

II

(Preparatory Acts)

COMMISSION

Proposal for a Council Directive on animal health problems affecting intra-Community trade and imports from third countries of semen of domestic animals of the bovine and porcine species*(Submitted by the Commission to the Council on 26 September 1983)*

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,

Having regard to the opinion of the European Parliament,

Having regard to the opinion of the Economic and Social Committee,

Whereas rules relative to problems of animal health concerning intra-Community trade in bovine animals and swine are already in force pursuant to Council Directive 64/432/EEC⁽¹⁾, as last amended by Directive 82/61/EEC⁽²⁾; whereas, in addition, rules exist in relation to problems of animal health when bovine animals and swine are imported from third countries into the Community pursuant to Council Directive 72/462/EEC⁽³⁾, as last amended by Directive 83/91/EEC⁽⁴⁾;

Whereas, by means of the aforesaid rules it has been possible to ensure that, in trade in bovine animals and swine between Member States and to Member States from third countries, animal health criteria have been certified by the exporting country so that the risk of spreading animal disease has been virtually eliminated; whereas a certain risk of spread of animal disease exists when semen is traded;

Whereas in continuation of the Community policy of harmonizing Member States' national rules on animal health when animals and their products are traded

between Member States it is now necessary to achieve a harmonized system when semen is traded between Member States and when imported from third countries into the Community;

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 semen 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;

Whereas, while awaiting harmonized rules for the control and eradication of foot and mouth disease within the Community, those Member States which do not practise vaccination against that disease and which do not allow vaccinated animals on their territory should be afforded additional safeguards; whereas in order to protect the Community as a whole from blue tongue disease and African swine fever, specific requirements should be laid down by means of the procedure of the Standing Veterinary Committee if and when a Member State becomes infected with either of these diseases;

Whereas Community arrangements regarding veterinary experts should be introduced to provide a means of settling problems between Member States concerning the implementation of this Directive; whereas a Community procedure should be provided under which Member States may have the possibility of refusing entry in respect of consignments of semen if the rules of the Directive are not followed or if there is suspicion of the presence of, or of contamination by, infectious animal disease in the consignment or if an outbreak of epizootic disease occurs in the consigning Member State;

⁽¹⁾ OJ No 121, 29. 7. 1964, p. 1977/64.

⁽²⁾ OJ No L 29, 6. 2. 1982, p. 13.

⁽³⁾ OJ No L 302, 31. 12. 1972, p. 28.

⁽⁴⁾ OJ No L 59, 5. 3. 1983, p. 34.

Whereas for imports of semen into the Community from third countries a list of suitable third countries or parts thereof should be drawn up taking into account certain animal health criteria; whereas notwithstanding 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 or parts thereof on the list, specific animal health conditions should be laid down according to circumstances;

Whereas in order to verify whether the provisions of the Directive are being implemented in third countries inspections should be undertaken on the spot;

Whereas safeguards concerning *inter alia* blue tongue disease and African swine fever should also be possible in respect of third countries; whereas official certification should be provided in respect of each consignment; whereas Member States should subject each importation to an import control to ensure that the provisions of the Directive have been complied with; whereas Member States may reject consignments of semen *inter alia* if epizootic disease occurs in the third country or part thereof;

Whereas provision should be made for the gradual implementation of this Directive particularly in relation to existing stocks of frozen semen; whereas during this transitional period national animal health rules should continue to apply,

HAS ADOPTED THIS DIRECTIVE:

CHAPTER I

General provisions

Article 1

This Directive shall apply to animal health problems affecting intra-Community trade and imports from third countries of semen of domestic animals of the bovine and porcine species.

Article 2

For the purposes of this Directive:

- (a) 'semen' means the ejaculate of a domestic animal of the bovine or porcine species;
- (b) 'semen collection centre' means an officially approved and supervised establishment situated in the territory of a Member State or in the territory of a third country in which semen is produced for use in artificial insemination;
- (c) 'designated veterinarian' means the veterinarian designated by the competent authority of the Member State or of the third country to be responsible for the routine observance of the provisions of this Directive on a semen collection centre;
- (d) 'consignment' means a quantity of semen covered by the same certificate;
- (e) 'Member State of collection' means the Member State in which semen is collected and from which it is sent to another Member State;
- (f) 'third country of collection' means the third country in which semen is collected and from which it is sent to the Community;
- (g) 'Member State of destination' means the Member State to which semen is sent from another Member State or from a third country;
- (h) 'officially tuberculosis-free bovine herd' means a bovine herd which satisfies the conditions laid down in Annex A (I) to Directive 64/432/EEC;
- (i) 'officially brucellosis-free bovine herd' means a bovine herd which satisfies the conditions laid down in Annex A (II) (A) (1) to Directive 64/432/EEC;
- (j) 'brucellosis-free swine herd' means a swine herd which satisfies the conditions laid down in Annex A (II) (B) (2) to Directive 64/432/EEC;
- (k) 'officially swine fever-free holding' means a holding as defined in Article 2 (p) of Directive 64/432/EEC;
- (l) 'approved laboratory' means a laboratory situated in the territory of a Member State or third country designated by the competent veterinary authority to carry out the test or tests required in this Directive.
- (m) 'third country' means any country in which Directive 64/432/EEC does not apply;
- (n) 'official veterinarian' means the veterinarian appointed by the competent authority of the Member State or third country to check the conditions of approval and the supervision of a semen collection centre.

CHAPTER II

Intra-Community trade in semen*Article 3*

1. Each Member State shall ensure that only semen complying with the following general conditions is sent from its territory to the territory of another Member State:

- (a) it must have been collected and processed for the purpose of artificial insemination in a semen collection centre approved and supervised for the purpose of intra-Community trade in accordance with Article 4 (1);
- (b) it must have been collected from domestic animals of the bovine or porcine species whose health status is in accordance with the provisions of Annex B;
- (c) it must have been collected, processed, stored and transported in accordance with the provisions of Annexes A and C;
- (d) it must be accompanied, during transport to the country of destination, by an animal health certificate in accordance with Article 5 (1).

2. Without prejudice to such provisions as the Community may adopt in relation to the control and eradication of foot and mouth disease, Member States which do not practice vaccination against foot and mouth disease and which by way of derogation from Directive 64/432/EEC do not allow on their territory animals vaccinated against the said disease may, prior to the introduction of semen into their territory and while complying with the general provisions of the Treaty, require that:

- (a) donor animals are located in semen collection centres in which no foot and mouth disease vaccination has taken place within the 30 days immediately prior to collection of semen for intra-Community trade;
- (b) when on the same centre vaccinated and unvaccinated animals are kept, the latter shall be housed separately and semen therefrom shall be certified as having come from unvaccinated animals;
- (c) when the donor animals have been vaccinated within the 12 months immediately prior to collection, an aliquot of semen from each ejaculate shall be subject to a virus isolation test for foot and mouth disease with negative results.

3. Semen from semen collection centres situated in Member States in which blue tongue disease, in the case of bovine semen, and African Swine fever, in the case of porcine semen, have been recorded shall not

be permitted to enter intra-Community trade. However, according to the procedure laid down in Article 17, it may be decided that under specific conditions such semen may enter intra-Community trade. In deciding, consideration shall be given to the following points:

- (a) the health status of the area surrounding the semen collection centre and vector survival therein;
- (b) the health status of the herd in the semen collection centre, including testing requirements;
- (c) the health status of the donor animal and testing requirements; and
- (d) testing requirements in relation to semen.

Article 4

1. The Member State on whose territory the semen collection centre is situated shall ensure that the approval provided for in Article 3 (1) (a) is granted only where the provisions of Annex A are observed and where that semen collection centre is able to satisfy the other provisions of this Directive. The Member State shall also ensure that an official veterinarian supervises the observance of those provisions and shall withdraw approval when one or more of the provisions is no longer observed.

2. All semen collection centres shall be registered on a list, each centre having an approval number. Each Member State shall communicate the list of semen collection centres and their approval numbers to the other Member States and to the Commission and notify them without delay of any withdrawal of approval.

3. When a Member State considers that the provisions governing approval are not, or are no longer, observed in a semen collection centre in another Member State, it shall inform the competent authority of that State accordingly. The latter shall take all necessary measures and notify the competent authority of the other Member State of the decisions taken and the reasons for such decisions.

If that other Member State fears that the necessary measures have not been taken or are inadequate, it may so inform the Commission, which shall seek the opinion of one or more veterinary experts. In the light of that opinion, Member States may be authorized under the procedure laid down in Article 18 to prohibit provisionally the introduction into their territory of semen coming from that centre.

Such authorization may be withdrawn under the procedure laid down in Article 18 in the light of a

new opinion delivered by one or more veterinary experts.

Veterinary experts must be nationals of a Member State other than those involved in the dispute.

After consulting the Member States, the Commission shall lay down general rules for applying this paragraph, in particular as regards the appointment of veterinary experts and the procedure to be followed as regards delivery of opinions by them.

Article 5

1. Each Member State shall authorize semen of bovine animals and swine to be imported only on submission of an animal health certificate in accordance with Annex D drawn up by a designated veterinarian of the Member State of collection.

This certificate must:

(a) be drawn up in the official languages of the Member State of collection and of the Member State of destination;

(b) accompany the consignment to its destination;

(c) be drawn up on a single sheet of paper;

(d) be made out to a single consignee.

2. (a) The Member State of destination may prohibit the introduction of consignments of semen of bovine animals or swine into its territory if the documentary control reveals that the provisions of Article 3 (1) (d) have not been observed.

(b) The Member State of destination may take the necessary measures, including storage in isolation, to ascertain the position as regards semen suspected of being affected or contaminated by a contagious or infectious animal disease.

(c) Decisions taken under points (a) or (b) above must, at the request of the consignor or his representative, authorize the return of the semen provided this is not contrary to considerations of animal health.

3. If the introduction of semen has been prohibited on any of the grounds set out in paragraph 2 (a) and (b) and the Member State of collection does not within 30 days authorize the return thereof, the competent veterinary authority of the Member State of destination may order the semen to be destroyed.

4. If, after the introduction of semen into the territory of the Member State of destination, facts come to light which would have justified the application of paragraph 3, the competent veterinary authority of the Member State of collection must, at the request of the competent veterinary authority of the Member State of destination, make the necessary investigations and notify the latter authority without delay of the outcome of such investigations.

5. The decisions taken by the competent veterinary authority under paragraphs 2 and 3 must be communicated to the consignor or his representative, together with the reasons for such decisions. These reasoned decisions must, on request, be communicated to him forthwith in writing with an indication of what appeals against them are open under current legislation and the form and time in which they must be commenced. The decisions must also be communicated to the competent veterinary authority of the Member State of collection.

Article 6

1. A Member State may, if there is a danger of animal diseases spreading as a result of the introduction of semen into its territory from another Member State, take the following measures:

(a) in the event of an outbreak of an epizootic disease in the other Member State, temporarily prohibit or restrict the introduction of semen from the affected areas of that Member State;

(b) if an epizootic disease becomes widespread or if there is an outbreak of a new serious naturally transmissible animal disease, temporarily prohibit or restrict the introduction of semen from the entire territory of that State.

2. Each Member State must immediately inform the other Member States and the Commission of the outbreak on its territory of any disease referred to in paragraph 1, and of the measures taken to control it. It must also notify them immediately of the elimination of the disease.

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

Under the procedure laid down in Article 18 a decision may be taken to repeal or amend those measures in particular in order to coordinate them with measures adopted by other Member States.

4. If the situation envisaged in paragraph 1 arises and if it appears necessary that other Member States also apply the measures taken under that paragraph, amended, where necessary, pursuant to paragraph 3, appropriate measures shall be adopted under the procedure laid down in Article 18.

Article 7

1. Rights of appeal existing under current legislation in the Member States against decisions taken pursuant to this Directive by the competent authority shall not be affected by this Directive.

2. Each Member State shall grant to consignors in respect of whose consignments of semen such measures as are provided for in Article 5 (2) have been taken, the right to obtain, before other measures are taken by the competent authority, the opinion of a veterinary expert to determine whether the conditions of Article 5 (2) have been fulfilled.

The veterinary expert must be a national of a Member State other than the Member State of collection or of destination.

The Commission, acting on a proposal from the Member States, shall draw up a panel of veterinary experts who may be instructed to formulate such opinions. After consulting the Member States it shall lay down general rules which are to be applied, in particular as regards the procedure for formulation of these opinions.

CHAPTER III

Imports of semen from third countries

Article 8

1. The Council, acting on a proposal from the Commission, shall draw up a list of third countries or parts thereof from which the Member States shall authorize importation of semen of bovine animals and swine taking into account the health situation in those countries or parts thereof. This list may be supplemented or amended according to the procedure laid down in Article 17.

2. In deciding whether a third country or part thereof 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 the third country, particular attention being paid to exotic animal diseases, and of the health situation of areas

adjacent to the country, which might endanger animal health in the Member States;

- (b) the regularity and rapidity of the information supplied by the third country relating to the existence of contagious animal diseases in its territory, in particular those diseases mentioned in lists A and B of the International Office of Epizootic Diseases;
- (c) the rules of the country on the prevention and control of animal diseases;
- (d) the structure of the veterinary services in the country and their powers;
- (e) the organization and implementation of measures to prevent and control contagious animal diseases; and
- (f) the guarantees which the third country can give with regard to compliance with the provisions of this Directive.

Article 9

1. In accordance with the procedure laid down in Article 17 one or more lists shall be drawn up of semen collection centres from which Member States may authorize the importation of semen from third countries. The list or lists 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 lists referred to in paragraph 1 particular account shall be taken of the veterinary control of semen production systems in the third country, the powers of the veterinary services and the supervision to which semen collection centres are subject.

3. A semen collection centre shall appear on the list or lists provided for in paragraph 1 only if:

- (a) it is situated in one of the countries on the list referred to in Article 8 (1);
- (b) it has been officially approved for exports to the Community by the veterinary services of the third country concerned;
- (c) it is under the supervision of a designated veterinarian of the third country concerned; and
- (d) it is subject to regular inspection by an official veterinarian of the third country concerned at least twice per year.

Article 10

1. Semen of bovine animals and swine must come from animals which immediately prior to collection of their semen have remained in the territory of part of

the territory of a third country on the list established in accordance with Article 8 (1) for not less than six months.

2. Notwithstanding the provisions of Article 8 (1), and paragraph 1 above, the Member States shall authorize the importation of semen of bovine animals and swine from a third country or part of a third country on the list only if the semen complies with the animal health requirements adopted in accordance with the procedure set out in Article 17 for imports of semen from that country according to the species of animal concerned.

In adopting such requirements in relation to blue tongue disease and African swine fever consideration shall be given to the following points:

- (a) the health status of the area surrounding the semen collection centre and vector survival therein;
- (b) the health status of the herd in the semen collection centre including testing requirements;
- (c) the health status of the donor animal and testing requirements; and
- (d) testing requirements in relation to semen.

3. The reference basis for fixing animal health conditions in accordance with paragraph 2 for bovine tuberculosis and bovine and swine brucellosis shall be the standards laid down in Annex A to Directive 64/432/EEC. It may be decided, in accordance with the procedure laid down in Article 17 on a case-by-case basis, to waive these conditions where the third country concerned provides similar animal health guarantees. In that case, animal health conditions at least equivalent to those in Annex A to that Directive shall be laid down in accordance with the same procedure.

Article 11

1. Member States shall authorize semen of bovine animals and swine to be imported only on submission of an animal health certificate drawn up by a designated veterinarian of the third country of collection.

This certificate must:

- (a) be drawn up in the language of the third country of collection and in at least one of the official languages of the Member State of destination;
- (b) accompany the semen in the original;
- (c) be drawn up on a single sheet of paper;
- (d) be made out to a single consignee.

2. The certificate must correspond to a specimen drawn up in accordance with the procedure laid down in Article 17.

Article 12

1. Member States shall ensure that each consignment of semen entering the geographical territory of the Community is subjected to an import control before it is placed under any temporary or final customs procedure except the procedure for external transit, and shall prohibit the introduction of such semen into the Community if the import control made on arrival reveals that:

- the semen does not come from the territory, or part thereof, of a third country included on the list drawn up in accordance with Article 8 (1),
- the semen does not come from a semen collection centre included on the list provided for in Article 9 (1),
- the semen comes from a territory, or part thereof, of a third country from which imports are prohibited in accordance with Article 15,
- the animal health certificate which accompanies the semen is not in conformity with the provisions of Article 11.

2. The Member State of destination may take the necessary measures, including storage in isolation, to ascertain the position as regards semen suspected of being affected or contaminated by a contagious or infectious animal disease.

3. If the introduction of semen has been prohibited on any of the grounds set out in paragraphs 1 and 2 above and the exporting third country does not within 30 days authorize the return thereof, the competent veterinary authority of the Member State of destination may order the semen to be destroyed.

Article 13

Each consignment of semen authorized for introduction into the Community by a Member State on the basis of the controls referred to in Article 12 (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 veterinary authority which was responsible for the examination carried out in accordance with Article 12.

Article 14

All expenditure incurred as a result of the application of Articles 12 and 13 and in particular the cost of controlling the semen, storage costs and the cost of

any destruction of semen shall be chargeable to the consignor, the consignee or their agent, without compensation by the State.

Article 15

1. Notwithstanding the provisions of Article 8, if in a third country a contagious animal disease which can be carried by semen breaks out or spreads and endangers the health of the livestock in one of the Member States or if any other reasons connected with animal health so justifies, the Member State of destination concerned shall prohibit the importation 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.

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 such communication and shall decide, in accordance with the procedure laid down in Article 18, whether these measures should be amended, in particular in order to coordinate them with measures adopted by other Member States, or withdrawn.

If the situation envisaged in paragraph 1 arises and if it appears necessary that other Member States also apply the measures taken under that paragraph, amended where necessary in accordance with the preceding subparagraph, appropriate measures shall be adopted under the procedure laid down in Article 18.

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

CHAPTER IV

Common provisions

Article 16

1. Veterinary experts from the Commission may, in so far as is necessary to ensure uniform application of this Directive, make on-the-spot checks; they may verify whether approved semen collection centres are actually complying with this Directive, particularly with Annexes A, B and C. However, verification of compliance with the provisions of Article 8 (2) shall not be obligatory where an on-the-spot inspection in

accordance with the provisions of Article 5 of Directive 72/462/EEC has taken place. The Commission shall inform the Member States of the results of the investigation.

A Member State in whose territory a check is being carried out shall give all necessary assistance to the experts in carrying out their duties.

The general provisions for implementing this Article shall be determined in accordance with the procedure laid down in Article 17.

In accordance with the same procedure, a code shall be established containing the rules to be followed for the purpose of the checks provided for in this paragraph.

2. Before 1 January 1988, the Council shall review this Article on the basis of a report from the Commission, which may also submit proposals in this connection.

Article 17

1. Where the procedure laid down in this Article is to be followed, matters shall be referred by the chairman, either on his own initiative or at the request of a Member State, to the Standing Veterinary Committee (hereinafter called 'the Committee') set up by Council Decision 68/361/EEC⁽¹⁾.

2. Within the Committee the votes of 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 measure to be adopted. The Committee shall deliver its opinion on such measures within two days. Opinions shall be delivered by a majority of 45 votes.

4. The Commission shall adopt the measures and shall apply them immediately where they are in accordance with the opinion of the Committee. If they are not in accordance with the opinion of the Committee or if no opinion is delivered, the Commission shall immediately submit to the Council the measures to be adopted. The Council shall adopt the measures by a qualified majority.

If, within three months from the date on which the proposal was submitted 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 by a simple majority against those measures.

⁽¹⁾ OJ No L 255, 18. 10. 1968, p. 23.

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 Committee.

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 deliver its opinion on such measures within two days. Opinions shall be delivered by a majority of 45 votes.

4. The Commission shall adopt the measures and shall apply them immediately where they are in accordance with the opinion of the Committee. Where they are not in accordance with the opinion of the Committee or if no opinion is delivered, the Commission shall immediately submit to the Council a proposal regarding the measures to be adopted. The Council shall adopt the measures by a qualified majority.

If, within 15 days from the date on which the proposal was submitted 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 by a simple majority against those measures.

Article 19

1. The provisions of Articles 3, 4, 5, 6 and 7 shall not be applicable to semen collected and processed in a Member State before 1 January 1985.

2. The provisions of Articles 8, 9, 10, 11, 12, 13, 14 and 15 shall not be applicable to semen collected and processed in a third country before 1 January 1985.

3. Until the date of entry into force of the provisions referred to in Article 9 the Member States shall not apply to imports of semen from third countries more favourable conditions than those resulting from Chapter II concerning intra-Community trade.

Article 20

The Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive on 1 January 1985, and shall immediately inform the Commission thereof.

Article 21

This Directive is addressed to the Member States.

ANNEX A

CHAPTER I

Conditions for the approval of semen collection centres

Semen collection centres must:

- (a) have at their disposal at least:
 - (i) animal accommodation including isolation facilities,
 - (ii) semen collection facilities including a separate disinfection room,
 - (iii) a semen processing room,
 - (iv) a semen storage room;
- (b) be so constructed or insulated that contact with outside livestock is prevented;
- (c) be so constructed that the animal housing, and the semen collecting, processing and storing facilities are readily capable of being cleansed and disinfected;
- (d) be so constructed that the health of the animals contained therein is catered for;
- (e) have at their disposal isolation accommodation which shall have no direct communication with the normal animal accommodation;
- (f) be so designed that the animal accommodation is physically separate from the semen processing room and both are separate 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 only animals of the species whose semen is to be collected are contained therein;
- (b) be so supervised that a register is kept of all animals at the centre, giving details of the breed, date of birth and identification of each of the animals;
- (c) be subject to regular inspection by an official veterinarian at least twice per year, at which time the conditions of approval and supervision shall be checked;
- (d) be so supervised that the entry of unauthorized persons is prevented. However, authorized visitors shall be permitted, according to the conditions laid down by the designated 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 an approved centre, without coming into contact with any other semen. However, semen not collected in an approved collection centre may be processed at an approved collection centre provided this is done at a separate time and with separate equipment,
 - (ii) collection, processing and storage of semen takes place only in the accommodation set aside for the purpose under conditions of the strictest hygiene,
 - (iii) all pieces equipment having contact with the semen or the donor animal during collection and processing are appropriately disinfected prior to use,
 - (iv) products of animal origin used in the processing of semen are obtained from sources which present no animal health risk to the species of animal in question or are so treated prior to use that such risk is prevented,
 - (v) storage flasks and transport flasks are appropriately disinfected prior to commencement of filling,
 - (vi) the cryogenic agent used has not been previously used for other products of animal origin,
 - (vii) each individual dose of semen is clearly marked in such a way that the date of collection, breed and identification of donor animal may be readily established.

ANNEX B

CHAPTER I

Conditions to be met prior to entry of animals into approved semen collection centres

1. All animals entering a semen collection centre shall:

- (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;

(b) prior to entry into the isolation described in (a) above have been obtained from herds which satisfy the following conditions:

— in the case of bovine animals they are:

- (i) officially tuberculosis free,
- (ii) officially brucellosis free or brucellosis free,
- (iii) herds in which no facts have been brought to the notice of the designated veterinarian which would lead him to conclude that a case of enzootic bovine leukosis has occurred within the three preceding years;

— in the case of swine they are brucellosis free.

Further in the case of swine they have been obtained from an officially swine fever-free holding.

(c) following at least 30 days in isolation described at (a) above and within 30 days prior to entering the semen collection centre have been subjected to the following tests with negative results:

— in the case of bovine animals:

- (i) an intradermal tuberculin test carried out in accordance with the procedure laid down in Annex B of Council Directive 64/432/EEC,
- (ii) a serum agglutination test complying with the procedure laid down in Annex C of Council Directive 64/432/EEC and have shown a brucella count of lower than 30 international units (iu) of agglutination per millilitre,
- (iii) a serological test for enzootic bovine leukosis carried out in accordance with the procedure laid down in Annex G of Council Directive 64/432/EEC,
- (iv) a fluorescent antibody test for campylobacter fetus infection on a sample of preputial material or vaginal washings or, test mating of maiden heifers. In the case of female animals a vaginal mucus agglutination test shall be carried out,
- (v) a microscopic and cultural test for Trichomonas foetus on a sample of preputial washings. In the case of females the test shall be done on a sample of vaginal washings;

— in the case of swine:

- (i) a sero-agglutination test in accordance with the provisions of Annex C of Council Directive 64/432/EEC showing a brucella count lower than 30 iu of agglutination per millilitre,
- (ii) a complement fixation test in accordance with the provision of Annex C of Council Directive 64/432/EEC;

(d) a serum neutralization test for Aujeszky's disease.

2. Tests, where appropriate, shall be carried out in a laboratory approved by the Member State.

3. (i) If an animal intended for entry to a semen collection centre has undergone a period of individual isolation and has reacted positively to:

- (a) the tests for tuberculosis, brucellosis or enzootic bovine leukosis it shall not be permitted to enter the semen collection centre,
- (b) the tests for campylobacteriosis, trichomoniasis or Aujeszky's disease it shall not be permitted to enter the semen collection centre but may be subjected to a further period of isolation and if similar tests carried out after this period prove to be negative it may then enter.

(ii) If an animal entering a semen collection centre has undergone a period of group isolation and has reacted positively to:

- (a) the tests for tuberculosis, brucellosis, and enzootic bovine leukosis none of the group shall be permitted to enter the semen collection centre. Eligibility of the non-reacting animals in the group may be re-established according to the provisions of Annex B, Chapter I, paragraph 1 (b) and (c) of this Directive,

- (b) the test for campylobacteriosis, trichomoniasis or Aujeszky's disease the procedure at 3
(i) (b) above may be applied to any or all of the animals in the group.
4. Animals entering the semen collection centre shall do so only with the express permission of the designated veterinarian. All movements both in and out shall be recorded.
5. All animals entering the semen collection centre shall show no clinical sign of disease on the day of consignment and shall have been obtained from isolation accommodation which on the day of consignment officially fulfils the following conditions:
- (i) is situated in the centre of an area 20 km in diameter in which for at least 30 days there has been no incidence of foot and mouth disease and in addition, in the case of swine, are situated in the centre of an area two km in diameter in which for at least 15 days there has been no incidence of swine fever, swine vesicular disease or contagious swine paralysis (Teschen disease);
 - (ii) has for at least three months been free from foot and mouth disease and brucellosis in the case of bovine animals and foot and mouth disease, swine vesicular disease, bovine and porcine brucellosis, swine fever and contagious porcine paralysis (Teschen disease) in the case of swine;
 - (iii) has for at least 30 days been free from all other compulsorily notifiable diseases which are contagious or infectious for the animal species in question according to Annex E of Council Directive 64/432/EEC.
6. Provided the conditions of paragraph 5 above are satisfied and the routine tests referred to in Chapter II have been carried out during the previous 12 months, animals may move from one semen collection centre to another without isolation and test provided the movement is direct, the animal in question does not come in contact, direct or indirect, with ruminating animals and swine of a lower health status and the means of transport has been disinfected. If the movement from one semen collection centre to another takes place between Member States it shall take place without prejudice to Council Directive 64/432/EEC.

CHAPTER II

1. Routine test to be applied to all bovine animals on an approved semen collection centre.

All bovine animals kept on an approved semen collection centre shall be subjected at least once per year to the following tests or treatments.

- (i) an intradermal tuberculin test for tuberculosis carried out in accordance with the procedure laid down in Annex B of Council Directive 64/432/EEC with negative results;
- (ii) a serum agglutination test for brucellosis giving a count of lower than 30 iu of agglutination per millilitre when carried out in accordance with the procedure laid down in Annex C of Council Directive 64/432/EEC;
- (iii) a serological test for enzootic bovine leukosis with negative results carried out in accordance with the procedure laid down in Annex G of Council Directive 64/432/EEC;
- (iv) a serum neutralization test for infectious bovine rhinotracheitis/infectious pustular vulvovaginitis with negative results or, in the case of an animal giving a positive reaction to this test, within 30 days following the test and prior to collection of semen, to a virus isolation test for infectious bovine rhinotracheitis virus with negative results;
- (v) a fluorescent antibody test for campylobacter fetus on preputial material or vaginal washings with negative results, or in the case of females a vaginal mucus agglutination test or, sheath lavage with an antibiotic suspension active against campylobacter fetus on each of three consecutive days;
- (vi) a microscopic and cultural test for *Trichomonas foetus* on a sample of preputial material.

2. Routine tests to be applied to all swine on approved semen collection centres.

All swine kept on an approved semen collection centre shall be subjected at least once per year to the following tests:

- (i) a serum agglutination test for brucellosis and show a brucella count of lower than 30 iu of agglutination per millilitre when carried out in accordance with the procedure laid down in Annex C of Council Directive 64/432/EEC;
 - (ii) a negative complement fixation reaction when given a serological examination for brucellosis in accordance with the procedure laid down in Annex C of Council Directive 64/432/EEC;
 - (iii) a serum neutralization test for Aujeszky's disease with negative results;
 - (iv) a serum neutralization test for swine fever with negative results, except where swine have been derived from officially swine fever-free holdings.
3. Tests, where appropriate, shall be carried out in a laboratory approved by the Member State.
4. Where a donor animal gives a positive reaction to any of the routine tests outlined in paragraphs 1 and 2 above, semen from that animal collected since the date of the most recent negative test of that animal for the disease in question shall not be permitted to enter intra-Community trade.

ANNEX C

Conditions relating to the semen collected at approved semen collecting centres for the purpose of intra-Community trade

1. Semen shall be obtained from animals which:

- (a) show no clinical sign of disease on the day of collection;
- (b) have not been vaccinated against foot and mouth disease within the 30 days immediately prior to collection;
- (c) have been resident on an approved semen collection centre for a continuous period of at least six months in the case of bovine semen and for at least three months in the case of porcine semen immediately prior to collection;
- (d) are not allowed to serve naturally;
- (e) are located in semen collection centres which on the day of collection are situated in the centre of an area of 20 km in diameter in which for at least 30 days there has been no incidence of foot and mouth disease and in addition, in the case of swine, are situated in the centre of an area two km in diameter in which for at least 15 days there has been no incidence of swine fever, swine vesicular disease, or contagious porcine paralysis (Teschen disease);
- (f)
 - (i) are located in semen collection centres, in the case of frozen semen, which for at least three months prior to collection until 30 days after collection have been free from foot and mouth disease in the case of bovine semen and foot and mouth disease, swine vesicular disease, bovine and porcine brucellosis, swine fever and contagious porcine paralysis (Teschen disease) in the case of porcine semen,
 - (ii) are located in semen collection centres which, in the case of fresh porcine semen for at least three months prior to collection until the day of consignment have been free from foot and mouth disease, swine vesicular disease, bovine and porcine brucellosis, swine fever and contagious swine paralysis (Teschen disease),
 - (iii) are located in semen collection centres where, if all bovine animals are not seronegative for IBR/IPV, the donor bull is seronegative on the day of collection or the semen therefrom has been subjected to a virus isolation test with negative results;

(g) are located in semen collection centres which have been free from all other compulsorily notifiable diseases which are infectious or contagious for the animal species in question according to Annex E of Council Directive 64/432/EEC during the period commencing 30 days prior to collection until 30 days after collection.

2. Semen for intra-Community trade shall:

- (i) be stored in approved accommodation for a minimum period of 30 days prior to dispatch except in the case of fresh porcine semen;
 - (ii) be transported to the Member State of destination in flasks which have been cleansed and disinfected before use and which have been suitably sealed prior to dispatch from the approved storage accommodation.
 - (iii) be sent direct to the place of loading under the responsibility of the designated veterinarian.
-

ANNEX D

**Animal Health Certificate
for trade between Member States of the EEC in semen of animals of the bovine and porcine species**

No

Country of collection:

Competent authority:

Competent local authority:

I. Identification of semen:

Species of donor animal:

No of doses	Date(s) of collection	Identification of donor animal	Breed	Date of birth

II. Origin of semen:

Address of semen collection centre(s):

Approval number of semen collection centre(s):

III. Destination of semen:

The semen will be sent from
(place of loading)

to
(country and place of destination)

by
(means of transport)

Name and address of consignor:

Name and address of consignee:

IV. I, the undersigned designated veterinarian, certify that:

1. The semen described above was collected, processed and stored under conditions which comply with the standards laid down in Directive .../.../EEC;
2. The semen described above was sent to the place of loading in a sealed container under conditions which satisfy the provisions of Directive .../.../EEC.

Done at on

Seal

.....
(Signature)

.....
(Name in block letters)