result of the reintroduction of emergency vaccination, in accordance with the penultimate subparagraph of Article 13 (3) of Directive 85/511/EEC;

(b) Where applicable, the transport of carcases to processing plants;

(c) any other measures which are essential for the eradication of the outbreak of the disease.

The Commission shall, in accordance with the procedure provided for in Article 41, define the nature of the other measures referred to in (c) which may be eligible for the same financial contribution by the Community and the cases in which point (a) (v) shall apply.

5. For the first time not later than 45 days after official confirmation of the first outbreak of foot-and-mout disease, and subsequently as and when required by the turn of events, the situation shall be re-examined within the Committee referred to in Article 42. This examination shall cover both the veterinary situation and the estimated expenditure already incurred or committed. Following this examination, a new decision concerning the financial contribution by the Community, which may exceed the figure of 60 % laid down in paragraph 4, may be adopted in accordance with the procedure laid down in Article 42. This decision shall set out the eligible costs and the level of the financial contribution by the Community. In addition, when this decision is adopted, any measures which the Member State concerned must take in order to ensure the success of the action may be adopted, in particular measures other than those referred to in paragraph 2.

6. However, by way of derogation from paragraph 4, the specific financial contribution by the Community for the measures referred to in that paragraph shall be 70 % until 1 January 1995.

Article 12

Any measure decided by the Community to assist the campaign against foot-and-mouth disease outside the Community, in particular measures taken pursuant to Article 6 and 8, may receive a Community financial contribution.

Article 13

The measures and the rules for the implementation of the measures referred to in Article 12, the conditions to which they may be subject and the level of financial contribution by the Community shall be decided in accordance with the procedure laid down in Article 42.

(1) OJ No L 315, 26. 11. 1985, p. 11.
(2) See p. 13 of this Official Journal.

Article 14

Community aid may be granted to set up a Community reserve of anti-foot-and-mouth disease vaccines as provided for in Article 14 (2) of Directive 85/511/EEC.

The level of Community participation and the conditions to which such participation may be subject shall be determined in accordance with the procedure provided for in Article 42.

Article 15

The appropriations required for measures as specified in Articles 12, 13 and 14 shall be decided each year as part of the budgetary procedure.

Should a serious outbreak of foot-and-mouth disease necessitate expenditure under the provisions of this chapter in excess of the appropriations determined in accordance with the first subparagraph, the Commission will take the necessary measures within its existing powers or put forward to the budgetary authority the necessary proposals to ensure that the financial commitments in relation to Article 11 are fulfilled.

The measures provided for in Article 11 shall be considered as an intervention within the meaning of Article 3 (1) of Regulation (EEC) No 729/70.

Chapter 3

Protection of animals

Article 16

The Community shall make a financial contribution to the establishment of an information policy in the field of animal protection, including:

— the installation and development of a system, including an appropriate database for gathering and storing all information relating to Community legislation concerning the protection of animals kept for farming purposes, the protection of animals during transport and the protection of animals for slaughter, and for disseminating such information to the competent authorities, producers and consumers,

— the performance of studies necessary for the preparation and development of legislation in the field of animal protection.

Article 17

The measures referred to in Article 16, the rules for their implementation and the level of financial contribution by the Community shall be decided in accordance with the procedure laid down in Article 41.

Article 18

The appropriations required for measures as specified in this chapter shall be decided each year as part of the budgetary procedure.

Chapter 4

Technical and scientific measures

Article 19

The Community shall undertake, or assist the Member States in undertaking, the technical and scientific measures necessary for the development of Community veterinary legislation.

Article 20

The measures referred to in Article 23, the rules for their implementation and the level of financial contribution by the Community shall be decided upon in accordance with the procedure laid down in Article 41.

Article 21

The appropriations required for the measures provided for in this chapter shall be decided each year as part of the budgetary procedure.

TITLE II

Programme for the eradication and monitoring of animal diseases

Article 22

1. Community financial participation in the eradication of bovine brucellosis, tuberculosis and leucosis shall — without prejudice to the provisions of Article 25 (1) — be fixed by:

— Directive 77/391/EEC,

— Directive 82/400/EEC,

— Decision 87/58/EEC.

2. The Community financial contribution towards the eradication of bovine contagious pleuropneumonia shall be fixed by Decision 89/145/EEC.

Article 23

1. The Community financial contribution towards the eradication of classical swine fever shall be fixed by Decision 80/1096/EEC.

2. The Community financial contribution towards the eradication of African swine fever shall be fixed by:

— Decision 86/649/EEC,

— Decision 86/650/EEC,

— Council Decision 90/217/EEC of 25 April 1990 on Community financial aid for the eradication of African swine fever in Sardinia (1).

(1) OJ No L 116, 8. 5. 1990, p. 24.

3. The Community financial contribution towards the eradication of ovine brucellosis shall be fixed by Council Decision 90/242/EEC of 21 May 1990 introducing a Community financial measure for the eradication of brucellosis in sheep and goats (1).

4. The Community financial contribution towards the eradication of infectious hematopoeitic necrosis shall be fixed, before 31 December 1990, under a Council Decision introducing a Community financial measure for the eradication of infectious salmonid hematopoeitic necrosis in the Community.

Article 24

1. A Community financial measure shall be introduced for the eradication and monitoring of the diseases listed in the Annex. This list may be supplemented or amended in line with developments in the health situation in the Community on the basis of a decision of the Council, acting by a qualified majority on a proposal from the Commission.

2. Before 1 October 1990, the Council, acting by a qualified majority on a proposal from the Commission, shall lay down the Community criteria applicable to the measure referred to in paragraph 1. However, for diseases for which the Community has already laid down the Community criteria applicable to the measure to be taken, Member States may submit to the Commission a programme in accordance with paragraph 3 once notification of this Decision has been given.

3. When submitting a programme to the Commission, the Member State concerned shall supply all appropriate financial information and shall indicate in particular the total estimated annual cost of carrying out the programme. This programme, which may have been amended following the Commission's examination, shall be approved according to the procedure laid down in Article 41.

4. For each programme, the level of the Community's financial contribution, and any conditions to which it may be subject, shall be decided upon in accordance with the procedure laid down in Article 41.

5. Requests for payment shall apply to expenditure incurred by the Member State concerned during the calendar year and shall be submitted to the Commission before 1 July of the following year.

6. The Commission shall take a decision on the aid, after consulting the Committee.

7. The Commission shall make regular on-the-spot checks, with the cooperation of the national competent authorities, on the application of programmes receiving a financial contribution from the Community.

8. The Commission shall regularly, at least once a year, give information to the Member States within the Committee, on the basis of information supplied by the authorities of the Member States concerned, which shall make a detailed report to the Commission along with their requests for payment and, where applicable, on the basis of reports from experts who, having been appointed by the Commission and acting on behalf of the Community, have made on-the-spot inspections.

9. The detailed rules for the implementation of this Article shall be adopted in accordance with the procedure laid down in Article 41.

Article 25

1. Notwithstanding Articles 22, 23, and 24, the level of Community financial participation for programmes relating to the diseases referred to in the said Articles shall be fixed by the Commission, according to the procedure provided for in Article 41, at 50 % of the costs incurred in the Member State by way of compensation for owners for the slaughter of cattle because of the disease concerned.

2. At the request of a Member State, the Commission shall, within the Standing Veterinary Committee, re-examine the situation with regard to the diseases covered by Articles 22, 23 and 24. This re-examination shall cover both the veterinary situation and the estimate of expenditure already committed or to be committed. Following this re-examination, any new decision on the Community's financial contribution, which may be in excess of 50 % of the costs incurred in Member States to compensate owners for slaughtering animals for the disease concerned, shall be adopted in accordance with the procedure provided for in Article 42.

When this decision is adopted, any measures which the Member State concerned must take in order to ensure the success of the action may be adopted.

Article 26

Estimated annual aid chargeable to the Community budget under the chapter on agricultural expenditure is ECU 70 million for the measures provided for under this Title.

TITLE III

VETERINARY INSPECTION

Article 27

The Community shall contribute towards improving the efficiency of veterinary inspection by:

— granting financial aid to liaison and reference laboratories,

— making a financial contribution towards carrying out inspections aimed at the prevention of zoonoses,

(1) OJ No L 140, 1. 6. 1990, p. 123.

— making a financial contribution towards implementing the new inspection strategy consequent upon the completion of the internal market.

Chapter 1

Liaison and reference laboratories

Article 28

1. Any liaison or reference laboratory designated as such in accordance with Community veterinary legislation and fulfilling the duties and requirements laid down therein, may receive Community aid.

2. Arrangements for granting the aid provided for in paragraph 1, the conditions to which it may be subject and its amount, shall be determined in accordance with the procedure laid down in Article 41.

3. The appropriations required for the measures provided for in this chapter shall be decided upon each year as part of the budgetary procedure.

Chapter 2

Checks aimed at the prevention of zoonoses

Article 29

Once Community rules to control zoonoses have been introduced, Member States may, as part of a national plan to be approved by the Commission in accordance with the procedure laid down in Article 41, seek a financial contribution from the Community towards their control plan.

Article 30

When submitting its control plan to the Commission, the Member State concerned shall supply all appropriate financial information and shall indicate in particular the total estimated annual cost of carrying out the plan.

Article 31

For each national control plan, the level of financial contribution by the Community, and any conditions to which it may be subject, shall be determined in accordance with the procedure laid down in Article 41.

Article 32

For the purposes of this chapter, paragraphs 5 to 8 of Article 24 shall apply.

Article 33

The appropriations required for the measures laid down in this chapter shall be decided each year in the framework of the budgetary procedure.

Chapter 3

New control strategy

Article 34

1. Each Member State shall draw up a programme for exchanges of officials working in the veterinary sector.

2. Within the Committee, the Commission shall, along with the Member States, coordinate the programmes for exchange.

3. The Member State concerned shall take all the measures necessary for the implementation of the coordinated programmes for exchange.

4. Each year, on the basis of reports by the Member States, the implementation of the programmes for exchange shall be examined within the Committee.

5. Member States shall take account of experience acquired in order to improve and extend the exchange programmes.

6. Community financial aid may be granted with a view to promoting the smooth operation of exchange programmes notably through the further training courses referred to in Article 36 (1). The level of financial contribution by the Community, and any conditions to which it may be subject, shall be determined in accordance with the procedure laid down in Article 41.

7. For the purposes of this Article, Articles 20 and 21 shall apply.

Article 35

Article 34 (6) and (7) shall apply in respect of programmes to be established under the decision provided for in Article 19 of Council Directive 89/662/EEC of 11 December 1989 on the veterinary checks applicable in intra-Community trade with a view to the completion of the internal market [1], with a view to organizing veterinary inspections at external frontiers on products introduced into the Community from third countries.

Article 36

1. The Commission may, either directly or through the competent national authorities, organize refresher courses or meetings for personnel in the Member States, in particular, personnel responsible for the checks referred to in Article 35.

[1] OJ No L 395, 30. 12. 1989, p. 13.

2. Arrangements for organizing the measures provided for in paragraph 1 and the level of the Community's financial contribution shall be established by the Commission in accordance with the procedure laid down in Article 41.

Article 37

1. The introduction of systems for identifying animals and notifying diseases under legislation concerning veterinary checks in intra-Community trade in live animals, with a view to the completion of the internal market, may receive Community financial assistance.

2. Arrangements for organizing the measure provided for in paragraph 1 and the level of the Community's financial contribution shall be established by the Commission after consultation of the Committee.

Article 38

1. Should a Member State experience, from a structural or geographical point of view, staffing or infrastructure problems in implementing the new control strategy brought about by the completion of the internal market for live animals and products of animal origin, it may, for a transitional period, obtain Community financial assistance which is progressively reduced.

2. The Member State concerned shall submit to the Commission a national programme, accompanied by all the appropriate financial information, designed to improve its control system.

3. For the purposes of this Article, Article 24 (3) and 24 (5) to (8) shall apply.

Article 39

The appropriations required for measures provided for in this chapter shall be decided each year as part of the budgetary procedure.

TITLE IV

FINAL PROVISIONS

Article 40

Articles 8 and 9 of Council Regulation (EEC) No 729/70 of 21 April 1970 on the financing of the common agricultural policy (1), as last amended by Regulation (EEC) No 2048/88 (2), shall apply *mutatis mutandis*.

(1) OJ No L 94, 28. 4. 1970, p. 13.
(2) OJ No L 185, 15. 7. 1988, p. 1.

Article 41

1. Where the procedure laid down in this Article is to be used, matters shall without delay be referred by the chairman, either on his own initiative or at the request of a Member State, to the Committee.

2. The representative of the Commission shall submit to the Committee a draft of the measures to be taken. The Committee shall deliver its opinion on the draft within a time limit which the chairman may lay down according to the urgency of the matter. The opinion shall be delivered by the majority laid down in Article 148 (2) of the Treaty in the case of decisions which the Council is required to adopt on a proposal from the Commission. The votes of the representatives of the Member States within the Committee shall be weighted in the manner set out in that Article. The chairman shall not vote.

3. (a) The Commission shall adopt the measures envisaged if they are in accordance with the opinion of the Committee.

(b) If the measures envisaged are not in accordance with the opinion of the Committee, or if no opinion is delivered, the Commission shall, without delay, submit to the Council a proposal relating to the measures to be taken. The Council shall act by a qualified majority.

If, on the expiry of a period of three months from the date of referral to the Council, the Council has not acted, the Commission shall adopt the proposed measures and implement them immediately.

Article 42

1. Where the procedure laid down in this Article is to be used, matters shall without delay be referred by the chairman, either on his own initiative or at the request of a Member State, to the Committee.

2. The representative of the Commission shall submit to the Committee a draft of the measures to be taken. The Committee shall deliver its opinion on the draft within two days. The opinion shall be delivered by the majority laid down in Article 148 (2) of the Treaty in the case of decisions which the Council is required to adopt on a proposal from the Commission. The votes of the representatives of the Member States within the Committee shall be weighted in the manner set out in that Article. The chairman shall not vote.

3. (a) The Commission shall adopt the measures envisaged if they are in accordance with the opinion of the Committee.

(b) If the measures envisaged are not in accordance with the opinion of the Committee, or if no opinion is delivered, the Commission shall, without delay, submit to the Council a proposal relating to the measures to be taken. The Council shall act by a qualified majority.

If, on the expiry of a period of 15 days from the date of referral to the Council, the Council has not acted, the Commission shall adopt the proposed measures and implement them immediately.

Article 43

1. Council Decision 77/97/EEC of 21 December 1976 on the financing by the Community of certain emergency measures in the field of animal health (1), as last amended by Regulation (EEC) No 3768/85 is hereby repealed with effect from the date of notification of this Decision.

In accordance with the procedure laid down in Article 41, the Commission shall determine the arrangements for defraying the measures for vaccination against African horse sickness from 1 September 1989.

2. However, decisions adopted under Decision 77/97/EEC shall remain in force.

Article 44

This Decision is addressed to the Member States.

Done at Luxembourg, 26 June 1990.

For the Council

The President

M. O'KENNEDY

(1) OJ No L 26, 31. 1. 1977, p. 78.

ANNEX

DISEASE LIST

Group 1

Endemic diseases, subject to mandatory or voluntary control and/or eradication measures on a herd or flock basis

— Bovine tuberculosis
— Bovine brucellosis
— IBR/IPV (AI + embryo units)
— Ovine and caprine brucellosis (B. melitensis)
— Enzootic bovine leukosis (EBL)
— Aujeszky's disease
— Salmonella pullorum
— Salmonella gallinarum
— Anthrax
— Maedi/Visna and CAEV
— IBR/IPV (other types of enterprise)
— Johnes disease (paratuberculosis)
— Mycoplasma gallisepticum

Group 2

Zoonoses or epizootics not covered elsewhere

— Rabies
— Echinococcosis
— Bovine spongiform encephalopathy (BSE) or any other slow developing disease.

COUNCIL DIRECTIVE

of 26 June 1990

concerning veterinary and zootechnical checks applicable in intra-Community trade in certain live animals and products with a view to the completion of the internal market

(90/425/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 43 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 the Community is to adopt measures designed to establish the internal market progressively over a period expiring on 31 December 1992;

Whereas the harmonious operation of the common organization of the market in animals and products of animal origin implies the dismantling of zootechnical and veterinary barriers to the development of intra-Community trade in the animals and products concerned; whereas, in this respect, the free movement of animals and agricultural products is a fundamental feature of the common organization of markets and should facilitate the rational development of agricultural production and the optimum use of the factors of production;

Whereas, in the veterinary field, frontiers are currently being used for carrying out checks aimed at safeguarding public health and animal health;

Whereas the ultimate aim is to ensure that veterinary checks are carried out at the place of dispatch only; whereas the attainment of this objective implies the harmonization of the basic requirements relating to the safeguarding of animal health;

Whereas, with a view to the completion of the internal market, pending the attainment of this objective, emphasis should be placed on the checks to be carried out at the place of dispatch and in organizing those that could be carried out at the place of destination; whereas such a solution would entail the suspension of veterinary checks at the Community's internal frontiers and whereas, in this context, there is good reason for retaining a health certificate or an identification document, as provided for in Community rules;

Whereas this solution implies increased confidence in the veterinary checks carried out by the State of dispatch, in particular by the setting up of a system for the rapid exchange of information; whereas the dispatching Member State must ensure that such veterinary checks are carried out in an appropriate manner;

Whereas, in the State of destination, spot veterinary checks could be carried out at the place of destination; whereas, however, in the event of a serious presumption of irregularity, the veterinary check could be carried out while the animals and products are in transit and whereas it is possible to continue to provide for the placing into quarantine in areas which have not been harmonized;

Whereas provision must be made for action to be taken where a veterinary check discloses that the consignment is irregular;

Whereas provision should be made for a procedure for resolving conflicts which could arise concerning consignments from a holding, centre or organization;

Whereas provision must be made for protective measures; whereas in this area, especially for reasons of effectiveness, responsibility must rest firstly with the Member State of dispatch; whereas the Commission must be able to act speedily, in particular by way of on-the-spot visits and adopting measures appropriate to the situation;

Whereas in order to be effective, the rules laid down by this Directive should cover all animals and products that are subject, in intra-Community trade, to veterinary requirements;

Whereas, however, in view of the current state of harmonization and pending Community rules, animals and products that are not the subject of harmonized rules should comply with the requirements of the State of destination provided that the latter are in conformity with Article 36 of the Treaty;

Whereas the abovementioned rules should be applied to zootechnical checks;

Whereas the provisions of existing Directives should be adapted to the new rules laid down in this Directive;

Whereas these rules should be re-examined before the end of 1993;

Whereas the Commission should be entrusted with the task of adopting measures for applying this Directive; whereas, to

(1) OJ No C 225, 31. 8. 1988, p. 4.
(2) OJ No C 326, 19. 12. 1988, p. 28.
(3) OJ No C 56, 6. 3. 1989, p. 20.

that end, provision should be made for procedures establishing close and effective cooperation between the Commission and the Member States within the Standing Veterinary Committee,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Member States shall ensure that the veterinary checks to be carried out on live animals and products which are covered by the Directives listed in Annex A or on those referred to in the first paragraph of Article 21 and which are intended for trade are no longer carried out, without prejudice to Article 7, at frontiers but are carried out in accordance with this Directive.

Member States shall further ensure that checks on zootechnical documents are subject to the control rules laid down by this Directive.

This Directive shall affect neither checks on the welfare of animals during transport nor checks carried out as part of tasks conducted in a non-discriminatory manner by authorities responsible for the general application of laws in a Member State.

Article 2

For the purposes of this Directive:

1. 'veterinary check' shall mean any physical check and/or administrative formality which applies to the animals or products referred to in Article 1 and which is intended for the protection, direct or otherwise, of public or animal health;

2. 'zootechnical check' shall mean any physical and/or administrative formality which applies to the animals covered by the Directives mentioned in section II of Annex A and which is intended for the direct or indirect improvement of the breeds;

3. 'trade' shall mean trade between Member States within the meaning of Article 9 (2) of the Treaty;

4. 'holding' shall mean an agricultural establishment or premises of a dealer, as defined by the national rules in force, situated in the territory of a Member State and in which the animals referred to in Annexes A and B, with the exception of equidae, are held or regularly kept and the holding as defined in Article 2 (a) of Council Directive 90/426/EEC of 26 June 1990 on animal health conditions governing the movement and import from third countries of live equidae [1];

5. 'centre or organization' shall mean any undertaking which produces, stores, processes or handles the products referred to in Article 1;

6. 'competent authority' shall mean the central authority of a Member State competent to carry out veterinary or zootechnical checks or any authority to which it has delegated that competence;

7. 'official veterinarian' shall mean the veterinarian appointed by the competent authority.

CHAPTER I

Checks at origin

Article 3

1. Member States shall ensure that only the animals and products referred to in Article 1 that fulfil the following conditions may be the subject of trade:

(a) the animals and products referred to in Annex A must satisfy the requirements of the relevant Directives listed in the said Annex and the animals and products referred to in Annex B must fulfil the animal health requirements of the Member State of destination;

(b) they must come from holdings, centres or organizations which are subject to regular official veterinary checks in accordance with paragraph 3;

(c) they must, on the one hand, be identified in accordance with the requirements of Community rules and, on the other hand, be registered in such a way that the original or transit holding, centre or organization can be traced; national identification or registration systems must be notified to the Commission within three months of the date of notification of this Directive.

Before 1 January 1993, Member States must take appropriate measures to guarantee that the identification and registration systems applicable to intra-Community trade are extended to the movement of animals within their territory;

(d) they must, when transported, be accompanied by health certificates and/or any other documents as provided for in the Directives referred to in Annex A and, for the other animals and products, by the rules of the Member State of destination;

Those certificates or documents, issued by the official veterinarian responsible for the holding, centre or organization of origin and, in the case of documents required by the zootechnical legislation referred to in section II of Annex A, by the competent authority, must accompany the animal, animals and products to its/their destination(s);

(e) susceptible animals, or products of susceptible animals, must not originate:

[1] See page 42 of this Official Journal.

(i) from holdings, centres or organizations, areas or regions which are subject to restrictions determined in accordance with Community rules, where applicable, for the animals concerned or products from the animals concerned because of the suspicion, outbreak or existence of a disease referred to in Annex C or because of the application of safeguard measures;

(ii) from a holding, centre, organization, area or region which is the subject of official restrictions because of the suspicion, outbreak or existence of a disease other than those referred to in Annex C or of the application of safeguard measures;

(iii) in cases where they are intended for holdings, centres or organizations situated in the Member States which have obtained the guarantees pursuant to Article 9 of Directive 64/432/EEC or other equivalent Community rules which have been or will be adopted or in a State recognized, by Community legislation, as free, in all or part of its territory, of a disease, from a holding which does not provide the guarantees which may be required by that Member State with respect to diseases other than those listed in Annex C;

(iv) when they are intended for a Member State or part of the territory of a Member State which has benefited from the additional guarantees pursuant to Article 9 of Directive 64/432/EEC or other equivalent Community rules which have been or will be adopted, from a holding, centre or organization and, should the case arise, from a part of the territory which does not offer the additional guarantees provided for.

The competent authority of the country of origin shall ensure, before issuing the certificate or accompanying document, that the holdings, centres or organizations comply with the requirements provided for in this point;

(f) where the transport operation involves several places of destination, animals and products must be grouped together in as many consignments as there are places of destination. Each consignment must be accompanied by the certificates and/or documents referred to in (d);

(g) where animals and products covered by the Directives referred to in Annex A which comply with Community rules are intended for export to a third country through the territory of another Member State, the transport operation must — except in cases of urgent need duly authorized by the competent authority in order to ensure the welfare of the animals — remain under customs supervision up to the point of exit from Community territory, in accordance with detailed arrangements to be drawn up by the Commission, acting under the procedure laid down in Article 18 or, where appropriate, in Article 19.

Moreover, in the cases of animals and products not complying with Community rules or animals and products referred to in Annex B, transit may take place only if it has been expressly authorized by the competent authority of the Member State of transit.

2. Member States shall also ensure that:

— the animals and products referred to in Article 1 which might have to be slaughtered under a national programme for the eradication of diseases not referred to in Annex C are not dispatched to the territory of another Member State;

— the animals and products referred to in Annex A or the animals and products referred to in Annex B are not dispatched to the territory of another Member State if they cannot be marketed on their own territory for health or animal health reasons justified by Article 36 of the Treaty.

3. Without prejudice to the monitoring duties assigned to the official veterinarian under Community legislation, the competent authority shall carry out checks on holdings, approved markets and assembly centres, centres or organizations in order to satisfy itself that animals and products intended for trade comply with Community requirements and in particular fulfil the conditions laid down in paragraph 1 (c) and (d) with regard to identification.

Where there are grounds for suspecting that Community requirements are not being met, the competent authority shall carry out the necessary checks and, if the suspicion is confirmed, take the appropriate measures, which may include isolation of the holding, centre or organization concerned.

4. Under the procedure laid down in Article 18 or, where appropriate, in Article 19, the Commission may adopt detailed rules for the application of this Article, in particular to take account of the species concerned.

Article 4

1. Member States of dispatch shall take the necessary measures to ensure that:

(a) the holders of livestock and products referred to in Article 1 comply with the national or Community health or zootechnical requirements referred to in this Directive at all stages of production and marketing;

(b) the animals and products referred to in Annex A are checked at least as carefully, from a veterinary viewpoint, as if they were intended for the national market, unless specifically provided otherwise by Community rules;

(c) animals are transported in suitable means of transport which satisfy hygiene rules.

2. The competent authority of the Member State of origin which issued the certificate or document accompanying the animals and products shall communicate, on the day on which they were issued and by means of the computerized system provided for in Article 20, to the central competent authority of the Member State of destination and to the competent authority of the place of destination, data to be determined by the Commission, according to the procedure provided for in Article 18.

3. Member States of dispatch shall take the appropriate measures to penalize any infringement of veterinary or zootechnical legislation by natural or legal persons where it is found that Community rules have been infringed, and in particular where it is found that certificates, documents or identification marks do not correspond to the status of the animals or to their holdings of origin or to the actual characteristics of the products.

CHAPTER II

Checks on arrival at destination

Article 5

1. Member States of destination shall implement the following inspection measures:

(a) the competent authority may, at the places of destination of animals and products, establish by means of non-discriminatory veterinary spot checks that the requirements of Article 3 have been complied with; it may take samples at the same time.

Furthermore, checks may also be carried out during the transport of animals and products in its territory where the competent authority of the Member State of transit or of the Member State of destination has information leading it to suspect an infringement;

(b) furthermore, where the animals referred to in Article 1 and originating in another State are intended:

(i) for an approved market or assembly centre as defined by Community rules, the operator thereof shall be responsible for the admission of animals not meeting the requirements of Article 3 (1).

The competent authority must check, by means of non-discriminatory inspections of the certificates or documents accompanying the animals, that the animals meet the said requirements;

(ii) for a slaughterhouse placed under the supervision of an official veterinarian, the latter must ensure, in particular on the basis of the certificate or accompanying document, that only animals that meet the requirements of Article 3 (1) are slaughtered.

The operator of the slaughterhouse shall be responsible for slaughtering animals which do not meet the requirements of Article 3 (1) (c) and (d);

(iii) for a registered dealer who divides up the consignments or for any establishment not subject to permanent supervision, such dealer or establishment shall be regarded by the competent authority as the consignee of the animals and the conditions laid down in the second subparagraph shall apply;

(iv) for holdings, centres or organizations including, where the consignment is partly unloaded during transport, each animal or group of animals must be accompanied, in accordance with Article 3 by the original of the health certificate or accompanying document until it reaches the consignee mentioned therein.

The consignees referred to in points (iii) and (iv) of the first subparagraph must, before the consignment is divided up or subsequently marketed, check that the identification marks, certificates or documents referred to in Article 3 (1) (c) and (d) are present, notify the competent authority of any irregularity or anomaly and, in the latter case, isolate the animals in question until the competent authority has taken a decision regarding them.

The guarantees which must be furnished by the consignees referred to in points (iii) and (iv) of the first subparagraph shall be specified in an agreement with the competent authority to be signed at the time of the prior registration provided for in Article 12. The competent authority shall carry out random checks to verify compliance with those guarantees.

This point shall apply *mutatis mutandis* to consignees of the products referred to in Article 1.

2. All the consignees appearing on the certificate or document provided for in Article 3 (1) (d):

(a) must, at the request of the competent authority of the Member State of destination and to the extent necessary to carry out the checks referred to in paragraph 1, report in advance the arrival of animals and products from another Member State and, in particular, the nature of the consignment and the anticipated arrival date.

However, the time limit for notification shall as a general rule not be more than one day; nevertheless, in exceptional circumstances, Member States may require two days' advance notification.

This notification is not required for registered horses bearing an identification document provided for by Directive 90/427/EEC;

(b) shall keep for a period of not less than six months, to be specified by the competent authority, the health

certificates or documents referred to in Article 3 for presentation to the competent authority should the latter so request.

3. The detailed rules for implementing this Article shall be adopted in accordance with the procedure laid down in Article 18 or, where appropriate, in Article 19.

Article 6

1. Where Community rules or, in areas which have not yet been harmonized, national provisions which comply with the general rules of the Treaty require that live animals be put into quarantine, the latter shall normally take place at the holding of destination.

2. A quarantine station may be used if this is justified from a veterinary viewpoint. Such station shall be regarded as the place of destination of the consignment. The Member State concerned shall notify the Commission of the grounds on which such action is being taken.

3. Obligations relating to quarantine and the location of the latter shall be specified in the veterinary requirements referred to in the second subparagraph of Article 21.

Article 7

1. Member States shall ensure that during the checks carried out at the places where animals and products referred to in Article 1 from a third country may be brought into Community territory, such as ports, airports and frontier posts with third countries, the following measures are taken:

(a) the certificates or documents accompanying the animals and products are checked;

(b) where animals and products are imported from third countries, they must be sent, under customs supervision, to inspection posts in order that veterinary checks may be carried out.

The animals and products referred to in Annex A may not be given customs clearance unless those checks have shown that they comply with Community rules;

(c) Community animals and products shall be subject to the control rules laid down in Article 5.

2. The animals and products referred to in Annex B and those which are imported on the basis of national animal health standards must be brought directly into Community territory via one of the inspection posts of the Member State which intends to import them and be inspected there in accordance with paragraph 1 (b).

Member States which make imports from third countries on the basis of national animal health rules shall inform the Commission and the other Member States, in particular Member States of transit, of the existence of such imports and of the requirements to which they subject such imports.

Member States of destination shall prohibit animals from being sent on from their territory unless they have remained there for the periods laid down in the specific Community legislation and likewise the products referred to in the second subparagraph unless they are bound, without transit, for another Member State using the same option.

However, pending the adoption of Community rules, those animals and products may be brought into the territory of a Member State other than that referred to in the second subparagraph following prior agreement given by that other Member State in a general manner and, where appropriate, by a Member State of transit on the arrangements for control. Member States shall inform the Commission and the other Member States in the framework of the Standing Veterinary Committee when they are making use of this derogation and of the control arrangements agreed upon.

3. However, from 1 January 1993 and by way of derogation from paragraph 1, all animals and products transported by regular, direct means of transport linking two geographical points of the Community shall be subject to the control rules laid down in Article 5.

Article 8

1. If, during a check carried out at the place of destination of a consignment or during transport, the competent authorities of a Member State establish:

(a) the presence of agents responsible for a disease referred to in Directive 82/894/EEC [1], as last amended by Commission Decision 90/134/EEC [2], a zoonosis or disease, or any cause likely to constitute a serious hazard to animals or humans, or that the products come from a region contaminated by an epizootic disease, they shall order that the animal or consignment of animals be put in quarantine at the nearest quarantine station or slaughtered and/or destroyed.

Costs relating to the measures provided for in the first subparagraph shall be borne by the consignor or his representative or the person responsible for the products or animals.

The competent authorities of the Member State of destination shall immediately notify the competent authorities of the other Member States and the Commission in writing, by the most appropriate means, of the findings arrived at, the decisions taken and the reasons for such decisions.

The protective measures provided for in Article 10 may be applied.

[1] OJ No L 378, 31. 12. 1982, p. 58.
[2] OJ No L 76, 22. 3. 1990, p. 23.

At a Member State's request and in accordance with the procedure laid down in Article 17, the Commission may, moreover, adopt any measure necessary for achieving a concerted approach by the Member States to deal with situations not covered by Community rules;

(b) that, without prejudice to point (a), the animals and products do not meet the conditions laid down by Community Directives or, where the Member State obtains the guarantees pursuant to Article 9 of Directive 64/432/EEC or equivalent Community rules which have been or will be adopted, by national animal health rules, they may, provided that public or animal health considerations so permit, give the consignor or his representative the choice of:

— maintenance of the animals and products under supervision until compliance with rules is confirmed where residues are present, and, in the event of failure to comply with those rules, application of the measures provided for by Community legislation,

— slaughtering of the animals or the destruction of the products,

— return of the animal or consignment, with the authorization of the competent authority of the Member State of dispatch and prior notification of the Member State(s) of transit.

However, if the certificate or documents are found to contain irregularities, the owner or his representative must be granted a period of grace before recourse is had to this last possibility.

2. In accordance with the procedure laid down in Article 18, the Commission shall draw up a list of the diseases referred to in paragraph 1 and detailed rules for the application of this Article.

Article 9

1. In the cases provided for in Article 8, the competent authority of the Member State of destination shall contact the competent authorities of the Member State of dispatch without delay. The latter authorities shall take all necessary measures and notify the competent authority of the first Member State of the nature of the checks carried out, the decisions taken and the reasons for such decisions.

If the competent authority of the Member State of destination fears that such measures are inadequate, the competent authorities of the two Member States shall together seek ways and means of remedying the situation; if appropriate, this may involve an on-the-spot inspection.

Where the checks provided for in Article 8 show repeated irregularities, the competent authority of the Member State of destination shall inform the Commission and the competent authorities of the other Member States.

The Commission, at the request of the competent authority of the Member State of destination or on its own initiative, and taking into account the nature of the infringements established, may:

— send inspectors, in collaboration with the competent national authorities, to the place concerned,

— instruct an official veterinarian, whose name shall be on a list to be prepared by the Commission at the suggestion of the Member States, and who is acceptable to the various parties concerned, to check the facts on the spot,

— request the competent authority to intensify checks on the holding, the centre, the organization, the approved market or assembly centre or the region of origin.

It shall inform the Member States of its findings.

Pending the Commission's findings, the Member State of dispatch must, at the request of the Member State of destination, intensify checks on animals and products coming from the holding, centre, organization, approved market or assembly centre or region in question, and if there are serious public or animal health grounds, suspend issue of any certificates or movement documents.

The Member State of destination may, for its part, intensify checks on animals coming from the same holding, centre, organization, approved market or assembly centre or region.

At the request of one of the two Member States concerned — where the irregularities are confirmed by the expert's opinion — the Commission must, in accordance with the procedure laid down in Article 17, take the appropriate measures, which may go as far as authorizing the Member States to prohibit provisionally the bringing into their territory of animals and products coming from that holding, centre, organization, approved market or assembly centre or region. These measures must be confirmed or reviewed as soon as possible in accordance with the procedure laid down in Article 17.

2. Except in cases provided for in the fourth subparagraph, rights of appeal existing under the laws in force in the Member States against decisions by the competent authorities shall not be affected by this Directive.

Decisions taken by the competent authority of the State of destination and the reasons for such decisions shall be notified to the consignor or his representative and to the competent authority of the Member State of dispatch.

If the consignor or his representative so requests, the said decisions and reasons shall be forwarded to him in writing

with details of the rights of appeal which are available to him under the law in force in the Member State of destination and of the procedure and time limits applicable.

However, in the event of a dispute, the two parties concerned may, if they so agree, within a maximum period of one month, submit the dispute for the assessment of an expert whose name appears on a list of Community experts to be drawn up by the Commission; the cost of consulting the expert shall be borne by the Community.

Such experts shall issue their opinions within not more than 72 hours or after receiving the results of any analyses. The parties shall abide by the expert's opinion, with due regard for Community veterinary legislation.

3. The costs of returning the consignment, holding or isolating the animals or, if appropriate, slaughtering or destroying them shall be borne by the consignor, his representative or the person responsible for the animals or products.

4. The detailed rules for the application of this Article shall be adopted in accordance with the procedure laid down in Article 18 or, where appropriate, in Article 19.

CHAPTER III

Common provisions

Article 10

1. Each Member State shall immediately notify the other Member States and the Commission of any outbreak in its territory, in addition to an outbreak of diseases referred to in Directive 82/894/EEC, of any zoonoses, diseases or other cause likely to constitute a serious hazard to animals or to human health.

The Member State of dispatch shall immediately implement the control or precautionary measures provided for in Community rules, in particular the determination of the buffer zones provided for in those rules, or adopt any other measure which it deems appropriate.

The Member State of destination or transit which, in the course of a check referred to in Article 5, has established the existence of one of the diseases or causes referred to in the first subparagraph may, if necessary, take the precautionary measures provided for in Community rules, including the quarantining of the animals.

Pending the measures to be taken in accordance with paragraph 4, the Member State of destination may, on serious public or animal health grounds, take interim protective measures with regard to the holdings, centres or organizations concerned or, in the case of an epizootic disease, with regard to the buffer zone provided for in Community rules.

The measures taken by Member States shall be notified to the Commission and to the other Member States without delay.

2. At the request of the Member State referred to in the first subparagraph of paragraph 1 or on the initiative of the Commission, one or more Commission representatives may go at once to the place concerned to examine, in collaboration with the competent authorities, what measures have been taken, and shall issue an opinion on those measures.

3. If the Commission has not been informed of the measures taken, or if it considers the measures taken to be inadequate, it may, in collaboration with the Member State concerned and pending the meeting of the Standing Veterinary Committee, take interim protective measures with regard to animals or products from the region affected by the epizootic disease or from a given holding, centre or organization. These measures shall be submitted to the Standing Veterinary Committee as soon as possible to be confirmed, amended or cancelled in accordance with the procedure laid down in Article 17.

4. The Commission shall in all cases review the situation in the Standing Veterinary Committee at the earliest opportunity. It shall adopt the necessary measures for the animals and products referred to in Article 1 and, if the situation so requires, for the products derived from those animals, in accordance with the procedure laid down in Article 17. The Commission shall monitor the situation and, by the same procedure, shall amend or repeal the decisions taken, depending on how the situation develops.

5. Detailed rules for the application of this Article, and in particular the list of zoonoses or causes likely to constitute a serious hazard to human health, shall be adopted in accordance with the procedure laid down in Article 18.

Article 11

Each Member State and the Commission shall appoint the veterinary department or departments responsible for carrying out the veterinary checks and collaborating with the other Member States' inspection departments.

Article 12

Member States shall ensure that all dealers engaging in intra-Community trade in the animals and/or products covered by Article 1:

(a) are required, at the request of the competent authority, to register beforehand in an official register;

(b) keep a record of deliveries and, for the consignees referred to in Article 5 (1) (b) (iii), of the subsequent destination of the animals and products.

The said record shall be preserved for a period to be determined by the competent national authority so that it can be presented to the competent authority on request.

Article 13

The Member States shall also ensure that the officials of their veterinary departments, if appropriate in collaboration with the officials of other departments empowered to that end, are able in particular to:

— carry out inspections of holdings, installations, means of transport and processes used for the marking and identification of animals,

— check, as regards the products listed in Annex A, that the personnel are complying with the requirements laid down in the texts referred to in that Annex,

— take samples from:

(i) animals held with a view to being sold, put on the market or transported;

(ii) products held with a view to being stored or sold, put on the market or transported,

— examine documentary or data processing material relevant to the checks carried out further to the measures taken under this Directive.

Member States must require the holdings, centres or organizations being checked to afford the collaboration necessary for the performance of the aforementioned tasks.

Article 14

1. Directive 64/432/EEC (1), as last amended by Directive 89/662/EEC (2), is hereby amended as follows:

(a) Article 6 is replaced by the following:

'*Article 6*

Animals for slaughter which have been taken on arrival in the country of destination either directly or via an approved market or assembly centre to a slaughterhouse must be slaughtered there as soon as possible, in accordance with animal health requirements.

Animals for slaughter which have been taken on arrival in the country of destination to a market adjoining a slaughterhouse under whose rules all animals may be removed, in particular after the market, only to a slaughterhouse approved for this purpose by the competent central authority must be slaughtered at that slaughterhouse not later than five days after arriving at the market.

The competent authority of the country of destination may, in the light of animal health considerations, designate the slaughterhouse to which those animals must be sent.'

(b) Article 7 (3) and the first subparagraph of Article 8 (2) are hereby deleted.

(c) Articles 9 and 10 are replaced by the following:

'*Article 9*

1. A Member State which has a national control programme for one of the contagious diseases not referred to in Annex E for all or part of its territory may submit the said programme to the Commission, outlining in particular:

— the distribution of the disease in the Member State,

— the reasons for the programme, taking into consideration the importance of the disease and the programme's likely benefit in relation to its cost,

— the geographical area in which the programme will be implemented,

— the status categories to be applied to the animal establishments, the standards which must be attained in each category, and the test procedures to be used,

— the programme monitoring procedures,

— the action to be taken if, for any reason, an establishment loses its status,

— the measures to be taken if the results of the tests carried out in accordance with the provisions of the programme are positive.

2. The Commission shall examine the programmes presented by the Member States. Programmes as referred to in paragraph 1 may be approved in compliance with the criteria laid down in paragraph 1 in accordance with the procedure provided for in Article 12. According to the same procedure, the additional guarantees, general or limited, which may be required in intra-Community trade, shall be defined at the same time or at the latest three months after approval of the programmes. Such guarantees must not exceed those which the Member State implements nationally.

3. Programmes submitted by Member States may be amended or supplemented in accordance with the procedure laid down in Article 12. Amendments or additions to programmes which have already been approved or to guarantees which have been defined in accordance with paragraph 2 may be approved under the same procedure.

Article 10

1. Where a Member State considers that its territory or part of its territory is free from one of the diseases to which bovine animals and swine are susceptible, it shall present to the Commission appropriate supporting documentation, setting out in particular:

(1) OJ No 121, 29. 7. 1964, p. 2012/64.
(2) OJ No L 395, 30. 12. 1989, p. 13.

— the nature of the disease and the history of its occurrence in its territory,

— the results of surveillance testing based on serological, microbiological, pathological or epidemiological investigation and on the fact that the disease must by law be notified to the competent authorities,

— the period over which the surveillance was carried out,

— where applicable, the period during which vaccination against the disease has been prohibited and the geographical area concerned by the prohibition,

— the arrangements for verifying the absence of the disease.

2. The Commission shall examine documentation submitted by Member States. The additional guarantees, general or specific, which may be required in intra-Community trade may be defined in accordance with the procedure laid down in Article 12. Such guarantees must not exceed those which the Member State implements nationally. Where justification is submitted before 1 July 1991, decisions on additional guarantees shall be taken before 1 January 1992.

3. The Member State concerned shall notify the Commission of any change in the particulars specified in paragraph 1 which relate to the disease. The guarantees defined as laid down in paragraph 2 may, in the light of such notification, be amended or withdrawn in accordance with the procedure laid down in Article 12.'

2. Subparagraphs 2 to 5 of Article 5 (2) and Articles 7 and 15 of Directive 88/407/EEC (1) are hereby deleted.

3. Subparagraphs 2 to 4 of Article 5 (2) and Article 14 of Directive 89/556/EEC (2) are hereby deleted.

4. In the fifth line of the first subparagraph of Article 13 of Directive 72/462/EEC (3), as last amended by Directive 89/227/EEC (4), 'three' is replaced by 'five'.

Article 15

1. The following Article is inserted in Directives 64/432/EEC and 89/556/EEC:

'Article 14

The rules laid down in Council Directive 90/425/EEC of 26 June 1990 concerning veterinary and zootechnical checks in intra-Community trade in certain live animals and products with a view to the completion of the internal market (*), shall apply in particular to checks at origin, to the organization of, and follow-up to, the checks to be carried out by the country of destination, and to the safeguard measures to be implemented.

(*) OJ No L 224, 18. 8. 1990, p. 29.

2. The following Article is inserted in Directive 88/407/EEC:

'Article 15

The rules laid down in Council Directive 90/425/EEC of 26 June 1990 concerning veterinary and zootechnical checks in intra-Community trade in certain live animals and products with a view to the completion of the internal market (*), shall apply in particular to checks at origin, to the organization of, and follow-up to, the checks to be carried out by the Member State of destination, and follow up to, the checks to be carried out by the Member State of destination, and to the safeguard measures to be implemented.

(*) OJ No L 224, 18. 8. 1990, p. 29.

3. Article 9 of Directive 90/426/EEC is replaced by the following:

'Article 9

The rules laid down in Council Directive 90/425/EEC of 26 June 1990 concerning veterinary and zootechnical checks in intra-Community trade in certain live animals and products with a view to the completion of the internal market (*), shall apply in particular to checks at origin, to the organization of, and follow-up to, the checks to be carried out by the Member State of destination, and to the safeguard measures to be implemented.

(*) OJ No L 224, 18. 8. 1990, p. 29.

Article 16

The Commission may, in accordance with the procedure laid down in Article 18, amend the list of diseases referred to in Annex C.

Article 17

Where reference is made to the procedure provided for in this Article, the Standing Veterinary Committee set up by Decision 68/361/EEC (5) shall take decisions in accordance with the rules established in Article 17 of Directive 89/662/EEC.

Article 18

Where reference is made to the procedure defined in this Article, the Standing Veterinary Committee shall take decisions in accordance with Article 18 of Directive 89/662/EEC.

(1) OJ No L 134, 22. 7. 1988, p. 10.
(2) OJ No L 302, 19. 10. 1989, p. 1.
(3) OJ No L 302, 31. 12. 1972, p. 28.
(4) OJ No L 93, 6. 4. 1989, p. 25.
(5) OJ No L 255, 18. 10. 1968, p. 23.

Article 19

Where reference is made to the procedure defined in this Article, the Standing Zootechnical Committee set up by Decision 77/505/EEC (1) shall take decisions in accordance with the rules established in Article 11 of Directive 88/661/EEC (2).

CHAPTER IV

Final and transitional provisions

Article 20

1. The Commission shall introduce, in accordance with the procedure laid down in Article 18, a computerized system linking veterinary authorities, with a view, in particular, to facilitating the exchange of information between the competent authorities of regions where a health certificate or document accompanying the animals and products of animal origin has been issued and the competent authorities of the Member State of destination.

2. The procedures for the Community's financial contribution, as provided for in Article 37 of Decision 90/424/EEC and necessary for the implementation of this programme, shall be adopted in accordance with the procedure provided for in Article 42 of the said Decision.

3. According to the procedure provided for in Article 18, the Commission shall adopt the procedure for applying this Article and, in particular, the appropriate standards for the exchange of data and rules for the security of data exchanged.

Article 21

Until 31 December 1992, trade in the animals and products listed in Annex B shall, pending the adoption of Community rules, and without prejudice to the maintenance of any national rules laid down for the identification of batches, be subject to the control rules laid down by this Directive, in particular those mentioned in the second part of the sentence of Article 3 (1) (a).

Member States shall communicate to the Commission and the other Member States, before the date laid down in Article 22, the conditions and procedures currently applicable to admission to their territory of the animals and products referred to in the first paragraph, including the rules for identification.

In accordance with the procedure laid down in Article 17, the Commission shall determine the measures necessary for the computerization of the statements of conditions mentioned in the second subparagraph.

The control rules provided for the animals and products referred to in Annex A shall be extended to the animals and products of animal origin not yet covered by this Annex when the harmonized rules governing trade therein are adopted. Before 1 January 1992 the Council shall decide on the inclusion on 31 December 1992 in the scope of Directive 89/662/EEC and of this Directive of the animals and products of animal origin not covered by the said Directives.

Article 22

1. Member States shall submit to the Commission before 1 October 1991 a programme setting out the national measures which they intend to take to achieve the stated objectives of this Directive, in particular the frequency of checks.

2. The Commission shall examine the programmes communicated by the Member States in accordance with paragraph 1.

3. Each year, and for the first time in 1992, the Commission shall address to the Member States a recommendation on a programme of checks for the following year; the Standing Veterinary Committee will have expressed its opinion on the recommendation in advance. This recommendation may be subject to later adaptations.

Article 23

1. Before 1 January 1991, the Council, acting by a qualified majority on a proposal from the Commission, shall decide on the rules and general principles applicable upon checks to be carried out in third countries and upon checks on imports from third countries of animals and products covered by this Directive. In the same way, the check posts at the external frontiers, as well as the requirements to be satisfied by those posts, shall be fixed before that date.

2. Before 1 January 1993, the Council shall, on the basis of a report from the Commission on the experience gained, accompanied by any relevant proposals, on which it will decide by a qualified majority, review the provisions of this Directive, and in particular those of Article 10 and Article 5 (2) (a).

Article 24

Until 31 December 1992 or at the latest 12 months after the date on which Member States have to conform to Directive 90/423/EEC, and in order to permit the gradual implementation of the checking arrangements laid down by this Directive, Member States may, by way of derogation from Article 5 (1):

— maintain documentary checks during transport of animals and products covered by Annexes A and B in order to satisfy themselves that the specific requirements laid down by Community rules have been complied with,

— operate documentary checks during transport on animals and products imported from third countries and intended for them.

(1) OJ No L 206, 12. 8. 1977, p. 11.
(2) OJ No L 382, 31. 12. 1988, p. 16.

Article 25

The Council, acting by a qualified majority on a proposal from the Commission, shall determine, before 1 October 1992, the arrangements which are to apply when the transitional provisions provided for in Article 24 expire.

Article 26

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with:

(i) Article 10 of this Directive and Article 9 of Directive 89/662/EEC, two months after the date of notification of this Directive;

(ii) the other provisions of this Directive, at a date to be set when the Decision to be adopted before 31 December 1990 but not later than 31 December 1991 is taken.

However, the Hellenic Republic shall have an additional time limit of one year in which to conform to these other provisions.

Article 27

This Directive is addressed to the Member States.

Done at Luxembourg, 26 June 1990.

For the Council

The President

M. O'KENNEDY

ANNEX A

I. VETERINARY LEGISLATION

Council Directive 64/432/EEC of 26 June 1964 on animal health problems affecting intra-Community trade in bovine animals and swine.

OJ No 121, 29. 7. 1964, p. 1977/64.

Council Directive 88/407/EEC of 14 June 1988 laying down the animal health requirements applicable to intra-Community trade in and imports of deep-frozen semen of domestic animals of the bovine species.

OJ No L 194, 22. 7. 1988, p. 10.

Council Directive 89/556/EEC of 25 September 1989 on animal health conditions governing intra-Community trade in and importation from third countries of embryos of domestic animals of the bovine species.

OJ No L 302, 19. 10. 1989, p. 1.

Council Directive 90/426/EEC of 26 June 1990 on the health policy conditions governing the movement of equidae and their import from third countries (1).

OJ No L 224, 18. 8. 1990, p. 42.

Council Directive 90/429/EEC of 26 June 1990, laying down the animal health requirements applicable to intra-Community trade in and imports of semen of domestic animals of the porcine species.

OJ No L 224, 18. 8. 1990, p. 62.

II. ZOOTECHNICAL LEGISLATION

Council Directive 77/504/EEC of 25 July 1977 on pure-bred breeding animals of the bovine species.

OJ No L 206, 12. 8. 1977, p. 8.

Council Directive 88/661/EEC of 19 December 1988 on the zootechnical standards applicable to breeding animals of the porcine species.

OJ No L 382, 31. 12. 1988, p. 36.

Council Directive 89/361/EEC of 30 May 1989 concerning pure-bred breeding sheep and goats.

OJ No L 153, 8. 6. 1989, p. 30.

Council Directive 90/427/EEC of 26 June 1990 on the zootechnical and genealogical conditions governing intra-Community trade in equidae.

OJ No L 224, 18. 8. 1990, p. 55.

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(1) From 1 January 1992.

ANNEX B

ANIMALS AND PRODUCTS NOT SUBJECT TO HARMONIZATION BUT TRADE IN WHICH WILL BE SUBJECT TO THE CHECKS PROVIDED FOR IN THIS DIRECTIVE

A. **Live animals of the following species**

- Sheep and goats
- Live poultry
- Domestic rabbits

B. **Products**

- Waste (pathogens)
- Hatching eggs

ANNEX C

LIST OF DISEASES OR EPIZOOTIC DISEASES, SUBJECT TO MANDATORY EMERGENCY ACTION, WITH TERRITORIAL RESTRICTIONS (MEMBER STATES, REGIONS OR ZONES)

- Foot and mouth disease (FMD)
- Classical swine fever (CSF)
- African swine fever (ASF)
- Swine vesicular disease (SVD)
- Newcastle disease (ND)
- Rinderpest
- Peste des petits ruminants (PPR)
- Vesicular stomatitis (VS)
- Blue tongue
- African horse sickness (AHS)
- Viral equine encephalomyelitis
- Teschen disease
- Avian influenza
- Sheep and goat pox
- Lumpy skin disease
- Rift valley fever
- Contagious bovine pleuropneumonia

COUNCIL DIRECTIVE

of 26 June 1990

on animal health conditions governing the movement and import from third countries of equidae

(90/426/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 43 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 equidae, being live animals, are included in the list of products in Annex II to the Treaty;

Whereas in order to ensure the rational development of equidae production, thereby increasing productivity in that sector, rules governing the movement of equidae between Member States must be laid down at Community level;

Whereas the breeding and rearing of equidae and in particular of horses is generally included in the farming sector; whereas it constitutes a source of income for part of the farming population;

Whereas disparities as regards animal health conditions in the Member States should be eliminated in order to encourage intra-Community trade in equidae;

Whereas, in order to encourage the harmonious development of intra-Community trade, a Community system should be laid down to govern imports from third countries;

Whereas the conditions for the movement on national territory of equidae bearing an identification document should also be regulated;

Whereas, in order to be the subject of trade, equidae must satisfy certain animal health requirements, so as to avoid the spreading of contagious diseases; whereas it appears in particular appropriate to provide for a possible regionalization of restrictive measures;

Whereas transport conditions should be laid down for the same reason;

Whereas, to ensure that those requirements are satisfied provision must be made for the issue by an official veterinarian of a health certificate to accompany the equidae to their place of destination;

Whereas the organization of and the follow-up to the checks to be carried out by the Member State of destination and the safeguard measures to be implemented should be fixed within the framework of rules to be laid down for veterinary checks in intra-Community trade in live animals in view of the completion of the internal market;

Whereas provision should be made for the possibility of checks by the Commission; whereas these checks should be carried out in cooperation with the competent national authorities;

Whereas defining Community provisions applicable to imports from third countries requires a list to be drawn up of third countries or parts of third countries from which equidae may be imported;

Whereas the choice of these countries must be based on criteria of a general nature such as the state of health of the livestock, the organization and powers of the veterinary services and the health regulations in force;

Whereas, in addition, imports of equidae should not be authorized from countries infected with contagious or infectious animal diseases which present a risk to Community livestock or which have been free from such infection for too short a period; whereas such considerations are also valid for imports from third countries in which vaccination against such diseases is carried out;

Whereas the general conditions applicable to imports from third countries must be supplemented by special conditions drawn up on the basis of the health situation in each of them; whereas the technical nature and the diversity of the criteria on which these special conditions depend require for their definition recourse to a flexible and rapid Community procedure in which the Commission and the Member States cooperate closely;

Whereas the presentation of a common standard form of certificate upon import of equidae constitutes an effective means of verifying that the Community rules are being applied; whereas such rules may include special provisions which may vary according to the third country concerned, and whereas this must be taken into account in drawing up the standard forms of certificates;

Whereas official Community veterinarians should be responsible for verifying that the requirements of this Directive are observed, particularly in third countries;

(1) OJ No C 327, 30. 12. 1989, p. 61.
(2) OJ No C 149, 18. 6. 1990.
(3) OJ No C 62, 12. 3. 1990, p. 46.

Whereas the checks carried out upon importation must cover the origin and the state of health of the equidae;

Whereas the Member States must be allowed, on the arrival of equidae in the territory of the Community and during transit to their place of destination, to take all measures, including slaughter and disposal, required for the purpose of safeguarding the health of humans and animals;

Whereas the general rules applicable to the checks to be carried out on importation must be defined within an overall context;

Whereas every Member State must have the right to place an immediate prohibition on imports from a third country when such imports may be dangerous for animal health; whereas in such a case coordination of the attitudes of the Member States with regard to that third country must be assured without delay, without prejudice to possible amendments to the list of countries authorized to export to the Community;

Whereas the provisions of this Directive should be revised in connection with the completion of the internal market;

Whereas provision should be made for a procedure establishing close and effective cooperation between the Commission and the Member State within the Standing Veterinary Committee,

HAS ADOPTED THIS DIRECTIVE:

CHAPTER 1

General provisions

Article 1

This Directive lays down animal health conditions for the movement between Member States and import from third countries of live equidae.

Article 2

For the purposes of this Directive:

(a) 'holding' means an agricultural or training establishment, a stable or, generally speaking, any premises or facilities in which equidae are habitually kept or bred, for whatever use;

(b) 'equidae' means wild or domesticated animals of the equine (including zebras) or asinine species or the offspring of crossings of those species;

(c) 'registered equidae' means any equidae registered as defined in Directive 90/427/EEC [1], identified by means of an identification document issued by the breeding authority or any other competent authority of the country where the animal originated which manages the studbook or register for that breed of animal or any international association or organization which manages horses for competition or racing;

(d) 'equidae for slaughter' means equidae intended to be transported either directly or after transit through a market or an approved marshalling centre to the slaughterhouse for slaughter;

(e) 'equidae for breeding and production' means equidae other than those mentioned in (c) and (d);

(f) 'Member State or third country free from African horse sickness' means any Member State or third country in which there has been no clinical, serological (in unvaccinated equidae) or epidemiological evidence of African horse sickness on the territory concerned in the previous two years and in which there have been no vaccinations against the disease during the previous 12 months;

(g) 'compulsorily notifiable diseases' means the diseases listed in Annex A;

(h) 'official veterinarian' means the veterinarian designated by the competent central authority of a Member State or of a third country;

(i) 'temporary admission' means the status of a registered animal originating in a third country and admitted into Community territory for a period of less than 90 days to be fixed by the Commission in accordance with the procedure laid down in Article 24, depending on the health situation in the country of origin.

CHAPTER II

Rules for the movement of equidae

Article 3

Member States shall authorize the movement of equidae registered in their territory or send equidae to another Member State only where they satisfy the conditions laid down in Articles 4 and 5.

However, the competent authorities in Member States of destination may grant general or limited exemption in respect of movement of equidae which:

— are being ridden or taken, for sporting or recreational purposes, along roads situated near internal borders of the Community,

— are taking part in cultural or similar events or in activities organized by authorized local bodies situated near internal borders of the Community,

— are intended solely for temporary pasturing or work near internal borders of the Community.

[1] OJ No L 224, 18. 8. 1990, p. 55.

Member States making use of such authorization shall inform the Commission of the content of the exemptions granted.

Article 4

1. Equidae must show no clinical sign of disease at inspection. Inspection must be carried out in the 48 hours prior to their embarkation or loading. In the case of registered equidae, however, this inspection shall, without prejudice to Article 6, be required for intra-Community trade only.

2. Without prejudice to the requirements of paragraph 5 regarding compulsorily notifiable diseases, the official veterinarian must, at the time of inspection, be satisfied that there are no grounds — in particular on the basis of declarations by the owner or breeder — for concluding that the equidae have been in contact with equidae suffering from an infectious or contagious disease during the 15 days immediately preceding inspection.

3. The equidae must not be intended for slaughter under a national programme of contagious or infectious disease eradication.

4. The equidae must be identified in the following manner:

(i) in the case of registered horses, by means of an identification document, as provided for in Directive 90/427/EEC [1], which must certify in particular that Article 5 (5) and (6) have been complied with. The offical veterinarian will have to suspend the validity of this document for the period of the prohibitions provided for in paragraph 5 or in Article 5. The document should, following the slaughter of the registered horse, be returned to the authority which issued it. The procedure for the implementation of this point shall be adopted by the Commission in accordance with the procedure laid down in Article 24;

(ii) for equidae for breeding and production, identification by a method to be established by the Commission in accordance with the procedure laid down in Article 24.

Until such time as this method is in use, the officially approved national identification methods shall remain applicable, provided that they are notified to the Commission and the other Member States within three months of the date on which this Directive is adopted.

5. In addition to the requirements laid down in Article 5, the equidae must not come from a holding which has been the subject of one of the following prohibition orders:

(a) if all the animals of species susceptible to the disease located on the holding have not been slaughtered, the period of prohibition concerning the holding of origin must be at least:

— six months in the case of equidae suspected of having contracted dourine, beginning on the date of the last actual or possible contact with a sick animal. However, in the case of a stallion, the prohibition shall apply until the animal is castrated,

— six months in the case of glanders or equine encephalomyelitis, beginning on the day on which the equidae suffering from the disease in question are slaughtered,

— in the case of infectious anaemia, until the date on which, the infected animals having been slaughtered, the remaining animals have shown a negative reaction to two Coggins tests carried out three months apart,

— six months in the case of vesicular stomatitis,

— one month from the last recorded case, in the case of rabies,

— 15 days from the last recorded case, in the case of anthrax;

(b) if all the animals of species susceptible to the disease located on the holding have been slaughtered and the premises disinfected, the period of prohibition shall be 30 days, beginning on the day on which the animals were destroyed and the premises disinfected, except in the case of anthrax, where the period of prohibition is 15 days.

The competent authorities may derogate from these prohibition measures for hippodromes and racecourses, and shall notify the Commission of the nature of any derogations granted.

6. Where a Member State draws up or has drawn up a voluntary or compulsory control programme for a disease to which equidae are susceptible, it may present the programme to the Commission, within six months of notification of this Directive outlining in particular:

— the distribution of the disease on its territory,

— the reasons for the programme, taking into consideration the significance of the disease and its cost/benefit advantages,

— the geographical area in which the programme will be implemented,

— the status categories to be applied to establishments, the standards which must be attained for each species and the test procedures to be used,

— the programme monitoring procedures,

— the action to be taken if, for any reason, a holding loses its status,

— the measures to be taken if the results of the tests carried out in accordance with the provisions of the programme are positive,

— the non-discriminatory nature of trade in the territory of the Member State concerned with respect to intra-Community trade.

The Commission shall examine the programmes presented by the Member States. Where appropriate it shall approve them in accordance with the procedure laid down in Article 24. Any additional guarantees, general or specific,

[1] OJ No L 224, 18. 8. 1990, p. 55.

which may be required in intra-Community trade may be defined in accordance with the same procedure. Such guarantees must not exceed those required by the Member State in its own territory.

Programmes submitted by Member States may be amended or supplemented in accordance with the procedure laid down in Article 25. Amendments or additions to programmes which have already been approved or to guarantees which have been defined in accordance with the second subparagraph may be approved under the same procedure.

Article 5

1. A Member State which is not free of African horse sickness within the meaning of Article 2 (f) may dispatch equidae from that part of its territory which is considered to be infected within the meaning of paragraph 2 of this Article only under the conditions set out in paragraph 3 of this Article.

2. (a) A part of the territory of a Member State shall be considered to be infected with African horse sickness if:

— clinical, serological (in unvaccinated animals) and/or epidemiological evidence has revealed the presence of African horse sickness in the past two years,

— vaccination against African horse sickness has been carried out in the past 12 months.

(b) The part of the territory considered to be infected with African horse sickness must comprise as a minimum:

— a protection zone with a radius of at least 100 km around any centre of infection,

— a surveillance zone of at least 50 km extending beyond the protection zone, in which no vaccination has been carried out in the last 12 months.

(c) The zones referred to in (b) must be clearly defined and take account of the geographical, ecological and epizootic factors connected with this epizootic disease.

(d) All vaccinated equidae found in the protection zone must be registered and identified at the time of vaccination by a clear, indelible mark, recognizable in accordance with the procedure laid down in Article 24.

The identification document and/or health certificate shall carry a clear reference to such vaccination.

(e) Equidae and their movements within the zones referred to in (b) must be subject to proper veterinary control under the responsibility of the competent central authority. Only equidae meeting the requirements laid down in paragraph 3 may leave the zones referred to in (b).

3. A Member State may dispatch from the territory referred to in paragraph 2 (b) only equidae which meet the following requirements:

(a) they must be dispatched only during certain periods of the year, having regard to the activity of vector insects, to be determined in accordance with the procedure laid down in Article 25;

(b) they must show no clinical symptom of African horse sickness on the day of the inspection referred to in Article 4 (1);

(c) if they have not been vaccinated against African horse sickness, they must have undergone and reacted negatively to a complement fixation test for African horse sickness as described in Annex D, on two occasions, with an interval of between 21 and 30 days between the two tests, the second of which must have been carried out during the 10 days prior to dispatch,

— if they have been vaccinated, they must not have undergone vaccination during the previous two months and must have undergone the fixation test described in Annex D at the aforementioned intervals without having recorded an increase in the antibody count. Under the procedure laid down in Article 24, the Commission may, following the opinion of the Scientific Veterinary Committee, recognize other monitoring methods;

(d) they must have been kept in a quarantine station for a minimum period of 40 days prior to despatch;

(e) they must have been protected from vector insects during the period of quarantine and during transportation from the quarantine station to the place of despatch.

4. On a transitional basis and pending the introduction of Community measures to harmonize rules for controlling and measures to combat African horse sickness, to be decided on by the Council acting before 1 July 1991 by a qualified majority on a proposal from the Commission, the Commission shall, in accordance with the procedure laid down in Article 25, determine the limits of the infected territory in accordance with paragraph 1 (b) before 1 November 1990.

5. The Commission may, acting in accordance with the procedure laid down in Article 25, amend the decision taken in accordance with paragraph 4, in the light of epidemiological circumstances.

6. The Council, acting by a qualified majority on a proposal from the Commission based on a report on experience acquired, shall if necessary review this Article within a period of two years.

Article 6

Member States which implement an alternative control system providing guarantees equivalent to those laid down in Article 4 (5) as regards movements within their territory of equidae and registered equidae, in particular by means of the

identification document, may grant one another derogations from the provisions of the second sentence of Article 4 (1) and the second indent of Article 8 (1) on a reciprocal basis.

They shall notify the Commission thereof.

Article 7

1. The equidae must be transported, as soon as possible, from the holding of origin either directly or via an approved market or marshalling centre as defined in Article 3 (6) of Directive 64/432/EEC to the place of destination in vehicles or containers which have been regularly cleansed and disinfected with a disinfectant at intervals to be fixed by the Member State of dispatch. The vehicles must be designed in such a way that equidae droppings, litter or fodder cannot escape from the vehicle during transportation. Transportation must be effected in such a way that the health and well-being of the equidae can be protected effectively.

2. The Member State of destination may, on a general or restricted basis, grant a derogation from some of the requirements of Article 4 (5) for any animal bearing a special mark indicating that it is scheduled for slaughter, provided that the health certificate mentions such derogation.

In the case of granting such a derogation equidae for slaughter must be transported directly to the designated slaughterhouse and be slaughtered within five days of arrival at the slaughterhouse.

3. The official veterinarian must record the identification number or identification document number of the slaughtered animal and forward to the competent authority of the place of dispatch, at the latter's request, an attestation to the effect that the animal has been slaughtered.

Article 8

1. Member States shall ensure that:

— registered equidae which leave their holdings are accompanied by the identification document laid down in Article 4 (4) together — if they are intended for intra-Community trade — with the attestation provided for in Annex B,

— equidae for breeding, production and slaughter are, during their transportion, accompanied by a health certificate complying with Annex C to this Directive.

The certificate, or in the case of an identification document, the form containing the health particulars, must, without prejudice to Article 6, be drawn up during the 48 hours preceding their embarkation or else no later than the last working day prior to it, in at least one of the official languages of the Member States of dispatch and destination. The duration of validity of the certificate is 10 days. The certificate must consist of a single sheet.

2. Imports of equidae other than registered equidae may be covered by a single health certificate per consignment rather than by the individual certificate referred to in the second indent of paragraph 1.

Article 9

The rules on checks and safeguard measures applicable to intra-Community trade in equidae shall be adopted by the Council under its Decision on veterinary checks applicable to intra-Community trade in live animals with a view to the completion of the internal market.

Article 10

Veterinary experts from the Commission may, to the extent necessary to ensure uniform application of this Directive and in cooperation with the competent national authorities, carry out on-the-spot inspections. The Commission shall inform the Member States of the outcome of such inspections.

The Member States in whose territory an inspection is carried out shall give the experts all the assistance necessary to carry out their task.

General arrangements for the application of this Article shall be adopted in accordance with the procedure laid down in Article 24.

CHAPTER III

Rules for imports from third countries

Article 11

1. Equidae imported into the Community must satisfy the conditions laid down in Articles 12 to 16.

2. Until the date of entry into force of the decisions adopted pursuant to Articles 12 to 16, the Member States shall apply to imports of equidae from third countries conditions at least equivalent to those resulting from the application of Chapter II.

Article 12

1. In order to be imported, the equidae must come from a third country or part of a third country appearing on a list included in a separate column to be added to the list drawn up in accordance with Article 3 of Directive 72/462/EEC.

2. The procedures and criteria for the preparation, modification and publication of the list of third countries or parts of third countries provided for in Article 3 of Directive 72/462/EEC shall apply to the list applicable to imports of equidae.

Article 13

1. The equidae must come from third countries:

(a) free from African horse sickness;

(b) which have been free for two years from Venezuelan equine encephalomyelitis (VEE);

(c) which have been free for six months from dourine and glanders.

2. The Commission may, in accordance with the procedure laid down in Article 24:

(a) decide that the provisions of paragraph 1 shall apply to only a part of the territory of a third country.

In the event that the African horse sickness requirements apply on a regional basis, at the very least the measures laid down in Article 5 (2) and (3) must be complied with;

(b) require additional guarantees for diseases alien to the Community.

Article 14

Before the day of loading for transportation to the Member State of destination, the equidae must have remained without interruption in the territory or part of the territory of a third country or, in the event of regionalization, in the part of the territory defined pursuant to Article 13 (2) (a) for a period to be determined in the decisions to be adopted pursuant to Article 15.

They must come from a holding placed under veterinary supervision.

Article 15

Importation of equidae from the territory of a third country or part thereof as defined in accordance with Article 13 (2) (a) on the list drawn up in accordance with Article 12 (1) shall be authorized only if the equidae, over and above the requirements of Article 13:

(a) comply with the animal health requirements adopted, with reference to the species in question and the categories of equidae, in accordance with the procedure laid down in Article 24 for imports of equidae from that country.

The reference basis for fixing animal health conditions in accordance with paragraph 1 shall be the standards laid down in Articles 4 and 5; and

(b) in the case of a third country not free of vesicular stomatitis or viral arteritis for at least six months, the equidae must meet the following requirements:

(i) they must come from a holding which has been free of vesicular stomatitis for at least six months and they must have reacted negatively to a serological test prior to dispatch;

(ii) in the case of viral arteritis, male equidae must — notwithstanding Article 19 (ii) — have reacted negatively to a serological test or to a virus isolation test or to any other test recognized in accordance with the procedure laid down in Article 24 which would guarantee freedom from the virus.

In accordance with the procedure laid down in Article 24, and following the opinion of the Scientific Veterinary Committee, the Commission may define the categories of male equidae to which this requirement shall apply.

Article 16

1. The equidae must be identified in accordance with Article 4 (4) and accompanied by a certificate drawn up by an official veterinarian of the exporting third country. This certificate must:

(a) be issued on the day of loading of the animals for dispatch to the Member State of destination or, in the case of registered horses, on the last working day before embarkation;

(b) be drawn up in at least one of the official languages of the Member States of destination and one of those of the Member State in which the import inspection is carried out;

(c) accompany the animals in the original;

(d) attest that the animals satisfy the requirements of this Directive and those laid down pursuant to this Directive with regard to importation from third countries;

(e) consist of a single sheet;

(f) be made out for a single consignee or, in the case of animals for slaughter, for a consignment, provided the animals are properly marked and identified.

Member States shall inform the Commission if they make use of this option.

2. The certificate must be drawn up on a form complying with a model established in accordance with the procedure laid down in Article 24.

Article 17

Checks shall be carried out on the spot by veterinary experts of the Member States and the Commission to verify whether the provisions of this Directive, and in particular those of Article 12 (2), are being applied in practice.

Should checks carried out within the terms of this Article bring to light serious facts as against an approved holding, the Commission shall immediately inform the Member States and forthwith adopt a decision provisionally suspending the approval. The final decision shall be taken according to the procedure provided for in Article 25.

The experts from the Member States who are to be entrusted with these checks shall be appointed by the Commission, acting on a proposal from the Member States.

These checks shall be made on behalf of the Community, which shall bear the cost of any expenditure incurred in this connection.

The frequency of and the procedure for these checks shall be determined in accordance with the procedure laid down in Article 24.

Article 18

1. Immediately upon arrival in the Member State of destination, equidae for slaughter shall be taken to a slaughterhouse, either directly or after transition through a market or a marshalling centre, and, in accordance with animal health requirements, be slaughtered within a period of time specified in the decisions to be adopted pursuant to Article 15.

2. Without prejudice to any special conditions which may be adopted in accordance with the procedure laid down in Article 24, the competent authority of the Member State of destination may, on animal health grounds, designate the slaughterhouse to which such equidae must be taken.

Article 19

The Commission, acting in accordance with the procedure laid down in Article 24:

(i) may decide that imports from a third country or part of a third country are to be confined to particular species or categories;

(ii) shall, notwithstanding Article 15, establish the special conditions for the temporary entry into Community territory of registered equidae or equidae intended for special uses or their re-entry into Community territory after being temporarily exported;

(iii) shall determine the conditions for converting temporary entry into permanent entry.

Article 20

1. The general procedures applicable during checks to be carried out in third countries or during checks on imported equidae from third countries shall be determined by the Council not later than 31 December 1990.

Pending implementation of the decision referred to in the first subparagraph, the national rules shall remain in force, in compliance with the general rules of the Treaty.

2. Equidae may not be imported if, during the import checks prescribed in paragraph 1, it is found that:

— the equidae do not come from the territory of a third country or part thereof as defined pursuant to Article 13 (2) (a) included in the list drawn up in accordance with Article 12 (1),

— the equidae are, or are suspected of being, infected with or contaminated by an infectious or contagious disease,

— the conditions laid down in this Directive have not been complied with by the exporting third country,

— the certificate accompanying the animals does not comply with the conditions set out in Article 17,

— the equidae have been treated with substances prohibited under Community rules.

3. Without prejudice to any special conditions which may be adopted in accordance with the procedure laid down in Article 24, the competent authority of the Member State of destination may, on animal health grounds or where permission has not been given for animals refused entry pursuant to paragraph 1 to be sent back, designate the slaughterhouse to which such equidae must be taken.

Article 21

1. Without prejudice to Article 13, if an infectious or contagious animal disease likely to endanger the health of livestock of one of the Member States breaks out or spreads in a third country or if any other reason connected with animal health justifies it, the Member State concerned shall prohibit the importation of animals of the species covered by this Directive, whether imported directly or indirectly through another Member State, from either the whole of the third country or part of its territory.

2. Measures taken by the Member States under paragraph 1, and notice of the withdrawal of such measures, must be communicated immediately to the other Member States and the Commission, together with the reasons therefor.

The Standing Veterinary Committee shall meet as soon as possible after the communication referred to in the first subparagraph and shall decide, in accordance with the procedure laid down in Article 25, whether these measures should be amended, in particular in order to ensure their coordination with measures adopted by the other Member States, or withdrawn.

If the situation referred to in paragraph 1 arises and if it appears necessary that other Member States should also apply the measures taken pursuant to that paragraph, amended where necessary in accordance with the preceding subparagraph, appropriate measures shall be adopted under the procedure laid down in Article 25.

3. Resumption of importation from the third country concerned shall be authorized in accordance with the same procedure.

CHAPTER IV

Final provisions

Article 22

The provisions of this Directive, and in particular those contained in the second sentence of Article 4 (1) and in Articles 6, 8 and 21, shall be re-examined before 1 January 1993 in the framework of the proposals relating to the completion of the internal market, on which the Council will decide by a qualified majority.

Article 23

The Annexes to this Directive shall be amended by the Commission in accordance with the procedure provided for in Article 25.

Article 24

1. Where the procedure laid down in this Article is to be followed, the chairman shall refer the matter without delay to the Standing Veterinary Committee set up by Directive 68/361/EEC [1], hereinafter referred to as the 'Committee', either on his own initiative or at the request of the representative of a Member State.

2. The representative of the Commission shall submit to the Committee a draft of the measures to be taken. The Committee shall deliver its opinion on the draft within a time limit which the chairman may lay down according to the urgency of the matter. The opinion shall be delivered by the majority laid down in Article 148 (2) of the Treaty in the case of decisions which the Council is required to adopt on a proposal from the Commission. The votes of the representatives of the Member States within the Committee shall be weighted in the manner set out in that Article. The chairman shall not vote.

3. The Commission shall adopt the measures envisaged if they are in accordance with the opinion of the Committee.

4. If the measures envisaged are not in accordance with the opinion of the Committee, or if no opinion is delivered, the Commission shall without delay submit to the Council a proposal relating to the measures to be taken. The Council shall act by a qualified majority.

If, within three months of the date of referral to the Council, the Council has not acted, the proposed measures shall be adopted by the Commission except where the Council has decided against the measures by a simple majority.

Article 25

1. Where the procedure laid down in this Article is to be followed, the chairman shall refer the matter without delay to the Committee either on his own initiative or at the request of the representative of a Member State.

2. The representative of the Commission shall submit to the Committee a draft of the measures to be taken. The Committee shall deliver its opinion on the draft within two days. The opinion shall be delivered by the majority laid down in Article 148 (2) of the Treaty in the case of decisions which the Council is required to adopt on a proposal from the Commission. The votes of the representatives of the Member States within the Committee shall be weighted in the manner set out in that Article. The chairman shall not vote.

3. The Commission shall adopt the measures envisaged if they are in accordance with the opinion of the Committee.

4. If the measures envisaged are not in accordance with the opinion of the Committee, or if no opinion is delivered, the Commission shall without delay submit to the Council a proposal relating to the measures to be taken. The Council shall act by a qualified majority.

If, within 15 days of the date of referral to the Council, the Council has not acted, the proposed measures shall be adopted by the Commission except where the Council has decided against the measures by a simple majority.

Article 26

Article 34 of Directive 72/462/EEC shall apply to the requirements set out in Chapter III of this Directive.

Article 27

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive no later than 1 January 1992. They shall forthwith inform the Commission thereof.

Article 28

This Directive is addressed to the Member States.

Done at Luxembourg, 26 June 1990.

For the Council

The President

M. O'KENNEDY

[1] OJ No L 255, 18. 10. 1968, p. 23.

ANNEX A

COMPULSORILY NOTIFIABLE DISEASES

The following diseases are compulsorily notifiable:

— Dourine

— Glanders

— Equine encephalomyelitis (of all types, including VEE)

— Infectious anaemia

— Rabies

— Anthrax

— African horse sickness

— Vesicular stomatitis

ANNEX B

HEALTH INFORMATION [a]

I, the undersigned, certify [b] that the equidae described above meet the following requirements:

(a) they have been examined today and show no clinical sign of disease;

(b) they are not intended for slaughter under a national programme of contagious or infectious disease eradication;

(c) they do not come from the territory or part of the territory of a Member State/third country which is the subject of restrictions for reasons of African horse sickness;

(d) they have not been obtained from a holding which was subject to prohibition for animal health reasons, nor had contact with equidae from a holding which was subject to prohibition for animal health reasons for the periods of time set out in Article 4 (6) of Directive 90/426/EEC;

(e) to the best of my knowledge, they have not been in contact with equidae suffering from an infectious or contagious disease during the period prior to embarkation as laid down in Article 4 (2).

Date	Lieu Place	Cachet et signature du vétérinaire officiel (1) Stamp and signature of the official veterinarian

(1) Name in block capitals and capacity.

[a] Not required where there is a bilateral agreement in accordance with Article 6.
[b] Valid for 10 days.

ANNEX C

MODEL

HEALTH CERTIFICATE

for trade between Member States of the EEC

EQUIDAE

No: .....

Member State of dispatch: .....

Ministry responsible: .....

Territorial Department responsible: .....

.....

I. **Number of equidae:** .....

II. **Identification of equidae:**

Number of equidae (1)	Species horse, ass, mule, hinny	Breed Age Sex	Method of identification and identification (2)

(1) In the case of animals for slaughter, nature of the special mark.
(2) A passport identifying the equine animal may be attached to this certificate provided that its number is stated.

III. **Origin and destination of animal/s:**

The animal/s is/are to be sent from:

.....
(Place of export)

to:.....
(Member State and place of destination)

Name and address of consignor: .....

.....

Name and address of consignee: .....

.....

IV. **Health information** [a]

I, the undersigned, certify that the animal/s described above meet/s the following requirements:

(1) it/they has/have been examined today and show/s no clinical sign of disease;

(2) it/they is/are not intended for slaughter under a national programme of contagious or infectious disease eradication;

(3) (a) it/they does/do not come from the territory or part of the territory of a Member State/third country which is the subject of restrictions for reasons of African horse sickness;

(b) it/they was/were vaccinated against African horse sickness on ..... [b];
it/they is/are not vaccinated against African horse sickness [b];

(4) it/they has/have not been obtained from a holding which was subject to prohibition for animal health reasons nor had contact with equidae from a holding which was subject to prohibition for animal health reasons for the periods of time set out in Article 4 (6) of Directive 90/426/EEC;

(5) to the best of my knowledge, it/they has/have not been in contact with equidae suffering from an infectious or contagious disease during the period prior to inspection as laid down in Article 4 (2) of the said Directive.

V. **This certificate is valid for 10 days.**

(Place) ....., (date) .....

Stamp

.....
(Signature)
(Name in block letters and capacity of signing veterinarian) (1)

---

[a] This information is not required where there is a bilateral agreement in accordance with Article 6 of Directive 90/426/EEC.

[b] Delete whichever does not apply.

(1) In Germany 'Beamteter Tierarzt'; in Belgium 'Inspecteur vétérinaire' or 'Inspecteur Dierenarts'; in France 'Vétérinaire officiel'; in Italy 'Veterinario provinciale'; in Luxembourg 'Inspecteur vétérinaire'; in the Netherlands 'Officieel Dierenarts'; in Denmark 'Autoriseret Dyrlæge'; in Ireland 'Veterinary Inspector'; in the United Kingdom 'Veterinary Inspector'; in Greece 'Επίσημος κτηνίατρος'; in Spain 'Inspector Veterinario' and in Portugal 'Inspector Veterinário'.

ANNEX D

AFRICAN HORSE SICKNESS

DIAGNOSIS

Complement fixation test

The antigen is prepared from the brains of one-month-old mice inoculated intracerebrally with a neurotropic strain of the virus. This can be done using the following method of Bourdin. The brains are frozen and then ground in Veronal buffer at the rate of 10 brains for 12 ml buffer. The resulting suspension is centrifuged for one hour at 10 000 rpm at 4 °C. The supernatant constitutes the antigen. It is used preferably without further modification but may be inactivated with beta-propiolactone. Inactivation may be effected by adding 0,1 ml of a 3 % solution of beta-propiolactone in distilled water to each 0,9 ml of antigen and shaking the mixture for three hours at room temperature in a ventilated cabinet and for 18 hours at 4 °C. One may also use Casals method (Casals J. (1949): *Pro Soc Exptl Bici Med,* 70.339).

In the absence of an international standard serum, the antigen should be titrated against a locally-prepared positive control serum.

Sera should be heated for 30 minutes at 60 °C. To avoid anticomplementary effects, sera should be separated from the blood as soon as possible, in particular sera from asses. Positive and negative control sera should be used in the test.

One may use either a macro-technique or a micro-technique. In both cases, the final point is represented by 50 % haemolysis.

To one volume of doubling dilutions of serum, add one volume antigen as indicated by titration so that there are two units. Mix and leave for 15 minutes at room temperature. Add two volumes of complement containing five units, mix, cover the plates and leave for 18 hours at 4 °C. The complement should be titrated in the presence of antigen to take into account all anticomplementary effects. After leaving the plates for a further 15 minutes at room temperature, add one volume of sensitized sheep erythrocytes diluted to 3 %. Mix and incubate at 37 °C for 30 minutes, mixing again after 15 minutes of incubation. If plates are used, centrifuge the plates for five minutes at 1 500 rpm at 4 °C.

COUNCIL DIRECTIVE

of 26 June 1990

on the zootechnical and genealogical conditions governing intra-Community trade in equidae

(90/427/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 43 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 equidae, being live animals, are included in the list of products in Annex II to the Treaty;

Whereas in order to ensure the rational development of equidae production, thereby increasing productivity in that sector, rules governing the marketing of equidae in intra-Community trade must be laid down at Community level;

Whereas the breeding and rearing of equidae and in particular of horses is generally included in the farming sector; whereas it constitutes a source of income for part of the farming population and should therefore be encouraged;

Whereas satisfactory results in that respect depend largely on the use of equidae registered in stud books maintained by officially approved organizations or associations;

Whereas disparities exist as regards entry in studbooks; whereas those disparities constitute a barrier to trade within the Community; whereas complete liberalization of trade calls for further harmonization, particularly regarding entry in studbooks;

Whereas intra-Community trade in registered equidae should be progressively liberalized; whereas complete liberalization of trade requires further additional harmonization, in particular as regards approval for the purpose of off-farm mating and the use of semen and ova in accordance with the characteristics of each studbook;

Whereas it is necessary to draw up, in accordance with a Community procedure, a harmonized model zootechnical origin and identification certificate;

Whereas the name of an animal is an essential factor in identifying equidae; whereas it is often impossible to trace an animal's descent and monitor its progress if its name is changed at a new owner's request; whereas the rules regarding the naming of equidae should be harmonized, in particular in order to prevent unfair practices;

Whereas provisions should be introduced preventing equidae from third countries from being imported on terms which are less stringent than those applicable within the Community;

Whereas it is advisable to adopt implementing measures regarding certain technical aspects; whereas, for the purposes of the measures envisaged, provision should be made for close and effective cooperation between Member States and the Commission within the Standing Committee on Zootechnics,

HAS ADOPTED THIS DIRECTIVE:

CHAPTER I

General provisions

Article 1

This Directive lays down the zootechnical and genealogical conditions governing intra-Community trade in equidae, their semen, ova and embryos.

Article 2

For the purposes of this Directive:

(a) 'equidae' means domestic animals of the equine or asinine species or crossbreeds thereof;

(b) 'registered equidae' means equidae which are entered or registered and eligible for entry in a studbook, in accordance with the rules laid down pursuant to Article 4 (2) (b) and identified by means of the identification document provided for in Article 8 (1);

(c) 'studbook' means any book, register, file or data medium:

(1) OJ No C 327, 30. 12. 1989, p. 61.
(2) OJ No C 149, 18. 6. 1990.
(3) OJ No C 62, 12. 3. 1990, p. 46.

— which is maintained either by an organization or an association officially approved or recognized by a Member State or by an official agency of the Member State concerned, and

— in which equidae are entered or registered with mention of all their known ascendants.

Article 3

Intra-Community trade in equidae and their semen, ova and embryos may not be prohibited or restricted on zootechnical or genealogical grounds other than those resulting from application of this Directive.

However, in the case of intra-Community trade in registered equidae, their semen, ova and embryos, national provisions which comply with the general rules of the Treaty shall be maintained pending the entry into force of the relevant Community decisions referred to in Articles 4 and 8.

CHAPTER II

Genealogical rules relating to registered equidae

Article 4

1. The following principles shall be taken into account when the decisions referred to in paragraph 2 are adopted:

(a) the recognition or approval of organizations and associations which maintain or establish studbooks shall be subject to compliance with the principles laid down by the organization or association which maintains the studbook of the origin of the breed;

(b) the criteria for entry and registration in studbooks shall be laid down on the basis of the characteristics of the breed and in particular for certain pure breeds of the need to regulate the entry and registration of equidae produced using artificial reproduction methods.

2. The Commission shall establish under the procedure laid down in Article 10 and in accordance with the principles set out in paragraph 1:

(a) the criteria for the approval or recognition of organizations and associations which maintain or establish studbooks;

(b) the criteria for entry and registration in studbooks;

(c) if necessary, the criteria and methods used to identify registered equidae;

(d) the criteria for drawing up the certificate of origin and the identification document referred to in Article 8;

(e) if necessary, rules to ensure coordination between the organizations or associations referred to in Article 5.

Article 5

The list of organizations and associations maintaining or establishing studbooks, which are recognized on the basis of the criteria to be determined in accordance with Article 4 (2) (a) and subsequent updatings, shall be communicated to the Commission and the other Member States within the Standing Committee on Zootechnics.

Article 6

1. In intra-Community trade, equidae which are registered in the Member State of dispatch must, except where a derogation has been agreed by common accord between the two organizations or associations concerned, be registered or entered in the appropriate studbook of the Member State of destination under the same name, with an indication, in accordance with international agreements, of the initial(s) of the country of foaling.

2. Where the constitution of the organizations or associations so permits:

— the original name of the animal may be preceded or followed by another name on a provisional or permanent basis, provided that throughout the animal's life the original name is retained in brackets and that the country of birth is indicated by means of the initial(s) recognized by international agreements,

— alternative measures may be taken to safeguard the continued identity of the animal in accordance with procedures to be determined by the Commission under the procedure laid down in Article 10.

CHAPTER III

Zootechnical rules relating to registered equidae

Article 7

The Commission, may, in so far as may be necessary to ensure uniform application of the provisions of this Directive and in compliance with the principles laid down in Article 4 (1), determine in accordance with the procedure laid down in Article 10:

(a) the methods of monitoring performance and assessing the genetic value of breeding animals;

(b) on the basis of the methods referred to in (a), the general criteria for the approval of a male breeding animal or, if

appropriate, of a female breeding animal for the purposes of breeding and using their semen, ova or embryos.

Article 8

Member States shall ensure that:

1. in their movements, registered equidae are accompanied by an identification document drawn up by the Commission in accordance with the procedure laid down in Article 10 and issued by the organizations or associations referred to in Article 5 of this Directive and Article 2 (c) of Directive 90/426/EEC of 26 June 1990, on animal health conditions governing the movement between Member States and import from third countries of equidae [1].

   The identification document, to be drawn up in the Community languages, for registered horses must include at least the information indicated in the Annex; that information may be supplemented or amended in accordance with the procedure laid down in Article 10;

2. When they are marketed, the semen, ova and embryos of registered equidae are accompanied by a zootechnical certificate of origin and identification issued by the competent authority at least in the language of the country of destination and conforming to a model to be drawn up by the Commission in accordance with the procedure laid down in Article 10.

Final provisions

Article 9

Pending implementation of relevant Community rules, the conditions applicable to imports of equidae and their semen, ova and embryos from third countries must not be more favourable than those governing intra-Community trade.

Article 10

Where the procedure laid down in this Article is to be used, the Standing Committee on Zootechnics set up by Decision 77/505/EEC [2], shall act in accordance with the rules set out in Article 11 of Directive 88/661/EEC [3].

Article 11

The Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 1 January 1991 at the latest. They shall forthwith inform the Commission thereof.

Article 12

This Directive is addressed to the Member States.

Done at Luxembourg, 26 June 1990.

For the Council
The President
M. O'KENNEDY

[1] See page 42 of this Official Journal.

[2] OJ No L 206, 12. 8. 1977, p. 11.
[3] OJ No L 382, 31. 12. 1988, p. 16.

ANNEX

MINIMUM INFORMATION IN THE IDENTIFICATION DOCUMENT

(1) N° d'identification:
Identification No:

(2) Nom:
Name:

(3) Sexe:
Sex:

(4) Robe:
Colour:

(5) Race:
Breed:

(6) par:
by:

(7) et:
and:

(6) par:
by:

(8) Date de Naissance:
(Date of foaling):

(9) Lieu d'élevage:
(Place where bred):

(10) Naisseur(s):
Breeder(s):

(11) Certificat d'origine validé le:
par:
Origin certificate validated on:
by:

— Nom de l'autorite compétente:
Name of the competent authority:

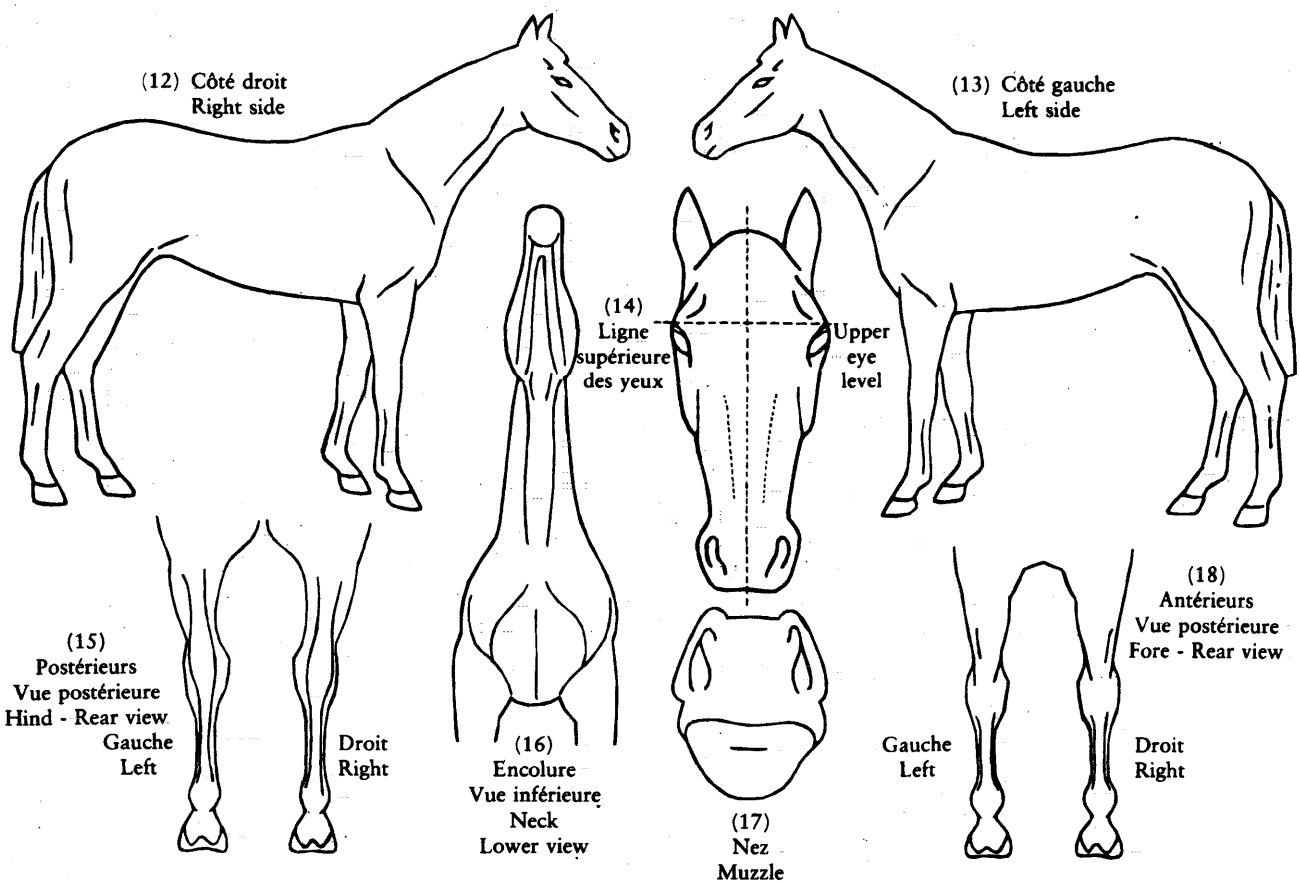
— Adresse:
Address:

— N° de téléphone:
Telephone No:

— N° de télécopie:
Telecopy No:

— Signature:
(nom en lettres capitales et qualité du signataire)
Signature:
(Name in capital letters and capacity of signatory)

— Cachet
Stamp



(2) Nom - Name: (5) Race - Breed: (3) Sexe - Sex: (4) Robe - Colour:

(19) Signalement relevé sous la mère par:
Description taken with dam by:

Tête:
Head:

Ant. G:
Foreleg L:

Ant. D:
Foreleg R:

Post G:
Hindleg L:

Post D:
Hindleg R:

Corps:
Body:

Marques:
Markings:

Le:
On:

(20) Circonscription:
District:

(21) Signature et cachet du vétérinaire agréé
(ou de l'autorité compétente)
Signature and stamp of qualified veterinary surgeon
(or competent authority)

(en lettres capitales)
(in capital letters)

COUNCIL DIRECTIVE

of 26 June 1990

on trade in equidae intended for competitions and laying down the conditions for participation therein

(90/428/CEE)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Articles 42 and 43 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 equidae, being live animals, are included in the list of products in Annex II to the Treaty;

Whereas in order to ensure the rational development of equidae production, thereby increasing productivity in the sector, rules governing intra-Community trade in equidae intended for competitions must be laid down at Community level;

Whereas the breeding and rearing of equidae and in particular of horses is generally included in the farming sector; whereas it constitutes a source of income for part of the farming population;

Whereas there are disparities in the Community as regards the rules for access to competitions; whereas those disparities constitute a barrier to intra-Community trade;

Whereas trade in equidae intended for competitions and participation in such competitions may be jeopardized by disparities existing in the rules concerning the allocation of a percentage of the prize money or profits for the safeguard, development and improvement of breeding in the Member States; whereas introducing free access to the competitions presupposes harmonization of these rules;

Whereas, pending such harmonization, in order, in particular, to maintain or increase productivity in that sector, Member States should be authorized to reserve a percentage of prize money or profits for the safeguard, development and improvement of their breeding activities; whereas, however, a ceiling should be fixed for that percentage;

Whereas it is advisable to adopt implementing measures regarding certain technical aspects; whereas, for the purposes of the planned measures, provision should be made for close and effective cooperation between Member States and the Commission within the Standing Committee on Zootechnics,

HAS ADOPTED THIS DIRECTIVE:

Article 1

This Directive lays down the conditions governing trade in equidae intended for competitions and the conditions governing their participation therein.

Article 2

For the purposes of this Directive, the definitions set out in Article 2 of Council Directive 90/427/EEC of 26 June 1990 on the zootechnical and genealogical conditions governing intra-Community trade in equidae (4) shall apply.

Furthermore, 'competition' means any equestrian competition, including horse racing, show-jumping, eventing, dressage, events reserved for horse-drawn vehicles and showing classes.

Article 3

1. The rules of competitions may not discriminate between equidae which are registered in the Member State in which the competition is being held and equidae registered in another Member State.

2. The rules of competitions may not discriminate between equidae originating in the Member State in which the competition is being held and equidae originating in another Member State.

Article 4

1. The obligations set out in Article 3 shall apply in particular to:

(a) the requirements for entering the competition, in particular the minimum or maximum requirements;

(b) the judging of the competition;

(1) OJ No C 327, 30. 12. 1989, p. 61.
(2) OJ No C 149, 18. 6. 1990.
(3) OJ No C 62, 12. 3. 1990, p. 46.

(4) See page 55 of this Official Journal.

(c) the prize money or profits which may accrue from the competition.

2. However,

— the obligations referred to in Article 3 shall not affect the organization of:

(a) competitions reserved for equidae registered in a specific studbook for the purpose of permitting the improvement of the breed;

(b) regional competitions with a view to selecting equidae;

(c) historic or traditional events.

Member States intending to avail themselves of these possibilities shall inform the Commission thereof beforehand in general terms.

— *for each competition or type of competition* Member States shall be authorized to reserve, through the bodies officially approved or recognized for that purpose, a certain percentage of the prize money or profits referred to in paragraph 1 (c) for the safeguard, development and improvement of breeding.

The percentage may not exceed *30%* in 1991, *25%* in 1992 and 20% from 1993.

The criteria for the distribution of these funds in the Member State concerned shall be communicated to the Commission and the other Member States within the Standing Committee on Zootechnics.

Before 31 December 1992 the Council shall re-examine the conditions for the application of these provisions on the basis of a Commission report that takes account of the progress made in harmonization in connection with all problems posed by the conditions for the breeding of competition horses, together with appropriate proposals on which the Council shall act by a qualified majority.

3. The general rules for the application of this Article shall be adopted in accordance with the procedure laid down in Article 6.

Article 5

1. Until relevant decisions are adopted pursuant to Article 4 of Directive 90/427/EEC, the grounds on which an animal registered in a Member State is refused entry to a competition must be communicated in writing to the owner or his authorized representative.

2. In the circumstances described in paragraph 1, the owner or his authorized representative is entitled to obtain an expert opinion in accordance with the conditions laid down in Article 8 (2) of Directive 89/662/EEC (1), which shall apply *mutatis mutandis*.

3. The Commission shall, in accordance with the procedure laid down in Article 6, adopt rules for the application of this Article.

Article 6

Where the procedure laid down in this Article is to be used, the Standing Committee on Zootechnics, set up by Decision 77/505/EEC (2), shall act in accordance with the rules set out in Article 11 of Directive 88/661/EEC (3).

Article 7

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive not later than 1 July 1991. They shall forthwith inform the Commission thereof.

Article 8

This Directive is addressed to the Member States.

Done at Luxembourg, 26 June 1990.

For the Council

The President

M. O'KENNEDY

(1) OJ No L 395, 30. 12. 1989, p. 13.
(2) OJ No L 206, 12. 8. 1988, p. 11.
(3) OJ No L 382, 31. 12. 1988, p. 36.

COUNCIL DIRECTIVE

of 26 June 1990

laying down the animal health requirements applicable to intra-Community trade in and imports of semen of domestic animals of the porcine species

(90/429/EEC

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 43 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 provisions relating to animal health problems in intra-Community trade in bovine animals and swine appear in Directive 64/432/EEC (4), as last amended by Directive 89/360/EEC (5); whereas in addition, Directive 72/462/EEC (6), as last amended by Directive 89/227/EEC (7) contains provisions relating to veterinary inspection problems encountered upon importation of bovine animals and swine from third countries;

Whereas the abovementioned provisions have ensured, with regard to intra-Community trade and imports into the Community of bovine animals and swine from third countries, that the country of provenance guarantees that animal health criteria have been fulfilled so that the risk of animal disease spreading has been virtually eliminated; whereas there is nevertheless a certain risk of the spread of such disease in the case of trade in semen;

Whereas in the context of the Community policy of harmonizing national animal health provisions governing intra-Community trade in animals and animal products, it is now necessary to create a harmonized system for intra-Community trade and imports into the Community of semen of porcine animals;

Whereas, in the context of intra-Community trade in semen, the Member State where the semen is collected should be under an obligation to ensure that such semen has been collected and processed at approved and supervised collection centres, has been obtained from animals whose health status is such as to ensure that the risk of spread of animal disease is eliminated, has been collected, processed, stored and transported in accordance with rules which preserve its health status and is accompanied during transport to the country of destination by an animal health certificate in order to ensure that this obligation has been fulfilled;

Whereas the difference in the policies pursued within the Community with regard to vaccination against certain diseases justifies the maintenance of derogations, limited in time, authorizing the requirement by the Member States, in respect of certain diseases, of additional protection against those diseases;

Whereas for imports of semen into the Community from third countries a list of third countries should be drawn up taking into account animal health criteria; whereas independently of such a list the Member States should authorize importation of semen only from semen collection centres which reach certain standards and which are officially supervised; whereas, in addition, in respect of countries on that list, specific animal health conditions should be laid down according to circumstances; whereas, in order to verify compliance with these standards, it must be possible to carry out on-the-spot checks;

Whereas the rules and procedures for checks laid down in Council Directive 89/662/EEC of 11 December 1989 concerning veterinary checks in intra-Community trade with a view to the completion of the internal market (8) should be extended to cover this Directive;

Whereas in order to prevent the transmission of certain contagious diseases, import controls should be carried out when a consignment of semen arrives on the territory of the Community, except in the case of external transit;

Whereas a Member State should be permitted to take emergency measures in the event of an outbreak of a contagious disease in another Member State or in a third country; whereas the dangers associated with such diseases and the protective measures they necessitate should be assessed in the same way throughout the Community; whereas to that end, an emergency Community procedure under which the necessary measures must be taken should be instituted within the Standing Veterinary Committee;

(1) OJ No C 267, 6. 10. 1983, p. 5.
(2) OJ No C 342, 19. 12. 1983, p. 11.
(3) OJ No C 140, 28. 5. 1984, p. 6.
(4) OJ No 121, 29. 7. 1964, p. 1977/64.
(5) OJ No L 153, 6. 6. 1989, p. 29.
(6) OJ No L 302, 31. 12. 1972, p. 28.
(7) OJ No L 93, 6. 4. 1989, p. 25.
(8) OJ No L 395, 31. 12. 1989, p. 13.

Whereas the Commission should be entrusted with taking certain measures for implementing this Directive; whereas to that end, a procedure should be established for close and effective cooperation between the Commission and the Member States within the Standing Veterinary Committee;

Whereas this Directive does not affect trade in semen produced before the date on which the Member States must comply with it,

HAS ADOPTED THIS DIRECTIVE:

CHAPTER I

General provisions

Article 1

This Directive lays down the animal health conditions applicable to intra-Community trade in and imports from third countries of semen of domestic animals of the porcine species.

Article 2

For the purposes of this Directive, the definitions contained in Article 2 of Directives 64/432/EEC, 72/462/EEC, 80/407/EEC (1) and 90/425/EEC (2) shall apply as necessary.

Moreover, 'semen' means the ejaculate of a domestic animal of the porcine species, in the unaltered state or prepared or diluted.

CHAPTER II

Intra-Community trade

Article 3

Each Member State shall ensure that only semen, meeting the following general conditions, is intended for trade:

(a) it must have been collected and processed, for the purpose of artifical insemination, in a collection centre approved from the point of view of animal health for the purposes of intra-Community trade in accordance with Article 5 (1);

(b) it must have been collected from domestic animals of the porcine species whose health status complies with Annex B;

(c) it must have been collected, processed, stored and transported in accordance with Annexes A and C.

(1) OJ No L 194, 22. 7. 1988, p. 10.
(2) See page 29 of this Official Journal.

Article 4

1. Until 31 December 1992, Member States in which all collection centres contain only animals which have not been vaccinated against Aujeszky's disease giving a negative reaction to the serum neutralization test, or to the ELISA test for Aujeszky's disease, in accordance with the provisions of this Directive:

— may refuse admission to their territory of semen from collection centres which do not have that status,

— may not prohibit the admission of semen from boars which have been vaccinated in the collection centre with the GI deleted vaccine, provided that:

  — such vaccination has only been carried out on boars that were serum-negative with regard to the virus of Anjeszky's disease,

  — serological examinations carried out at the earliest three weeks after vaccination of such boars do not reveal the presence of antibodies induced by the disease virus.

  In this event a sample of semen from each daily collection intended for trade may be subjected to a virus isolation test in an approved laboratory in the Member State of destination.

  The provisions of this paragraph shall not come into effect until such time as the Commission, acting in accordance with Article 18, not later than 1 July 1991, has laid down the protocols for the tests to be used for these examinations following the opinion of the Scientific Veterinary Committee, in particular in connection with the frequency of the tests to be carried out in the centre, the virus isolation tests and the effectiveness and safety of the GI deleted vaccine.

2. In accordance with the procedure referred to in Article 18, it may be decided to extend the provisions of paragraph 1 to part of the territory of a Member State if all the collection centres in that part of the territory contain only animals giving a negative reaction to the serum neutralization test or the ELISA test for Aujeszky's disease.

3. The Council shall, before 31 December 1992, review this Article on the basis of a report from the Commission, accompanied by any proposals.

Article 5

1. The Member State on whose territory the semen collection centre is situated shall ensure that the approval provided for in Article 3 (a) is granted only if it meets the conditions of Annex A and satisfies the other provisions of this Directive.

The Member State shall also ensure that the official veterinarian supervises the observance of those provisions. The official veterinarian shall propose that approval be withdrawn when one or more of the provisions is no longer observed.

2. All approved semen collection centres shall be registered, each centre being given a veterinary registration number. Each Member State shall send a list of semen collection centres and their veterinary registration numbers to the other Member States and to the Commission and shall notify them of any withdrawal of approval.

3. The general rules for applying this Article shall be adopted in accordance with the procedure laid down in Article 18.

Article 6

1. Member States shall ensure that each consignment of semen is accompanied by an animal health certificate drawn up in accordance with the specimen in Annex D by an official veterinarian of the Member State of collection.

This certificate must:

(a) be drawn up in at least one of the official languages of the Member State of collection and one of those of the Member State of destination;

(b) accompany the consignment to its destination in its original form;

(c) be drawn up on a single sheet of paper;

(d) be made out to a single consignee.

2. The Member State of destination may, in addition to measures provided for in Article 8 of Directive 90/425/EEC, take the necessary measures, including storage in quarantine, provided this does not affect the viability of the semen, in order to obtain definite proof in cases where semen is suspected of being infected or contamined by pathogenic organisms.

CHAPTER III

Imports from third countries

Article 7

1. A Member State may authorize importation of semen only from those third countries which appear on a list drawn up in accordance with the procedure laid down in Article 19. That list may be supplemented or amended in accordance with the procedure laid down in Article 18.

2. In deciding whether a third country may appear on the list referred to in paragraph 1, particular account shall be taken of:

(a) the state of health of the livestock, other domestic animals and wildlife in that country, with particular reference to exotic animal diseases, and of the environmental health situation in that country, which might endanger animal health in the Member States;

(b) the regularity and rapidity of the information supplied by that country concerning the existence of contagious animal diseases in its territory transmissible by semen, in particular those diseases mentioned in lists A and B of the International Office of Epizootic Diseases;

(c) that country's rules on animal disease prevention and control;

(d) the structure of the veterinary services in that country and their powers;

(e) the organization and implementation of measures to prevent and control contagious animal diseases; and

(f) the guarantees which that country can give with regard to compliance with this Directive.

3. The list referred to in paragraph 1 and all amendments thereto shall be published in the *Official Journal of the European Communities*.

Article 8

1. Under the procedure laid down in Article 19, a list shall be drawn up of semen collection centres from which Member States may authorize the importation of semen originating in third countries. The list may be amended or supplemented according to the same procedure.

2. In deciding whether a semen collection centre in a third country may appear on the list referred to in paragraph 1, particular account shall be taken of the veterinary services and the supervision to which semen collection centres are subject.

3. A semen collection centre may appear on the list provided for in paragraph 1 only if:

(a) it is situated in one of the countries on the list referred to in Article 7 (1);

(b) it fulfils the requirements of Chapters I and II of Annex A;

(c) it has been officially approved for exports to the Community by the veterinary services of the third country concerned;

(d) it is placed under the supervision of a centre veterinarian of the third country concerned; and

(e) it is subject to inspection by an official veterinarian of the third country concerned at least twice a year.

Article 9

1. Semen must come from animals which, immediately prior to collection of their semen, have remained for at least three months in the territory of a third country on the list referred to in Article 7 (1).

2. Without prejudice to Article 7 (1) and paragraph 1 of this Article, Member States shall not authorize the importation of semen from a third country on the list unless the semen complies with the animal health requirements adopted under the procedure laid down in Article 18, for imports of semen from that country.

In adopting the requirements referred to in the first subparagraph, consideration shall be given to:

(a) the health situation in the area surrounding the semen collection centre, with particular reference to the diseases appearing on list A of the International Office of Epizootic Diseases;

(b) the state of health of the herd in the semen collection centre and testing requirements;

(c) the state of health of the donor animal and testing requirements;

(d) testing requirements in relation to semen.

3. The reference basis for fixing animal health conditions shall be the standards laid down in Chapter II and the corresponding Annexes. It may be decided, in accordance with the procedure laid down in Article 18, on a case-by-case basis, to waive these conditions where the third country concerned provides similar animal health guarantees, that are at least equivalent.

4. Article 4 shall apply.

Article 10

1. Member States shall authorize the importation of semen only on submission of an animal health certificate drawn up and signed by an official veterinarian of the third country of collection.

This certificate must:

(a) be drawn up in at least one of the official languages of the Member State of destination and one of those of the Member State where the import control provided for in Article 11 is carried out;

(b) accompany the semen to its destination in its original form;

(c) be drawn up on a single sheet of paper;

(d) be made out to a single consignee.

2. The animal health certificate must correspond to a specimen drawn up under the procedure laid down in Article 19.

Article 11

1. Member States shall ensure that each consignment of semen entering the customs territory of the Community is subjected to control before being released for free circulation or placed under a customs procedure and shall prohibit the introduction of the semen into the Community if the import control made on arrival reveals that:

— the semen does not come from the territory of a third country on the list drawn up in accordance with Article 7 (1),

— the semen does not come from a semen collection centre on the list provided for in Article 8 (1),

— the semen comes from the territory of a third country from which imports are prohibited in accordance with Article 15 (2),

— the animal health certificate which accompanies the semen is not in conformity with the conditions laid down in Article 10 and fixed pursuant thereto.

This paragraph shall not apply to consignments of semen which arrive in the customs territory of the Community and are placed under a customs transit procedure for consignment to a destination situated outside the said territory.

However, it shall be applicable where customs transit is waived during transport through the territory of the Community.

2. The Member State of destination may take the necessary measures, including storage in quarantine provided that this does not affect the viability of the semen, in order to obtain definite proof in cases where semen is suspected of being infected or contamined by pathogenic organisms.

3. If the admission of semen has been prohibited on any of the grounds set out in paragraphs 1 and 2 and the exporting third country does not authorize the return of the semen within 30 days in the case of deep-frozen semen, or immediately in the case of fresh semen, the competent veterinary authority of the Member State of destination may order it to be destroyed.

Article 12

Each consignment of semen authorized for admission into the Community by a Member State on the basis of the control referred to in Article 11 (1) must, when sent to the territory of another Member State, be accompanied by the original certificate or an authenticated copy thereof, suitably endorsed, in either case, by the competent authority which was responsible for the control carried out in accordance with Article 11.

Article 13

If it is decided to take destruction measures pursuant to Article 11 (3), any costs incurred shall be chargeable to the consignor, the consignee or their agent, without compensation by the State.

CHAPTER IV

Precautionary and control measures

Article 14

The rules set out in Directive 90/425/EEC shall apply in particular with regard to checks at origin, the organization and the monitoring of the checks to be carried out by the Member State of destination.

Article 15

1. The precautionary measures provided for in Article 10 of Directive 90/425/EEC shall apply to intra-Community trade.

2. Without prejudice to Articles 8, 9 and 10, if in a third country a contagious animal disease which can be carried by semen and is liable to endanger the health of the livestock in a Member State breaks out or spreads or if any other reason connected with animal health so justifies, the Member State of destination concerned shall prohibit the import of that semen, whether imported directly or indirectly through another Member State, either from the whole of the third country or from part of its territory.

Measures taken by the Member States on the basis of the first subparagraph and the repeal of such measures must be communicated immediately to the other Member States and the Commission together with the reasons for such measures.

Under the procedure laid down in Article 18, it may be decided that those measures must be amended, in particular in order to coordinate them with measures adopted by the other Member States, or that they must be repealed.

If the situation envisaged in the first subparagraph arises and if it is necessary that other Member States also apply the measures taken under that subparagraph, amended where necessary in accordance with the third subparagraph, appropriate steps shall be taken under the procedure laid down in Article 18.

Resumption of imports from the third country concerned shall be authorized under the procedure laid down in Article 18.

Article 16

1. Veterinary experts from the Commission may, in cooperation with the competent authorities of the Member States and third countries, make on-the-spot checks in so far as that is indispensable for ensuring uniform application of this Directive.

The country of collection within whose territory a check is being carried out shall give all necessary assistance to the experts in carrying out their duties. The Commission shall inform the country of collection concerned of the results of the checks.

The country of collection concerned shall take any measures which may prove necessary to take account of the results of this check. If the country of collection does not take those measures, the Commission may, after the situation has been examined by the Standing Veterinary Committee, have recourse to the provisions of the third subparagraph of Article 6 (2) and of Article 5.

2. The general provisions for implementing this Article, especially as regards the frequency and method of carrying out the checks referred to in the first subparagraph of paragraph 1, shall be laid down under the procedure set out in Article 19.

CHAPTER V

Final provisions

Article 17

The Annexes to this Directive shall be ameneded in accordance with the procedure set out in Article 18 to adapt them to advances in technology.

Article 18

1. Where the procedure laid down in this Article is to be followed, matters shall without delay be referred by the chairman, either on his own initiative or at the request of a Member State, to the Standing Veterinary Committee (hereinafter referred to as 'the Committee') set up by Decision 68/361/EEC (1).

2. Within the Committee, the votes of the Member States shall be weighted as provided for in Article 148 (2) of the Treaty. The chairman shall not vote.

3. The representative of the Commission shall submit a draft of the measures to be adopted. The Committee shall deliever its opinion on the draft within a time limit which the chairman may lay down according to the urgency of the matter. Opinions shall be delivered by a majority of 54 votes.

4. The Commission shall adopt the measures and apply them immediately where they are in accordance with the Committee's opinion. Where they are not in accordance with the Committee's opinion or in the absence of any opinion, the Commission shall forthwith submit to the Council a proposal relating to the measures to be taken. The Council shall adopt the measures by a qualified majority.

If, on the expiry of three months from the date on which the matter was referred to it, the Council has not adopted any measures, the Commission shall adopt the proposed

(1) OJ No L 255, 18. 10. 1968, p. 23.

measures and apply them immediately, save where the Council has decided against the said measures by a simple majority.

Article 19

1. Where the procedure laid down in this Article is to be followed, matters shall without delay be referred to the Committee by the chairman, either on his own initiative or at the request of a Member State.

2. Within the Committee, the votes of the Member States shall be weighted as provided for in Article 148 (2) of the Treaty. The chairman shall not vote.

3. The representative of the Commission shall submit to the Committee a draft of the measures to be adopted. The Committee shall deliver its opinion on such measures within two days. The opinion shall be delivered by a majority of 54 votes.

4. The Commission shall adopt the measures and apply them immediately where they are in accordance with the Committee's opinion. Where they are not in accordance with the Committee's opinion, or in the absence of any opinion, the Commission shall forthwith submit to the Council a proposal relating to the measures to be taken. The Council shall adopt the measures by a qualified majority.

If, on the expiry of 15 days from the date on which the matter was referred to it, the Council has not adopted any measures, the Commission shall adopt the proposed measures and apply them immediately, save where the Council has decided against the said measures by a simple majority.

Article 20

1. This Directive shall not be applicable to semen collected and processed in a Member State before 31 December 1991.

2. Until the date of entry into force of the decisions adopted pursuant to Article 8, 9 and 10, Member States shall not apply to imports of semen from third countries more favourable conditions than those resulting from application of Chapter II.

Article 21

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 31 December 1991 at the latest. They shall forthwith inform the Commission thereof.

Article 22

This Directive is addressed to the Member States.

Done at Luxembourg, 26 June 1990.

For the Council

The President

M. O'KENNEDY

ANNEX A

CHAPTER I

Conditions for the approval of semen collection centres

Semen collection centres must:

(a) be placed under the permanent supervision of a centre veterinarian;

(b) have at least

(i) animal housing including isolation facilities,

(ii) semen collection facilities including a separate room for the cleaning and disinfection or sterilization of equipment;

(iii) a semen processing room which need not necessarily be on the same site,

(iv) a semen storage room which need not necessarily be on the same site;

(c) be so constructed or isolated that contact with livestock outside is prevented;

(d) be so constructed that the animal housing and the semen collecting, processing and storage facilities can be readily cleaned and disinfected;

(e) have isolation accommodation which shall have no direct communication with the normal animal accommodation;

(f) be so designed that the animal accommodation is physically separated from the semen processing room and both are separated from the semen storage room.

CHAPTER II

Conditions relating to the supervision of semen collection centres

The collection centres must:

(a) be so supervised that they contain only male animals of the species whose semen is to be collected;

(b) be so supervised that a record, file or computer record is kept of all porcine animals at the centre, giving details of the breed, date of birth and identification of each of the animals, and also a record, file or computer record of all checks for diseases and all vaccinations carried out, giving also information from the disease/health file of each animal;

(c) be regularly inspected by an official veterinarian, at least twice a year, at which time checks on the conditions of approval and supervision shall be carried out;

(d) be so supervised that the entry of unauthorized persons is prevented. Furthermore, authorized visitors must be required to comply with the conditions laid down by the centre veterinarian;

(e) employ technically competent staff suitably trained in disinfection procedures and hygiene techniques relevant to the control of the spread of disease;

(f) be so supervised that:

(i) only semen collected at an approved centre is processed and stored in approved centres, without coming into contact with any other consignment of semen,

(ii) collection, processing and storage of semen takes place only on the premises set aside for the purpose and under conditions of the strictest hygiene,

(iii) all implements which come into contact with the semen or the donor animal during collection and processing are properly disinfected or sterilized prior to use,

(iv) products of animal origin used in the processing of semen — including additives or a diluent — are obtained from sources which present no animal health risk or are so treated prior to use that such risk is prevented,

(v) storage flasks and transport flasks are properly disinfected or sterlized before the beginning of each filling operation,

(vi) the cryogenic agent used has not been previously used for other products of animal origin,

(vii) each collection of semen, whether or not it is separated into individual doses, is clearly marked in such a way that the date of collection of the semen and the breed and identification of the donor animal, as well as the name and the registration number of the centre, preceded by the name of the country of origin, where appropriate, in the form of a code, can be readily established; the characteristics and form of this marking will be established under the procedure laid down in Article 19.

ANNEX B

CHAPTER I

Conditions applying to the admission of animals to approved semen collection centres

1. All boars admitted to a semen collection centre must:

   (a) have been subjected to a period of isolation of at least 30 days in accommodation specifically approved for the purpose by the competent authority of the Member State, and where only boars having at least the same health status are present;

   (b) prior to their entering the isolation accommodation described in (a) have been chosen from herds or holdings:

      (i) which are officially free of classical swine fever,

      (ii) which are free of brucellosis,

      (iii) in which no animal vaccinated against foot-and-mouth disease has been present in the preceding 12 months,

      (iv) in which no clinical, serological or virological sign of Aujeszky's disease has been detected in the preceding 12 months,

      (v) which are not covered by any prohibition in accordance with the requirements of Directive 64/432/EEC with regard to African swine fever, swine vesicular disease, Teschen's disease and foot-and-mouth disease.

      The animals may not previously have been kept in other herds of a lower status;

   (c) before the period of isolation specified in (a), and within the previous 30 days, have been subjected to the following tests with negative results:

      (i) a complement fixation test carried out in accordance with the provisions of Annex C of Directive 64/432/EEC in respect of brucellosis,

      (ii) — a serum neutralization or an ELISA test using all the viral antigens in the case of non-vaccinated pigs,

      — an ELISA test for GI antigens in the case of pigs vaccinated with a GI deleted vaccine,

      (iii) pending the introduction of a Community policy to combat foot-and-mouth disease, an ELISA test for the presence of foot-and-mouth disease,

      (iv) an ELISA test or a serum neutralization test for the presence of classical swine fever.

      The competent authority may give authorization for the tests referred to in (c) to be carried out in the isolation accommodation, provided that the results are known before the beginning of the 30-day isolation period laid down in (d);

   (d) during the period of isolation of at least 30 days specified in (a), have been subjected to the following tests with negative results:

      (i) a serum agglutination test complying with the procedure laid down in Annex C to Directive 64/432/EEC and showing a brucella count lower than 30 IU of agglutination per millilitre and a complement fixation test showing a brucella count lower than 20 EEC units per millilitre (20 ICFT units) in the case of animals coming from brucellosis-free herds,

      (ii) — a serum neutralization or an ELISA test using all the viral antigens in the case of non-vaccinated pigs,

      — an ELISA test for GI antigens in the case of pigs vaccinated with a GI deleted vaccine,

      (iii) until the introduction of a Community policy on combating foot-and-mouth disease, an ELISA test for the presence of foot-and-mouth disease,

      (iv) a microscopic agglutination test for the presence of leptospirosis (sero-vars pomona, grippotyphosa, tarassovi, hardjo, bratislava and ballum serum viruses), or have been treated for leptospirosis with two injections of streptomycin at an interval of 14 days (25 mg per kg of live body weight).

   Without prejudice to the provisions applicable in cases where foot-and-mouth disease and swine fever is found, if any of the above tests should prove positive, the animal must be removed forthwith from the isolation accommodation. In the case of group isolation, the competent authority must take all necessary measures to allow the remaining animals to be admitted to the collection centre in accordance with this Annex.

2. All tests must be carried out in a laboratory approved by the Member State.

3. Animals may only be admitted to the semen collection centre with the express permission of the centre veterinarian. All animal movements, both in and out, must be recorded.

4. No animal admitted to the semen collection centre may show any clinical sign of disease on the day of admission; all animals must, without prejudice to paragraph 5, have come from isolation accommodation as referred to in paragraph 1 (a) which, on the day of consignment, officially fulfils the following conditions:

   (a) is situated in the centre of an area of 10 kilometres radius in which there has been no case of foot-and-mouth disease or swine fever for at least 30 days;

   (b) has for at least three months been free from foot-and-mouth disease and brucellosis;

   (c) has for at least 30 days been free from Aujeszky's disease and from those porcine diseases which are compulsorily notifiable in accordance with Annex E to Directive 64/432/EEC.

5. Provided that the conditions laid down in paragraph 4 are satisfied and the routine tests referred to in Chapter II have been carried out during the previous 12 months, animals may be transferred from one approved semen collection centre to another of equal health status without isolation or testing if transfer is direct. The animal in question must not come into direct or indirect contact with cloven-hoofed animals of a lower health status and the means of transport used must have been disinfected before use. If the movement from one semen collection centre to another takes place between Member States, it must take place in accordance with Directive 64/432/EEC.

CHAPTER II

Compulsory routine tests for boars kept at an approved semen collection centre

1. All boars kept at an approved semen collection centre must be subjected when leaving the centre to the following tests with negative results:

   (i) — a serum neutralization or an ELISA test using all the viral antigens in the case of non-vaccinated pigs,
   — an ELISA test for GI antigens in the case of pigs vaccinated with a GI deleted vaccine,

   (ii) until the introduction of a Community policy on combating foot-and-mouth disease, an ELISA test for the presence of foot-and-mouth disease,

   (iii) a complement fixation test conducted in accordance with Annex C to Directive 64/432/EEC regarding brucellosis,

   (iv) an ELISA test or serum neutralization test for the presence of classical swine fever.

   In addition, boars kept more than 12 months at the collection centre must be subjected to the tests referred to in points (i) and (iii) not later than 18 months after their admission.

2. All tests must be carried out in a laboratory approved by the Member State.

3. Without prejudice to the provisions applicable in cases where foot-and-mouth disease or swine fever is found, if any of the above tests should prove positive, the animal must be isolated and the semen collected from it since the last negative test may not be the subject of intra-Community trade.

   Semen collected from all other animals at the centre since the date when the positive test was carried out shall be held in separate storage and may not be the subject of intra-Community trade until the health status of the centre has been re-established.

ANNEX C

Conditions which semen collected at approved centres must satisfy for the purposes of intra-Community trade

1. Semen must be obtained from animals which:

   (a) show no clinical signs of disease on the day the semen is collected;

   (b) have not been vaccinated against foot-and-mouth disease;

   (c) satisfy the requirements of Annex B, Chapter I;

   (d) are not allowed to serve naturally;

   (e) are kept in semen collection centres which have been free from foot-and-mouth disease for at least three months prior to dispatching of the semen, and are situated in the centre of an area of 10 kilometres radius in which for at least 30 days there has been no case of foot-and-mouth disease; furthermore the centres must not be situated in a restricted area designated under the provisions of the Directives relating to contagious diseases of the porcine species;

   (f) have been kept in semen collection centres which, during the 30-day period immediately prior to collection, have been free from those porcine diseases which are compulsorily notifiable in accordance with Annex E to Directive 64/432/EEC and from Aujeszky's disease.

2. An effective combination of antibiotics, in particular against leptospires and mycoplasmas, must be added to the semen after final dilution. This combination must produce an effect at least equivalent to the following dilutions:

   not less than: 500 IU per ml streptomycin,
   500 IU per ml penicillin,
   150 µg per ml lincomycin,
   300 µg per ml spectinomycin.

   Immediately after the addition of the antibiotics the diluted semen must be kept at a temperature of at least 15 °C for a period of not less than 45 minutes.

3. Semen for intra-Community trade must:

   (i) be stored as laid down in Chapters I and II of Annex A prior to dispatch;

   (ii) be transported to the Member State of destination in flasks which have been cleaned and disinfected or sterilized before use and which have been sealed prior to dispatch from the approved storage facilities.

ANNEX D

1. Consignor (name and full address)	**ANIMAL HEALTH CERTIFICATE** No ORIGINAL
	2. Member State of collection
3. Consignee (name and full address)	4. Competent authority
Notes (a) A separate certificate must be issued for each consignment of semen (b) The original of this certificate must accompany the consignment to the place of destination	5. Competent local authority
6. Place of loading	7. Name and address of semen collection centre
8. Means of transport	
9. Place and Member State of destination	
11. Number and code-mark of semen containers	10. Registration number of semen collection centre

12. Identification of semen

(a) Number of doses	(b) Date(s) of collection	(c) Breed
(d) Identification of donor animal		

13. I, the undersigned official veterinarian, certify that:

(a) the semen described above was collected, processed and stored under conditions which comply with the standards laid down in Directive 90/429/EEC;

(b) the semen described above was collected from boars:

(i) on a collection centre which only contains animals that have not been vaccinated against Aujeszky's disease and which have reacted negatively to the serum neutralization test or to the ELISA test for Aujeszky's disease, in accordance with the provisions of Directive 90/429/EEC (1),

or

(ii) on a centre in which some or all the boars have been vaccinated against Aujeszky's disease using a GI deleted vaccine; such boars having been seronegative with regard to Aujeszky's disease before vaccination and subjected three weeks later to a further serological examination which did not reveal the presence of antibodies induced by the disease virus; and, in that case, the semen of each batch has been subjected to a virus isolation test for Aujeszky's disease in the laboratory ..... (2), and gave a negative reaction (1);

(c) the semen described above was sent to the place of loading in sealed containers under conditions which comply with the provisions of Directive No 90/429/EEC.

Stamp

Done at ....., ...

Signature .....

Name and qualification (in block letters) .....

.....

.....

(1) Delete whichever of points (i) or (ii) does not apply.
(2) Name of the laboratory specified in accordance with Article 4 (1) of Directive 90/429/EEC.