

Council Directive 92/65/EEC of 13 July 1992 laying down animal health requirements governing trade in and imports into the Community of animals, semen, ova and embryos not subject to animal health requirements laid down in specific Community rules referred to in Annex A (I) to Directive 90/425/EEC

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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 proposals 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 are included in the list of products in Annex II to the Treaty; whereas the placing on the market of such animals and products constitutes a source of income for part of the farming population;

Whereas in order to ensure the rational development in this sector and increase productivity, animal health rules for the animals and products should be laid down at Community level;

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

Whereas in view of the abovementioned objectives the Council has laid down animals health rules applicable to cattle, swine, sheep and goats, equidae, poultry and hatching eggs, fish and fish products, bivalve molluscs, semen of bulls and boars, ovine embryos, fresh meat, poultrymeat, meat products, game meat and rabbit meat;

Whereas animal health rules should be adopted for the placing on the market of animals and products of animal origin which are not yet covered by the abovementioned rules;

Whereas provision should be made for applying this Directive without prejudice to Council Regulation (EEC) No 3626/82 of 3 December 1982 on the implementation in the Community of the Convention on International Trade in Endangered Species of Wild Fauna and Flora (4);

Whereas, as regards certain technical aspects, reference must be made to Council Directive 64/432/EEC of 26 June 1964 on animal health problems affecting intra-Community trade in bovine animals and swine (5) and Directive 85/511/EEC of 18 November 1985 introducing Community measures for the control of foot-and-mouth disease (6);

Whereas, in respect of the organization of checks and the follow-up thereto, as well as the safeguard measures to be implemented, reference must be made to the general rules laid down in Council Directive 90/425/EEC 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 (7);

Whereas, save where otherwise provided, trade in animals and products of animal origin must be liberalized, without prejudice to recourse to possible safeguard measures;

Whereas, given the significant risk of the spread of diseases to which animals are exposed, for certain animals and products of animal origin particular requirements should be specified to be imposed when they are placed on the market for the purposes of trade, particularly when intended for regions with a high health status;

Whereas the specific situation pertaining in the United Kingdom of Great Britain and Northern Ireland and in Ireland given the insular position of those countries, and the fact that they have been free of rabies for a considerable period of time, warrants particular provisions to ensure that the placing on the market in the United Kingdom and Ireland of dogs and cats which do not originate in those countries does not involve a risk of introducing rabies into those States, without however affecting the abolition of veterinary checks at the frontiers between Member States;

Whereas a health certificate is the most appropriate means of guaranteeing and monitoring compliance with these requirements;

Whereas, to maintain the health situation in the Community, when the animals and products of animal origin referred to in this Directive are placed on the market, they should be made subject to the minimum requirements laid down for trade and compliance therewith monitored in accordance with the principles and rules laid down in Council Directive 90/675/EEC of 10 December 1990 laying down the principles

governing the organization of veterinary checks on products entering the Community from third countries (8);

Whereas provision should be made for a procedure establishing close co-operation between the Member States and the Commission within the Standing Veterinary Committee;

Whereas the deadline for transposition into national law, set at 1 January 1994 in Article 29, should not affect the abolition of veterinary checks at frontiers on 1 January 1993,

HAS ADOPTED THIS DIRECTIVE:

CHAPTER I General provisions

Article 1

This Directive lays down the animal health requirements governing trade in and imports into the Community of animals, semen, ova and embryos not subject to animal health requirements laid down in specific Community rules referred to in Annex A(I) to Directive 90/425/EEC.

This Directive shall apply without prejudice to the provisions adopted pursuant to Regulation (EEC) No 3626/82.

This Directive shall not affect the national rules applicable to pet animals, although their retention may not jeopardize the abolition of veterinary checks at the frontiers between Member States.

Article 2

1. For the purposes of this Directive:

(a) 'trade' means trade as defined by Article 2 (3) of Directive 90/425/EEC;

(b) 'animals' means specimens of animal species other than those referred to in Directives 64/432/EEC, 90/426/EEC ⁽²⁾, 90/539/EEC ⁽³⁾, 91/67/EEC, 91/68/EEC, 91/492/EEC and 91/493/EEC;

(c) 'approved body, institute or centre' means any permanent, geographically limited establishment, approved in accordance with Article 13, where one or more species of animal are habitually kept or bred, whether or not for commercial ends, and exclusively for one or more of the following purposes:

- display of the animals and education of the public

- conservation of the species;

- basic or applied scientific research or breeding of animals for the purposes of such research;

(d) 'notifiable diseases' means the diseases listed in Annex A.

2. In addition, the definitions, other than those of approved centres and bodies, contained in Article 2 of Directives 64/432/EEC, 91/67/EEC and 90/539/EEC shall apply *mutatis mutandis*.

⁽²⁾ Council Directive 90/426/EEC of 26 June 1990 on animal health conditions governing the movement and import from third countries of equidae. Amended by Directive 91/496/EEC.

⁽³⁾ Council Directive 90/539/EEC of 15 October 1990 on animal health conditions governing intra-Community trade in, and imports from third countries of, poultry and hatching. Last amended by Directive 91/496/EEC.

Council Directive 91/67/EEC of 28 January 1991 concerning the animal health conditions governing the placing on the market of aquaculture animals and products.

Council Directive 91/68/EEC of 28 January 1991 on animal health conditions governing intra-Community trade in ovine and caprine animals.

Council Directive 91/492/EEC of 15 July 1991 laying down the health conditions for the production and the placing on the market of live bivalve molluscs.

Council Directive 91/493/EEC of 22 July 1991 laying down the health conditions for the production and the placing on the market of fishery products.

CHAPTER II Provisions applicable to trade

Article 3

The Member States shall ensure that the trade referred to in Article 1, first paragraph, is not prohibited or restricted for animal health reasons other than those arising from the application of this Directive or from Community legislation, and in particular any safeguard measures taken.

Article 4

Member States shall take the necessary measures to ensure that, for the purposes of applying Article 4 (1) (a) of Directive 90/425/EEC, the animals referred to in Articles 5 to 10 of this Directive may without

prejudice to Article 13 and to the particular provisions to be adopted in implementation of Article 24, be the subject of trade only if they satisfy the conditions laid down in Articles 5 to 10 and come from the holdings or businesses referred to in Article 12 (1) and (3) of this Directive which are registered by the competent authority and which undertake to:

- have the animals held examined regularly in accordance with Article 3 (3) of Directive 90/425/EEC,
- notify the competent authority, aside from the outbreak of notifiable diseases, of the outbreak of the diseases referred to in Annex B for which the Member State concerned has drawn up a control or monitoring programme,
- comply with the specific national measures to control a disease which is of particular importance to a given Member State and is covered by a programme drawn up in accordance with Article 14 or a decision under Articles 15 (2),
- place on the market for the purposes of trade only animals which show no signs of disease and which come from holdings or areas not subject to any ban on animal health grounds and with respect to animals not accompanied by a health certificate or a commercial document provided for in Articles 5 to 11, only animals accompanied by self-certification by the operator stating that the animals in question do not at the time of dispatch show any obvious signs of disease and that his holding is not subject to any animal-health restrictions,
- comply with the requirements ensuring the welfare of the animals held.

Article 5

1. Member States shall ensure that trade in apes (*simiae* and *prosimiae*) is restricted solely to animals consigned from and to a body, institute or centre approved by the competent authorities of the Member States in accordance with Article 13 and that such animals are accompanied by a veterinary certificate corresponding to the specimen in Annex E, the declaration in which must be completed by the official veterinarian of the body, institute or centre of origin to guarantee the animals' health.

2. The competent authority of a Member State may, by way of derogation from paragraph 1, authorize the acquisition by an approved body, institute or centre of apes belonging to an individual.

Article 6

A. Without prejudice to Article 14 and 15, Member States shall ensure that ungulates of species other than those referred to in Directives 64/432/EEC, 90/426/EEC and 91/68/EEC may be the subject of trade only if they meet the following requirements:

1. in general they:

- (a) must be identified in accordance with Article 3 (1) (c) of Directive 90/425/EEC;
- (b) must not be intended for slaughter under a programme for the eradication of an infectious disease;
- (c) must not have been vaccinated against foot-and-mouth disease and must satisfy the relevant requirements of Directive 85/511/EEC and Article 4a of Directive 64/432/EEC;
- (d) must come from a holding referred to in Article 3 (2) (b) and (c) of Directive 64/432/EEC which is not the subject of animal health measures, particularly those taken under Directives 85/511/EEC, 80/217/EEC ⁽¹⁾ and 91/68/EEC and have been kept therein permanently since birth or for the last thirty days before dispatch;

(e) if imported:

- must come from a third country included in a column entitled 'other ungulates' to be inserted in the list drawn up in accordance with Article 3 of Directive 72/462/EEC ⁽²⁾,

⁽¹⁾ Council Directive 80/217/EEC of 22 January 1980 introducing Community measures for the control of classical swine fever. Last amended by Directive 87/486/EEC.

⁽²⁾ Council Directive 72/462/EEC of 12 December 1972 on health and veterinary inspection problems upon importation of bovine animals and swine and fresh meat from third countries. Last amended by Directive 91/497/EEC.

- must meet specific animal health conditions, to be laid down under the procedure provided for in Article 26, which are at least equivalent to the requirements of this Article;

(f) must be accompanied by a certificate corresponding to the specimen given in Annex E bearing the following declaration:

'Declaration

I, the undersigned (official veterinarian) certify that the ruminant/suida (a) other than that covered by Directive 64/432/EEC:

- (a) belongs to the species;

(b) at the time of examination, does not show any clinical sign of any disease to which it is susceptible;
(c) comes from an officially tuberculosis-free/officially brucellosis-free or brucellosis-free herd/a holding not subject to swine-fever restrictions (a) or from a holding where it was subjected with negative results to the tests laid down in Article 6 (2) (a) (ii) of Directive 92/65/EEC.

(a) Delete as appropriate';

2. in the case of ruminants:

(a) they must come from an officially tuberculosis-free and officially brucellosis-free herd in accordance with Directive 64/432/EEC or Directive 91/68/EEC and satisfy, as regards animal health rules, the relevant requirements laid down for the bovine species in Article 3 (2) (c), (d), (f), (g) and (h) of Directive 64/432/EEC or Article 3 of Directive 91/68/EEC;

(b) where they do not come from a herd meeting the conditions laid down in (a), they must come from a holding in which no case of brucellosis or tuberculosis has been recorded in the 42 days preceding loading of the animals and in which the ruminants have, in the 30 days prior to their dispatch, undergone with negative results:

- a tuberculosis reaction test, and

- a test designed to show the absence of antibodies to brucellosis.

The requirements as regards these tests and the definition of the tuberculosis and brucellosis status of these holdings shall be established in accordance with the procedure laid down in Article 26 of this Directive.

Pending the decisions provided for in the preceding subparagraph, national rules shall continue to apply, particularly as regards tuberculosis;

3. in the case of suidae:

(a) they must not have come from an area which is the subject of prohibition measures associated with the presence of African swine fever in accordance with Article 9a of Directive 64/432/EEC;

(b) they must come from a holding which is not subject to any of the restrictions laid down in Directive 80/217/EEC as a result of classical swine fever;

(c) they must come from a brucellosis-free holding in accordance with Directive 64/432/EEC and satisfy the relevant animal health requirements laid down for swine in Directive 64/432/EEC;

(d) where they do not come from a herd meeting the conditions set out in (c), they must, in the 30 days prior to their dispatch, have undergone with negative results a test designed to show the absence of antibodies to brucellosis.

B. Directive 64/432/EEC is amended as follows:

1. in Article 2 (b) and (c), for 'bovine animal(s)' read 'animal(s) of the bovine species (including Bubalus bubalus)';

2. the following Article is inserted:

'Article 10a

Under the procedure laid down in Article 12, the health certificates, a specimen of which is reproduced in Annex F, may be amended or supplemented, in particular in order to take account of the requirements of Article 6 of Directive 92/65/EEC.'

Article 7

A. Member States shall ensure that birds other than those referred to in Directive 90/539/EEC may be the subject of trade only if they meet the following requirements:

1. in general they must:

(a) come from a holding in which avian influenza has not been diagnosed in the 30 days preceding the dispatch;

(b) come from a holding or an area not subject to restrictions under measures to be applied to combat Newcastle disease.

Pending the implementation of the Community measures referred to in Article 19 of Directive 90/539/EEC, national requirements for combating Newcastle disease shall continue to apply, in compliance with the general provisions of the Treaty;

(c) have, in accordance with the third indent of Article 10 (1) of Directive 91/496/EEC, been quarantined, if they have been imported from a third country, in the holding to which they were taken after they entered the territory of the Community;

2. in addition, psittacidae must:

(a) not come from a holding nor have been in contact with animals from a holding on which psittacosis

(*Chlamydia psittaci*) has been diagnosed.

The period of prohibition since the last recorded case and the period of treatment under veterinary supervision recognized under the procedure provided for in Article 26 must be at least two months;
(b) be identified in accordance with Article 3 (1) (c) of Directive 90/425/EEC.

The methods for identifying psittacidae, and in particular sick psittacidae, shall be established under the procedure provided for in Article 26;

(c) be accompanied by a commercial document signed by the official veterinarian or by the veterinarian responsible for the holding or business of origin and empowered for this purpose by the competent authority.

B. In the second subparagraph of Article 2 (2) of Council Directive 91/495/EEC of 27 November 1990 concerning public health and animal health problems affecting the production and placing on the market of rabbit meat and farmed game meat ⁽¹⁾, the words 'and ratites (Ratitae)' shall be inserted in the third line after the words 'Directive 90/539/EEC'.

In point 1 of Article 2 (2) of Council Directive 90/539/EEC of 15 October 1990 on animal health conditions governing intra-Community trade in, and imports from, third countries of poultry and hatching eggs ⁽²⁾, the words 'and ratites (Ratitae)' shall be inserted after the words 'and partridges.'

Article 8

Member States shall ensure that bees (*Apis mellifera*) may be the subject of trade only if they meet the following requirements:

(a) come from an area which is not the subject of a prohibition order associated with an occurrence of American foulbrood.

The period of prohibition must continue for at least 30 days following the last recorded case and the date on which all hives within a radius of three kilometres have been checked by the competent authority and all infected hives burned or treated and inspected to the satisfaction of the said competent authority.

In accordance with the procedure laid down in Article 26, and after consulting the Scientific Veterinary Committee, the requirements applied to bees (*Apis mellifera*) or equivalent requirements may be applied to bumble bees;

(b) are accompanied by a health certificate corresponding to the specimen in Annex E the declaration in which is completed by the competent authority to certify that the requirements laid down in (a) are met.

Article 9

1. Member States shall ensure that lagomorphs may be the subject of trade only if they meet the following requirements:

(a) they must not come from or have been in contact with animals from a holding on which rabies is present or is suspected of having been present within the last month;

(b) they must come from a holding in which no animal shows clinical signs of myxomatosis.

2. Member States which require a health certificate for movements of lagomorphs in their territory may require animals being sent to them to be accompanied by a health certificate corresponding to the specimen in Annex E, supplemented by the following declaration:

'I, the undersigned, . . ., certify that the above consignment satisfies the requirements of Article 9 of Directive 92/65/EEC and that the animals showed no clinical sign of disease on examination.'

This certificate must be issued by the official veterinarian or by the veterinarian responsible for the holding of origin and empowered for this purpose by the competent authority and for industrial breeding, by the official veterinarian. Member States wishing to use this option shall inform the Commission which must ensure that the requirement laid down in the first paragraph has been satisfied.

3. Ireland and the United Kingdom may require the submission of a health certificate guaranteeing that the requirement laid down in paragraph 1 (a) has been satisfied.

Article 10

1. Member States shall ensure that there is a prohibition on trade in ferrets, mink and foxes which come from or have been in contact with animals from a holding on which rabies is present or is suspected of having been present within the previous six months, inasmuch as no systematic vaccination programme is applied.

2. To be the subject of trade, with the exception of trade between the Member States referred to in paragraph 3, dogs and cats must satisfy the following requirements:

(a) animals more than three months old must:

- show no sign of disease, and particularly of contagious diseases of the species, on the day they are dispatched from the holding,
- be tattooed or have a micro-chip identification system implanted in accordance with detailed rules to be laid down under the procedure provided for in Article 26,
- have after the age of three months, been vaccinated against rabies with an annual booster injection or, at intervals authorized by the Member States of dispatch for that vaccine, by injection of an inactivated vaccine of at least one international antigenic unit (WHO standard) measured in accordance with the activity test by the method described by the European Pharmacopoeia and recognized under the procedure laid down in Article 26.

The vaccination must be certified by an official veterinarian or by the veterinarian responsible for the holding of origin and empowered for this purpose by the competent authority. The vaccination certificate must bear the name of the vaccine and its batch number (self-adhesive label if possible):

- dogs must have been vaccinated against canine distemper,
- be accompanied by an individual passport allowing the animal to be clearly identified and showing the dates of vaccination and/or a certificate corresponding to the specimen shown in Annex E supplemented by the following declaration completed by an official veterinarian or by the veterinarian responsible for the holding of origin and empowered for this purpose by the competent authority:

'I, the undersigned certify that the cats/dogs covered by this certificate satisfy the requirements of Article 10 (2) (a) and (b) and (3) (b) of Directive 92/65/EEC (a) and come from a holding in which no case of rabies has been recorded in the last six months.

(a) Delete as applicable';

(b) animals less than three months old must:

- satisfy the requirements of the first and fifth indents of (a),
- not come from a holding which is the subject of restrictions on the movement of animals on animal health grounds,
- have been born on the holding of origin and have been maintained in captivity since birth.

3. As from 1 July 1994, by way of derogation from paragraph 2, the placing on the market in the United Kingdom and Ireland of cats and dogs not originating in those countries shall be subject to the following conditions:

(a) in general, cats and dogs must

- (i) come from a registered holding, registration of which must be suspended by the competent authority where the conditions provided for in Article 4 are no longer met;
- (ii) on the day they are dispatched from the holding in question, show no sign of contagious disease;
- (iii) have been provided with a system of identification in accordance with detailed rules to be established under the procedure laid down in Article 26;
- (iv) have been born on the holding and have been maintained in captivity there since birth with no contact with wild animals susceptible to rabies;
- (v) in the case of dogs, have been vaccinated against canine distemper;
- (vi) be transported in a means of transport recognized for these purposes by the competent authority of the Member States of dispatch;
- (vii) be accompanied by an individual vaccination record allowing the animal and its origin to be clearly identified and showing the dates of vaccination, and by a certificate corresponding to a specimen to be drawn up under the procedure laid down in Article 26

and completed by an official veterinarian or by the veterinarian responsible for the holding of origin and empowered for this purpose by the competent authority;

(b) in addition, they must:

- (i) either have been vaccinated against rabies after the age of three months and at least six months before dispatch by injection of an inactivated vaccine of at least 1 international antigenic unit (WHO standard) measured in accordance with the activity test by the method described by the European pharmacopoeia and recognized under the procedure laid down in Article 26, with annual booster injection, or at intervals authorized by the Member State of dispatch for that vaccine.

The vaccination must be certified by an official veterinarian or by the veterinarian responsible for the holding of origin and empowered for this purpose by the competent authority. The vaccination certificate must bear the name of the vaccine and its batch number (self-adhesive label if possible).

Moreover, have undergone, following a vaccination, a serological test showing a protective antibody titre of at least 0,5 international units, which serological test should be carried out in accordance with WHO specifications. If the test is carried out after the first vaccination it must be carried out between the first and third month after the vaccination.

(ii) or, where the conditions provided for in (i) are not met, be sent under supervision to a quarantine station approved by the Member State of destination to undergo a six-month period of quarantine.

Until 1 July 1994, national regulations applicable with respect to rabies shall remain in force, although such retention may not affect the abolition of veterinary checks at the frontiers between Member States.

4. Ireland and the United Kingdom may without prejudice to paragraphs 2 and 3, retain their national regulations on quarantine for all carnivores, primates, bats and other animals susceptible to rabies covered by this Directive which cannot be shown to have been born on the holding of origin and kept in captivity since birth, although the retention of those regulations may not jeopardize the abolition of veterinary checks at the frontiers between Member States.

5. Decision 90/638/EEC is amended as follows:

1. the following indent is added to Article 1:

'- for programmes to control rabies: the criteria set out in Annex III.';

2. the following Annex is added:

'ANNEX III

Criteria for programmes to control rabies

Programmes to control rabies shall contain at least:

(a) the criteria referred to in points 1 to 7 of Annex 1;

(b) detailed information regarding the region or regions in which the oral immunization of foxes is to take place and its natural limits. This region or these regions must cover at least 6 000 km² or the total national area of a Member State and may include adjacent areas of a third country;

(c) detailed information regarding the vaccines to be used, the distribution system, the density and frequency of bait-laying;

(d) where appropriate, all details and the cost and purpose of schemes to conserve or preserve flora and fauna undertaken by voluntary organizations on the territory covered by these projects.'

6. The Council, acting by a qualified majority on a proposal from the Commission, shall designate a specific institute to establish the criteria necessary for the standardization of the serological tests and shall decide on its responsibilities.

7. Member States shall ensure that the costs of applying the serological test are borne by the importers.

8. This Article, and in particular the application of the serological test provided for in paragraph 3 (b), will be reviewed before 1 January 1997 in the light of developments in the rabies situation in the Member States.

Article 11

1. The Member States shall ensure that, without prejudice to the decisions to be taken in implementation of Articles 21 and 23, only semen, ova and embryos meeting the conditions laid down in paragraphs 2, 3 and 4 are the subject of trade.

2. Semen of the ovine, caprine and equine species must, without prejudice to any criteria to be complied with for the entry of equids in stud books for certain specific breeds:

- have been collected and processed with a view to artificial insemination in a centre approved from the health point of view in accordance with Annex D (I), or, in the case of ovine and caprine animals by way of derogation from the above, in a holding satisfying the requirements of Directive 91/68/EEC,

- have been collected from animals meeting the conditions laid down in Annex D (II) (admission and routine checks on animals),

- have been collected, processed and preserved in accordance with Annex D (III),

- have been accompanied during transport to another Member State by a health certificate corresponding to a specimen to be determined under the procedure provided for in Article 26.

3. Ova and embryos of the ovine/caprine and equine species and of swine must:

- have been removed by a collection team approved by the competent authority of the Member State and processed in an appropriate laboratory from donor females meeting the conditions laid down in Annex D (IV),

- have been treated and stored in accordance with Annex D (III),

- be accompanied during transport to another Member State by a health certificate corresponding to a

specimen to be defined under the procedure laid down in Article 26.

Semen used for the insemination of donor females must comply with the provisions of paragraph 2 in the case of sheep, goats and equids and with the provisions of Directive 90/429/EEC for swine. Any additional guarantees may be determined under the procedure laid down in Article 26.

4. Before 31 December 1997 the Commission shall submit a report together with any appropriate proposals on the implementation of this Article in the light in particular of scientific and technological developments.

Article 12

1. The rules on checks established by Directive 90/425/EEC shall apply, in particular as regards the organization of and follow-up to the checks to be carried out, to the animals, semen, ova and embryos covered by this Directive which are accompanied by a health certificate. Other animals must come from holdings subject to the principles of that Directive as regards checks on origin and destination.

2. Article 10 of Directive 90/425/EEC shall apply to animals, semen, ova and embryos covered by this Directive.

3. For the purpose of trade, Article 12 of Directive 90/425/EEC shall extend to dealers who keep, on a permanent or occasional basis, animals referred to in Articles 7, 9 and 10.

4. The communication of the place of destination as provided for in Article 4 (2) of Directive 90/425/EEC shall, in respect of animals, semen, ova or embryos accompanied by a health certificate in accordance with this Directive, take place using the Animo system.

5. Without prejudice to the specific provisions of this Directive, the competent authority shall, where it is suspected that this Directive has not been complied with or there is doubt as to the health of the animals or the quality of the semen, ova and embryos referred to in Article 1, carry out any checks it deems appropriate.

6. Member States shall take the appropriate administrative or penal measures to penalize any infringement of this Directive, in particular where it is found that the certificates or documents drawn up do not correspond to the actual state of the animals referred to in Article 1, that the identification of the animals or the marking of the semen, ova and embryos in question does not comply with this Directive or that the animals or products in question have not undergone the checks provided for in this Directive.

Article 13

1. Trade in animals of species susceptible to the diseases listed in Annex A or to the diseases listed in Annex B, where the Member State of destination applies the guarantee provided for in Articles 14 and 15, and trade in semen, ova or embryos of such animals consigned to and from bodies, institutes or centres approved in accordance with Annex C shall be subject to production of a transport document corresponding to the specimen in Annex E. This document, which must be completed by the veterinarian responsible for the body, institute or centre of origin, must specify that the animals, semen, ova or embryos come from a body, institute or centre approved in accordance with Annex C and must accompany them during transport.

2. (a) To be approved, bodies, institutes or centres shall, as regards notifiable diseases, submit to the competent authority of the Member State all relevant supporting documents relating to the requirements contained in Annex C.

(b) After receiving the file relating to the request for approval or for renewal of approval, the competent authority shall examine it in the light of the information it contains and, where appropriate, of the results of the tests conducted on the spot.

(c) The competent authority shall withdraw approval in accordance with point 3 of Annex C.

(d) Each Member State shall send the Commission a list of approved bodies, institutes and centres, together with any changes to the list. The Commission shall forward this information to the other Member States.

Article 14

1. Where a Member State draws up or has drawn up, either directly or through the breeders, a voluntary or compulsory control or monitoring programme for one of the diseases referred to in Annex B, it may present the programme to the Commission outlining in particular:

- the distribution of the disease in its territory,
- whether the disease is notifiable,
- reasons for undertaking the programme, taking account of its cost-effectiveness and the significance of

the disease,

- the geographical area in which the programme is to be implemented,
- the status categories to be applied to establishments, the requirements for each species when being introduced into a holding and the test procedures to be used,
- the programme monitoring procedures, including the extent of the breeders' involvement in implementing the control or monitoring programme,
- 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 under the programme are positive,
- the non-discriminatory nature of trade in the territory of the Member State concerned with respect to intra-Community trade.

2. The Commission shall examine the programmes presented by the Member States. Programmes may be approved under the procedure provided for in Article 26 in compliance with the criteria laid down in paragraph 1. Under the same procedure, the additional guarantees, general or limited, which may be required in trade, shall be defined at the same time or at the latest three months after presentation 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 under the procedure laid down in Article 26. Under the same procedure, amendments may be made to the guarantees referred to in paragraph 2.

Article 15

1. Where a Member State considers that its territory or part of its territory is free from one of the diseases listed in Annex B to which the animals covered by this Directive are susceptible, it shall present to the Commission appropriate supporting documentation, setting out in particular:

- 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,
- the period during which this disease was notifiable 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 the documentation provided for in paragraph 1 and submit to the Standing Veterinary Committee a decision approving or rejecting the plan submitted by the Member State. If the plan is accepted, the additional guarantees, general or specific, which may be required in trade shall be defined under the procedure laid down in Article 26. They must not exceed those which the Member State implements nationally.

Pending a decision, the Member State concerned may maintain in its trade dealings the relevant requirements needed in order to maintain its status.

3. The Member State concerned shall notify the Commission of any change in the particulars specified in paragraph 1. The guarantees defined as laid down in paragraph 2 may, in the light of such notification, be amended or withdrawn under the procedure laid down in Article 26.

CHAPTER III Provisions applicable to imports into the Community

Article 16

The conditions applicable to imports of animals, semen, ova and embryos covered by this Directive must be at least equivalent to those laid down in Chapter II.

Article 17

1. For the purposes of uniform application of Article 16, the provisions of the following paragraphs shall apply.

2. Only animals, semen, ova and embryos referred to in Article 1 which satisfy the following requirements may be imported into the Community:

(a) they must come from a third country on a list to be drawn up in accordance with paragraph 3 (a);

(b) they must be accompanied by a health certificate corresponding to a specimen to be drawn up under the procedure laid down in Article 26, signed by the competent authority of the exporting country and

certifying that the animals, semen, ova and embryos meet the additional conditions or offer the equivalent guarantees referred to in paragraph 4 and come from approved centres, bodies, institutes or collection centres offering such guarantees.

3. The following shall be established under the procedure laid down in Article 26:

(a) without prejudice to the list provided for in Article 6 (A) (1) (e), a provisional list of third countries or parts of third countries able to provide Member States and the Commission, before the date laid down in Article 29, with guarantees equivalent to those provided for in Chapter II and a list of the collection centres for which they are able to give these guarantees.

This provisional list shall be compiled from the lists of establishments approved and inspected by the competent authorities once the Commission has checked that these establishments comply with the principles and general rules laid down in this Directive

(b) updates of that list in the light of the checks provided for in paragraph 4;

(c) the specific animal health requirements - in particular for the protection of the Community from certain exotic diseases - or guarantees equivalent to those provided for in this Directive.

The specific requirements and equivalent guarantees established for third countries may not be more favourable than those provided for in Chapter II.

4. The list provided for in paragraph 3 may include only third countries or parts of third countries:

(a) from which imports are not prohibited:

- as a result of the existence of one of the diseases referred to in Annex A or of any other disease exotic to the Community,

- pursuant to Articles 6, 7 and 14 of Directive 72/462/EEC and Article 17 of Directive 91/495/EEC and of Directive 71/118/EEC ⁽¹⁾ or, in the case of the other animals covered by this Directive, under a decision taken in accordance with the procedure laid down in Article 26 account being taken of their state of health;

(b) which, in view of their legislation and the organization of their veterinary services and inspection services, the powers of such services and the supervision to which ⁽¹⁾ Council Directive 71/118/EEC of 15 February 1971 on health problems affecting trade in fresh poultrymeat. Last amended by Directive 90/654/EEC.

they are subject, have been recognized, in accordance with Article 3 (2) of Directive 72/462/EEC, as capable of guaranteeing the implementation of their legislation in force;

(c) the veterinary services of which are able to guarantee that health requirements at least equivalent to those laid down in Chapter II are being complied with.

5. Experts from the Commission and the Member States shall carry out on-the-spot inspections to verify whether the guarantees given by the third country regarding the conditions of production and placing on the market can be considered equivalent to those applied in the Community.

The experts from the Member States responsible for these inspections shall be appointed by the Commission acting on a proposal from the Member States.

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

6. Pending the organization of the inspections referred to in paragraph 5, national rules applicable to inspection in third countries shall continue to apply, subject to notification, through the Standing Veterinary Committee, of any failure to comply with the guarantees offered in accordance with paragraph 3, found during these inspections.

Article 18

1. Member States shall ensure that the animals, semen, ova and embryos covered by this Directive are imported into the Community only if they:

- are accompanied by a certificate to be drawn up by the official veterinarian.

The specimen certificate shall, depending on the species, be drawn up under the procedure laid down in Article 26,

- have satisfied the checks required by Directives 90/675/EEC and 91/496/EEC ⁽²⁾,

- have undergone, prior to shipment to Community territory, a check by an official veterinarian to ensure that the transport conditions specified in Directive 91/628/EEC ⁽³⁾ have been complied with, in particular as regards watering and feeding,

- have, in the case of the animals referred to in Articles 5 to 10, been quarantined before being placed on the market, in accordance with detailed rules to be established under the procedure laid down in Article

26.

(²) Council Directive 91/496/EEC of 15 July 1991 laying down the principles governing the organization of veterinary checks on animals entering the Community from third countries and amending Directive 89/662/EEC, 90/425/EEC and 90/675/EEC

(³) Council Directive 91/628/EEC of 19 November 1991 on the protection of animals during transport and amending Directives 90/425/EEC and 91/496/EEC

2. Pending the establishment of specific rules for this Article, the national rules applicable to imports from third countries for which such requirements have not been adopted at Community level shall continue to apply, provided they are not more favourable than those laid down in Chapter II.

Article 19

The following shall be decided under the procedure laid down in Article 26:

(a) specific animal health requirements, for imports into the Community, and the nature and content of accompanying documents for animals intended for zoos, circuses, amusement parks or experimental laboratories, according to the species;

(b) additional guarantees to those provided for in respect of the various animal species covered by this Directive, to protect the Community species concerned.

Article 20

The principles and rules laid down in Directive 90/675/EEC shall apply, with particular reference to the organization of and follow-up to the inspections to be carried out by the Member States and the safeguard measures to be implemented.

Pending implementation of the decisions provided for in Article 8 (3) and Article 30 of Directive 91/496/EEC, the relevant national rules for applying Article 8 (1) and (2) of the said Directive shall continue to apply, without prejudice to compliance with the principles and rules referred to in paragraph 1 of this Article.

CHAPTER IV Common final provisions

Article 21

Any specimens of certificates applicable to trade and the animal health conditions to be met in order for it to be possible to trade in animals, semen, ova and embryos other than those covered by Article 5 to 11 shall, where the need arise, be determined under the procedure laid down in Article 26.

Article 22

The Annexes to this Directive shall, where the need arises, be amended under the procedure laid down in Article 26.

Article 23

Under the procedure laid down in Article 26, special requirements may be laid down, if appropriate, by way of derogation from Article 6 (A) (1) (e) and from Chapter II, for the movement of circus and fairground animals and for trade in animals, semen, ova and embryos intended for zoos.

Article 24

1. The Member States shall be authorized to subject the entry into their territory of the animals (including cage birds), semen, ova and embryos referred to in this Directive which have passed through the territory of a third country to production of a health certificate certifying compliance with the requirements of this Directive.

2. Member States which have recourse to the possibility laid down in paragraph 1 shall inform the Commission and the other Member States within the Standing Veterinary Committee.

Article 25

The following shall be added to Annex A to Directive 90/425/EEC:

'Council Directive 92/65/EEC of 13 July 1992 laying down animal health requirements governing trade in and imports into the Community of animals, semen, ova and embryos not subject to animal health requirements laid down in specific Community rules referred to in Annex A (1) to Directive 90/425/EEC

Article 26

Where reference is made to the procedure provided for in this Article, the Standing Veterinary Committee set up by Decision 68/361/EEC ⁽¹⁾ shall act in accordance with the rules laid down in Article 17 of Directive 89/662/EEC.

Article 27

Member States which implement an alternative control system providing guarantees equivalent to those laid down in this Directive as regards movements within their territory of the animals, semen, ova and embryos which it covers, may grant one another derogations from Article 6 (A) (1) (f), Article 8 (b) and Article 11 (1) (d) on a reciprocal basis.

Article 28

Under the procedure laid down in Article 26, transitional measures may be adopted for a period of three years to ⁽¹⁾ facilitate the transition to the new arrangements established by this Directive.

Article 29

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive before 1 January 1994. They shall forthwith inform the Commission thereof. When these measures are adopted by the Member States, they shall contain a reference to this Directive or shall be accompanied by such reference on the occasion of their official publication. The methods of making such a reference shall be laid down by the Member States.
2. Member States shall communicate to the Commission the texts of the main provisions of national law which they adopt in the field governed by this Directive.
3. The setting of the deadline for transposition into national law at 1 January 1994 shall be without prejudice to the abolition of veterinary checks at frontiers provided for in Directive 89/662/EEC and 90/425/EEC.

Article 30

This Directive is addressed to the Member States.

Done at Brussels, 13 July 1992.

For the Council
The President
J. GUMMER

ANNEX A

NOTIFIABLE DISEASES IN THE CONTEXT OF THIS DIRECTIVE (a)

Diseases

Species concerned

Newcastle disease, avian influenza

Birds

Psittacosis

Psittacidae

American fowlbrood

Bees

Foot-and-mouth disease

Ruminants

Brucellosis (*Brucella* spp.)

Tuberculosis

Classical swine fever

Suidae

African swine fever

Foot-and-mouth disease

Rabies (b)

All susceptible species

(a) Without prejudice to the notifiable diseases provided for in Annex I to Directive 82/894/EEC.

(b) In accordance with Article 2 of Directive 89/455/EEC.

ANNEX B

LIST OF DISEASES FOR WHICH NATIONAL PROGRAMMES MAY BE RECOGNIZED UNDER THIS DIRECTIVE

Mink

Viral enteritis

Aleutian disease

Bees

European foulbrood

varroasis and acariosis

Apes and felids

Tuberculosis

Ruminants

Tuberculosis

Lagomorphs

Myxomatosis

Viral haemorrhagic disease

Tularaemia

ANNEX C

CONDITIONS GOVERNING APPROVAL OF BODIES, INSTITUTES OR CENTRES 1. In order to be granted official approval under Article 13 (2) of this Directive, a body, institute or centre as defined in Article 2 (1) (c) must:

(a) be clearly demarcated and separated from its surroundings;

(b) be situated at a reasonable distance from agricultural establishments whose health status might be jeopardized by the presence of the approved body, institute or centre;

(c) be under the control of a veterinarian ⁽¹⁾ who monitors the animals, which it must be possible to catch, confine and cage at any time;

(d) have adequate quarantine facilities;

(e) have one or more appropriate premises to practise post-mortem examination;

(f) be free of the diseases listed in Annex A and, as regards the diseases covered in the country concerned by a programme pursuant to Article 14, the diseases listed in Annex B;

(g) keep up-to-date records indicating:

- the number of animals of each species present in the establishment, with information as to their ages,

- the number of animals arriving in the establishment or leaving it, together with information on their transport and the animals' health,

- observations made during the quarantine period,

- the results of regular examinations of excreta,

- the results of blood tests or any other diagnostic procedures,

- cases of disease and, where appropriate, the treatment administered,

- the results of the dissection of any animals that die in the establishment, including still-born animals;

(h) have facilities for appropriate disposal of the bodies of animals which die of a disease;

(i) be monitored by an official veterinarian who must carry out at least two health checks per year.

Health checks must include at least:

- one inspection of all the animals in the establishment,

- representative samples taken from all the species susceptible to the diseases referred to in Annexes A and B ⁽²⁾ or detection of these diseases by other methods. These samples must be analysed by an approved laboratory to check whether they contain agents of the diseases for each species in Annex A. Samples may be taken throughout the year.

The results of the laboratory tests on the samples taken during the health checks must reveal no evidence

of the pathogens in question;

- examination of the records which must be kept.

2. Approval shall be retained where the following requirements are met:

(a) the animals brought into the establishment must come from another approved centre, institute or body;

(b) if animals covered by Directive 64/432/EEC are held in an approved centre, institute or body, they may leave the establishment only under official control;

(c) health checks in the approved centre, institute or body must be carried out twice a year, in accordance with point 1 (h) of this Annex.

(d) the results of the laboratory tests on the samples must reveal no trace of agents of the diseases referred to in Annexes A and B ⁽²⁾;

⁽¹⁾ Responsible for day-to-day compliance with the animal health requirements of this Directive.

⁽²⁾ Inasmuch as one of these diseases is notifiable in the Member State concerned.

(e) any suspect deaths or the presence of any other symptom suggesting that animals have contracted one or more of the diseases referred to in Annexes A and B ⁽¹⁾ must be notified without delay to the competent authority.

3. Approval may be suspended, restored or withdrawn in the following circumstances:

(a) where notification is given within the meaning of 2 (d) of this Annex, the competent authority shall temporarily suspend approval of the approved centre, body or institute;

(b) a sample taken from a suspect animal is forwarded to the approved laboratory to test for the presence of the pathogens in question. The test results shall immediately be forwarded to the competent authority;

(c) where the official department has been informed of suspicions as to the presence of one of the diseases referred to in Annexes A and B ⁽¹⁾, it shall react, as regards the laboratory tests, the epizootiological examination, the measures to be taken against the disease and the withdrawal of approval, as if the disease had been notified, in accordance with the Directive governing measures in this field to be taken against the diseases and trade in animals;

(d) where the test results show no signs of the pathogens concerned, the official department shall reinstate approval;

(e) the body, institute or centre shall again be approved only where, after eradication of the sources of infection, the conditions laid down in point 1 of this Annex, with the exception of point 1 (f), are again fulfilled;

(f) the competent authority shall inform the Commission of the suspension, restoration or withdrawal of approval.

⁽¹⁾ Inasmuch as one of these diseases is notifiable in the Member State concerned.

ANNEX D

CHAPTER I I. Conditions governing the approval of semen collection centres

Semen collection centres must:

1. be placed under the supervision of a 'centre veterinarian';

2. have different and physically separate premises for:

- accommodating and isolating animals,

- collecting semen,

- cleaning and disinfecting equipment,

- processing semen,

- storing semen;

3. be built or kept separate in such a way as to prevent any contact with animals outside the centre;

4. have premises such as described at 2 which are easily cleaned and disinfected,

II. Conditions for the supervision of semen collection centres

Semen collection centres must:

1. be monitored to ensure that only animals whose semen is to be collected are kept there. However, other domestic animals may stay in these centres provided they meet the general conditions set out below,

2. be monitored to ensure that a register is kept showing

- the identity of the animals present in the centre,

- any movements of animals (entering and leaving),

- the health checks made,

- the health history,

- the destination of the semen,

- the storage of the semen;
- 3. be inspected at least twice a year by an official veterinarian to ensure that the approval and supervision conditions are met;
- 4. employ competent staff who have received adequate training on disinfection and hygiene techniques to allow the spread of disease to be avoided;
- 5. be monitored to ensure that
 - the collection, processing and storage of semen is carried out only in premises set aside for these purposes,
 - all utensils coming into contact with the semen or the donor animal during collection or processing are properly disinfected or sterilized before each use,
 - any recipient for the storage or transport of semen is disinfected or sterilized before use;
- 6. be sure to use:
 - products of animal origin used in the processing of the semen (additive or diluent) which present no health risks or which have undergone prior processing to preclude such risks,
 - a cryogenic agent which has not previously been used for other products of animal origin;
- 7. ensure that each quantity of semen is adequately identified in such a way that the date of collection, the breed and the identity of the donor animal may be established as well as the name of the approved centre which made the collection.

CHAPTER II Conditions applicable in collection centres

Requirements as regards the admission of donor males

A. STALLIONS

Only stallions which, to the satisfaction of the official veterinarian, meet the following requirements may be used for the collection of semen:

1. they must be in good health at the time of collection
2. they must satisfy the requirements of Directive 90/426/EEC and come from holdings which also satisfy those requirements;
3. during the 60 days before the first collection they must have undergone with negative results the following tests:

- (a) to detect equine infectious anaemia, an agar-gel immunodiffusion test, known as the 'Coggins test';
- (b) to detect viral arteritis, a sero-neutralization test (dilution $< 1/4$) supplemented, in the event of a positive result, by virological examination of total semen with a negative result;
- (c) to detect contagious equine metritis by isolating the *Taylorella equigenitalis* germ, at least a test of samples taken from the urethra and the pre-ejaculatory fluid.

The result of these tests must be certified by a laboratory recognized by the competent authority.

During the period mentioned in the first paragraph of 3 above, and during the collection period, stallions may not be allowed to serve naturally.

B. SHEEP AND GOATS

1. Only sheep and goats from centres or holdings which, to the satisfaction of the official veterinarian, meet the following requirements may be used for the collection of semen:

- (a) they are in good health on the day the semen is collected;
- (b) they meet the requirements laid down in Articles 4, 5 and 6 of Directive 91/68/EEC on intra-Community trade.

In addition, donor animals must undergo, during the thirty days before the collection, with negative results:

- a test to detect brucellosis (*B. melitensis*) in accordance with Annex C to Directive 91/68/EEC,
- a test for contagious epididymitis (*B. ovis*) in accordance with Annex D to Directive 91/68/EEC,
- a test for the Border disease virus;
- (c) they have undergone the relevant tests or checks designed to guarantee compliance with the requirements set out in (a) and (b) above.

2. The tests referred to in 1. must be carried out by a laboratory approved by the Member State.

C. If any of the tests referred to in A or B proves positive, the animal must be isolated and the semen collected from it since the last negative test may not be placed on the market. The same applies to semen collected from the other animals at the holding or collection centre since the date on which the positive test was carried out. Trade may not resume until the health status of the centre has been re-established.

CHAPTER III Requirements applicable to semen, ova and embryos

Semen, ova and embryos must have been collected, processed, washed and preserved with a biological product free of living micro-organisms in accordance with the following principles:

- (a) the washing of ova and embryos must be carried out in accordance with Article 11 (3) of this Directive. Their pellucid zone must remain intact before and after washing. Only ova and embryos from one and the same donor may be washed at any one time. After washing, the pellucid zone of each ovum or embryo must be examined over its entire surface area under a magnification of at least 50 and be certified as being intact and free of any foreign body adhering to it;
- (b) the medium and solutions used for the collection, freezing and conservation of ova and embryos must be sterilized in accordance with approved methods as laid down in Article 11 (3) and handled in such a way that they remain sterile. Antibiotics must be added to the collection, washing and conservation mediums in accordance with detailed rules to be determined under the procedure laid down in Article 26;
- (c) all materials used for the collection, handling, washing, freezing and conservation of ova or embryos must be sterilized before use;
- (d) they must have been subjected, in accordance with Article 11 (2), to additional tests to be established under the procedure provided for in Article 26, in particular of the collection or washing liquids, so as to establish that no pathogens are present;
- (e) they must be kept in sterile recipients (ampoules, straws, duly identified by a method to be established under the procedure laid down in Article 26):
 - containing only products from one male or female donor,
 - sealed at the time of freezing in alcohol or fresh liquid nitrogen, and labelled,and be placed in sterilized liquid nitrogen containers which present no risk of contamination to the products;
- (f) they must be stored in approved conditions for a minimum period of 30 days prior to dispatch;
- (g) they must be transported in flasks which have been cleaned, disinfected or sterilized before use.

CHAPTER IV Donor females

Females may be used for the collection of embryos or ova only if they meet, to the satisfaction of the official veterinarian, the requirements of the relevant Directives on intra-Community trade in live animals for breeding and production for the breed concerned, viz. Directive 64/432/EEC for swine, Directive 90/426/EEC for equids and Directive 91/68/EEC for ovine and caprine animals and come from herds which also meet the said requirements.

ANNEX E

CERTIFICATE missing