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COUNCIL DIRECTIVE

of 14 June 1988

laying down the animal health requirements applicable to intra-Community trade in and imports of ►M3 ——————— ◄ semen of domestic animals of the bovine species

(88/407/EEC)

(OJ L 194, 22.7.1988, p. 10)

Amended by:

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►**M1**	Council Directive 90/120/EEC of 5 March 1990	L 71	37	17.3.1990
►**M2**	Council Directive 90/425/EEC of 26 June 1990	L 224	29	18.8.1990
►**M3**	Council Directive 93/60/EEC of 30 June 1993	L 186	28	28.7.1993

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COUNCIL DIRECTIVE

of 14 June 1988

laying down the animal health requirements applicable to intra-Community trade in and imports of ►M3 ——————— ◄ semen of domestic animals of the bovine species

(88/407/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 43 thereof,

Having regard to the proposal from the Commission [1],

Having regard to the opinion of the European Parliament [2],

Having regard to the opinion of the Economic and Social Committee [3],

Whereas provisions relating to animal health problems in intra-Community trade in bovine animals and swine appear in Directive 64/432/EEC [4], as last amended by Regulation (EEC) No 3768/85 [5]; whereas in addition, Directive 72/462/EEC [6], as last amended by Regulation (EEC) No 3768/85 contains provisions relating to veterinary inspection problems upon importation of bovine animals and swine from third countries;

Whereas the abovementioned provisions have ensured, with regard to intra-Community trade and imports into the Community of bovine animals and swine from third countries, that the country of provenance guarantees that animal health criteria have been fulfilled so that the risk of animal disease spreading has been virtually eliminated; whereas there is nevertheless a certain risk of the spread of such disease in the case of trade in semen;

Whereas in the context of the Community policy of harmonizing national animal health provisions governing intra-Community trade in animals and animal products, it is now necessary to create a harmonized system for intra-Community trade and imports into the Community of semen of bovine animals;

Whereas, in the context of intra-Community trade in semen, the Member State where the semen is collected should be under an obligation to ensure that such semen has been collected and processed at approved and supervised 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 in order to ensure that this obligation has been fulfilled;

Whereas the difference in the policies pursued within the Community with regard to vaccination against certain diseases justifies the maintenance of derogations, limited in time, authorizing the requirement by the Member States, in respect of certain diseases, of additional protection against those diseases;

Whereas for imports of semen into the Community from third countries a list of third countries should be drawn up taking into account animal health criteria; whereas without prejudice to such a list the Member States should authorize importation of semen only from semen collection centres which reach certain standards and which are officially

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(1) OJ No C 267, 6. 10. 1983, p. 5.
(2) OJ No C 342, 19. 12. 1983, p. 11.
(3) OJ No C 140, 28. 5. 1984, p. 6.
(4) OJ No 121, 29. 7. 1964, p. 1977/64.
(5) OJ No L 362, 31. 12. 1985, p. 8.
(6) OJ No L 302, 31. 12. 1972, p. 28.

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supervised; whereas, in addition, in respect of countries on that list, specific animal health conditions should be laid down according to circumstances; whereas, in order to verify compliance with these standards, on-the-spot checks may be carried out;

Whereas a procedure should be provided for the purpose of settling any disputes which arise between Member States as to whether approval of a collection centre is justified;

Whereas the Member States may refuse a consignment of semen where it has been established that it does not comply with the provisions of this Directive; whereas it must be possible to return such semen if this is not contrary to considerations of animal health and if the consignor or his representative so requests; whereas the consignor or his representative should be allowed to know the reasons for a prohibition or restriction and to obtain the opinion of an expert;

Whereas in order to prevent the transmission of certain contagious diseases, import controls should be carried out when a consignment of semen arrives on the territory of the Community, except in the case of external transit;

Whereas after such control, in the case of internal transit, the measures to be taken by Member States must be defined;

Whereas a Member State should be permitted to take emergency measures in the event of an outbreak of a contagious disease in another Member State or in a third country; whereas the dangers associated with such diseases and the protective measures they necessitate should be assessed in the same way throughout the Community; whereas to that end, an emergency Community procedure under which the necessary measures must be taken should be instituted within the Standing Veterinary Committee;

Whereas the Commission should be entrusted with taking certain measures for implementing this Directive; whereas to that end, a procedure should be established for close and effective cooperation between the Commission and the Member States within the Standing Veterinary Committee;

Whereas this Directive does not affect trade in semen produced before the date on which the Member States must comply with it.

HAS ADOPTED THIS DIRECTIVE:

CHAPTER I

General provisions

Article 1

This Directive lays down the animal health conditions applicable to intra-Community trade in and imports from third countries of ►M3 ——— ◄ semen of domestic animals of the bovine species.

Article 2

For the purposes of this Directive, the definitions contained in Article 2 of Directive 64/432/EEC and Article 2 of Directive 72/462/EEC shall apply as necessary.

Moreover:

(a) ‘semen’ means the prepared or diluted ejaculate of a domestic animal of the bovine species;

(b) ‘semen collection centre’ means an officially approved and supervised establishment situated in the territory of a Member State or third country, in which semen is produced for use in artificial insemination;

(c) ‘official veterinarian’ means the veterinarian designated by the competent central authority of a Member State or a third country;

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(d) 'centre veterinarian' means the veterinarian responsible for day-to-day compliance in the centre with the requirements laid down in this Directive;

(e) 'consignment' means a quantity of semen covered by a single certificate;

(f) 'country of collection' means the Member State or third country in which semen is collected and from which it is sent to a Member State;

(g) '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 tests laid down in this Directive;

(h) 'collection' means a quantity of semen taken from a donor at any time.

CHAPTER II

Intra-Community trade

Article 3

Each Member State shall ensure that only semen meeting 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 from the point of view of animal health for the purposes of intra-Community trade in accordance with Article 5 (1);

(b) it must have been collected from domestic animals of the bovine species whose health status complies with Annex B;

(c) it must have been collected, processed, stored and transported in accordance with Annexes A and C;

(d) it must be accompanied, during transport to the country of destination, by an animal health certificate complying with Article 6 (1).

Article 4

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1. Without prejudice to paragraph 2, Member States shall authorize the admission of semen from bulls giving a negative reaction to the serum neutralization test or the Elisa test for infectious bovine rhinotracheitis/infectious pustular vulvo-vaginitis or showing a positive result after vaccination in accordance with this Directive.

Member States may, until 31 December 1998, authorize the admission of semen of bulls giving a positive reaction to the serum neutralization test or the Elisa test for infectious bovine rhinotracheitis/infectious pustular vulvo-vaginitis and not having been vaccinated in accordance with this Directive.

In that case, each consignment must pass an examination by inoculation into a live animal and/or virus isolation test.

This requirement shall not apply in respect of the semen of animals which, prior to their first routine vaccination at the insemination centre, reacted negatively to the tests referred to in the first subparagraph. However, the semen of animals given emergency vaccinations following an outbreak of IBR must pass a virus isolation test.

These examinations may, by bilateral agreement, be carried out either in the country of collection or in the country of destination.

In that case, at least 10 % of each collection of semen (with a minimum of five straws) must be treated.

Protocols for tests to be used in accordance with this Article shall be laid down in accordance with the procedure in Article 18.

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2. Member States in which all centres contain only animals giving a negative reaction to the serum neutralization test or the Elisa test may refuse admission to their territory of semen from centres which do not have that status.

In accordance with the procedure referred to in Article 19, it may be decided to extend the above provisions to part of the territory of a Member State if all the centres of that part of the territory contain only animals giving a negative reaction to the serum neutralization test or the Elisa test.

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3. Member States may not oppose the admission of semen from bulls vaccinated against foot-and-mouth disease. However, where the semen was obtained from a bull which had been vaccinated against foot-and-mouth disease during the 12 month period prior to collection, 5 % of the semen from each collection (with a minimum of five straws) intended for sending to another Member States shall be subjected, in a laboratory in the Member State of destination or in a laboratory designated by it, to a virus isolation test for foot-and-mouth disease, with negative results.

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Article 5

1. The Member State on whose territory the semen collection centre is situated shall ensure that the approval provided for in Article 3 (a) is granted only where the provisions of Annex A are observed and where the semen collection centre is able to satisfy the other provisions of this Directive.

The Member State shall also ensure that the 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 approved semen collection centres shall be registered, each centre being given a veterinary registration number. Each Member State shall send a list of semen collection centres and their veterinary registration numbers to the other Member States and to the Commission and shall notify them of any withdrawal of approval.

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The general rules for applying this Article shall be adopted in accordance with the procedure laid down in Article 18.

Article 6

1. Member States shall make the admission of semen conditional upon submission of an animal health certificate drawn up by an official veterinarian of the Member State of collection in accordance with Annex D.

This certificate must:

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

(b) accompany the consignment to its destination in its original form;

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

(d) be made out to a single consignee.

2. (a) The Member State of destination may prohibit the admission of consignments if a documentary check reveals that Article 3 has not been observed.

(b) The Member State of destination may take the necessary measures, including storage in quarantine, in order to obtain definite proof in cases where semen is suspected of being infected or contaminated by pathogenic organisms.

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(c) Decisions taken under (a) or (b) 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 admission 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 of the semen, the competent veterinary authority of the Member State of destination may order it to be destroyed.

4. 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 therefor.

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CHAPTER III

Imports from third countries

Article 8

1. A Member State may authorize importation of semen only from those third countries which appear on a list drawn up in accordance with the procedure laid down in Article 19. That list may be supplemented or amended in accordance with the procedure laid down in Article 18.

2. In deciding whether a third country may appear on the list referred to in paragraph 1, particular account shall be taken of:

(a) the state of health of the livestock, other domestic animals and wildlife in the third country, with particular reference to exotic animal diseases, and of the environmental health situation in that country, which might endanger animal health in the Member States;

(b) the regularity and rapidity of the information supplied by the third country concerning 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) that country's rules on animal disease prevention and control;

(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 this Directive.

3. The list referred to in paragraph 1 and all amendments thereto shall be published in the *Official Journal of the European Communities*.

Article 9

1. In accordance with the procedure laid down in Article 19, a list shall be drawn up of semen collection centres from which Member States may authorize the importation of semen originating in third countries. The list may be amended or supplemented according to the same procedure.

2. In deciding whether a semen collection centre in a third country may appear on the list referred to in paragraph 1, particular account shall be taken of the veterinary supervision of semen production systems in the third country, the powers of the veterinary services and the supervision to which semen collection centres are subject.

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

(a) it is situated in one of the countries on the list referred to in Article 8 (1);

(b) it fulfils the requirements of Chapters I and II of Annex A;

(c) it has been officially approved for exports to the Community by the veterinary services of the third country concerned;

(d) it is under the supervision of a centre veterinarian of the third country concerned; and

(e) it is subject to regular inspection by an official veterinarian of the third country concerned at least twice a year.

Article 10

1. Semen must come from animals which, immediately prior to collection of their semen, have remained for at least six months in the territory of a third country on the list drawn up in accordance with Article 8 (1).

2. Without prejudice to Article 8 (1) and paragraph 1 of this Article, the Member States shall not authorize the importation of semen from a third country on the list unless the semen complies with the animal health requirements adopted, in accordance with the procedure laid down in Article 18, for imports of semen from that country.

In adopting the requirements referred to in the preceding subparagraph, consideration shall be given to:

(a) the health situation in the area surrounding the semen collection centre, with particular reference to the diseases appearing on list A of the International Office of Epizootic Diseases;

(b) the state of health of the herd in the semen collection centre, including testing requirements;

(c) the state of health of the donor animal and testing requirements;

(d) testing requirements in relation to semen.

3. The reference basis for fixing animal health conditions in accordance with paragraph 2 for bovine tuberculosis and 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 18, 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 in order to permit the entry of such animals into semen collection centres.

4. Article 4 shall apply *mutatis mutandis*.

Article 11

1. Member States shall authorize the importation of semen only on submission of an animal health certificate drawn up and signed by an official veterinarian of the third country of collection.

This certificate must:

(a) be drawn up in at least one of the official languages of the Member State of destination and one of those of the Member State where the import control provided for in Article 12 is carried out;

(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 19.

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Article 12

The 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 [1] shall apply in particular to the organization and follow-up of checks to be carried out by the Member States and the safeguard measures to be applied.

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CHAPTER IV

Safeguard and control measures

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Article 15

The rules laid down in Council Directive 90/425/EEC of 26 June 1990 concerning veterinary and zootechnical checks in intra-Community trade in certain live animals and products with a view to the completion of the internal market [2], shall apply in particular to checks at origin, to the organization of, and follow-up to, the checks to be carried out by the Member State of destination, and follow up to, the checks to be carried out by the Member State of destination, and to the safeguard measures to be implemented.

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Article 16

1. Veterinary experts from the Commission may, in cooperation with the competent authorities of the Member States and third countries, make on-the-spot checks in so far as that is indispensable for ensuring uniform application of this Directive.

The country of collection within whose territory a check is being carried out shall give all necessary assistance to the experts in carrying out their duties. The Commission shall inform the country of collection concerned of the results of the investigation.

The country of collection concerned shall take any measures which may prove necessary to take account of the results of the investigation. If the country of collection does not take those measures, the Commission may, after the situation has been examined by the Standing Veterinary Committee, have recourse to the provisions of the fourth subparagraph of Article 5 (2) and 9 (1).

2. The general provisions for implementing this Article, especially as regards the frequency and method of carrying out the checks referred to in the first subparagraph of paragraph 1, shall be laid down in accordance with the procedure set out in Article 19.

CHAPTER V

Final provisions

Article 17

Amendments to the Annexes to this Directive, in particular to adapt them to advances in technology, shall be decided by the Council acting by a qualified majority on a proposal from the Commission.

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(1) OJ No L 373, 31. 12. 1990, p. 1. Directive as last amended by Regulation (EEC) No 1601/92 (OJ No L 173, 27. 6. 1992, p. 13.

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

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Article 18

1. Where the procedure laid down in this Article is to be followed, matters shall without delay be referred by the chairman, either on his own initiative or at the request of a Member State, to the Standing Veterinary Committee (hereinafter called 'the committee') set up by the Council Decision of 15 October 1968.

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 54 votes.

4. The Commission shall adopt the measures and apply them immediately where they are in accordance with the committee's opinion. Where they are not in accordance with the committee's opinion or in the absence of any opinion, the Commission shall forthwith submit to the Council a proposal relating to the measures to be taken. The Council shall adopt the measures by a qualified majority.

If, on the expiry of three months from the date on which the matter was referred to it, the Council has not adopted any measures, the Commission shall adopt the proposed measures and apply them immediately, save where the Council has decided against the said measures by a simple majority.

Article 19

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

2. Within the committee the votes of the Member States shall be weighted as provided for in Article 148 (2) of the Treaty. The chairman shall not vote.

3. The representative of the Commission shall submit to the committee a draft of the measures to be adopted. The committee shall deliver its opinion on the draft within a time limit which the chairman may lay down according to the urgency of the matter. The opinion shall be delivered by a majority of 54 votes.

4. The Commission shall adopt the measures and apply them immediately where they are in accordance with the committee's opinion. Where they are not in accordance with the committee's opinion, or in the absence of any opinion, the Commission shall forthwith submit to the Council a proposal relating to the measures to be taken. The Council shall adopt the measures by a qualified majority.

If, on the expiry of 15 days from the date on which the matter was referred to it, the Council has not adopted any measures, the Commission shall adopt the proposed measures and apply them immediately, save where the Council has decided against the said measures by a simple majority.

Article 20

1. This Directive shall not be applicable to semen collected and processed in a Member State before 1 January 1990.

2. Until the date of entry into force of the decisions adopted pursuant to Articles 8, 9 and 10, the Member States shall not apply to imports of semen from third countries more favourable conditions than those resulting from application of Chapter II.

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Article 21

The Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 1 January 1990 at the latest. They shall forthwith inform the Commission thereof.

Article 22

This Directive is addressed to the Member States.

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ANNEX A

CHAPTER I

CONDITIONS FOR THE APPROVAL OF SEMEN COLLECTION CENTRES

Semen collection centres must:

(a) be placed under the permanent supervision of a centre veterinarian;

(b) have a least

(i) animal housing including isolation facilities;

(ii) semen collection facilities including a separate room for the cleaning and disinfection or sterilization of equipment;

(iii) a semen processing room which need not necessarily be on the same site;

(iv) a semen storage room which need not necessarily be on the same site;

(c) be so constructed or isolated that contact with livestock outside is prevented;

(d) be so constructed that the animal housing and the semen collecting, processing and storage facilities can be readily cleaned and disinfected;

(e) have isolation accommodation which shall have no direct communication with the normal animal accomodation;

(f) be so designed that the animal accommodation is physically separated from the semen processing room and both are separated from the semen storage room.

CHAPTER II

CONDITIONS RELATING TO THE SUPERVISION OF SEMEN COLLECTION CENTRES

The collection centres must:

(a) be so supervised that they contain only animals of the species whose semen is to be collected. Other domestic animals which are strictly necessary for the normal operation of the collection centre may nonetheless also be admitted, provided that they present no risk of infection to those species whose semen is to be collected and they fulfil the conditions laid down by the centre veterinarian;

(b) be so supervised that a record is kept of all bovine animals at the centre, giving details of the breed, date of birth and identification of each of the animals, and also a record of all checks for diseases and all vaccinations carried out, giving also information from the disease/health file of each animal;

(c) be regularly inspected by an official veterinarian, at least twice a year, at which time standing checks on the conditions of approval and supervision shall be carried out;

(d) be so supervised that the entry of unauthorized persons is prevented. Furthermore, authorized visitors must be required to comply with the conditions laid down by the centre veterinarian;

(e) employ technically competent staff suitably trained in disinfection procedures and hygiene techniques relevant to the control of the spread of disease;

(f) be so supervised that:

(i) only semen collected at an approved centre is processed and stored in approved centres, without coming into contact with any other consignment of semen. However, semen not collected in an approved centre may be processed in approved collection centres provided that:

— such semen is produced from bovine animals which fulfil the conditions laid down in Chapter I. 1 (d) (i), (ii), (iii) and (v) of Annex B,

— processing is carried out with separate equipment or at a different time from semen intended for intra-Community trade, the equipment in the latter case being cleaned and sterilized after use,

— such semen may not be the subject of intra-Community trade and cannot at any time come into contact with or be stored with semen intended for intra-Community trade,

— such semen is identifiable by a marking different from that provided for in point (vii);

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deep-frozen embryos may also be stored in approved centres provide that:

— such storage is authorized by the competent authority,

— the embryos meet the requirements of Council Directive 89/556/EEC of 25 September 1989 on animal health conditions governing intra-Community trade in and importation from third countries of embryos of domestic animals of the bovine species (*),

— the embryos are stored in separate storage flasks in the premises for storing approved semen.

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(ii) collection, processing and storage of semen takes place only on the premises set aside for the purpose and under conditions of the strictest hygiene;

(iii) all implements which come into contact with the semen or the donor animal during collection and processing are properly disinfected or sterilized prior to use;

(iv) products of animal origin used in the processing of semen — including additives or a diluent — are obtained from sources which present no animal health risk or are so treated prior to use that such risk is prevented;

(v) storage flasks and transport flasks are properly disinfected or sterilized before the commencement of each filling operation;

(vi) the cryogenic agent used has not been previously used for other products of animal origin;

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(vii) each individual dose of semen is clearly marked in such a way that the date of collection of the semen, the breed and identification of the donor animal, the name of the centre and the serological status of the donor animal in respect of infectious bovine rhinotracheitis and infectious pustular vulvo-vaginitis, possibly in code, can be readily established; the characteristics and form of this marking will be established in accordance with the procedure laid down in Article 19.

(*) OJ No L 302, 19. 10. 1989, p. 1. Directive as amended by Directive 90/425/EEC (OJ No L 224, 18. 8. 1990, pl. 29).

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ANNEX B

CHAPTER I

CONDITIONS APPLYING TO THE MOVEMENT OF ANIMALS INTO APPROVED SEMEN COLLECTION CENTRES

1. All bovine animals admitted to a semen collection centre must:

(a) have been subjected to a period of isolation of at least 30 days in accommodation specifically approved for the purpose by the competent authority of the Member State, and where only other cloven-hoofed animals having at least the same health status are present;

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(b) prior to their stay in the isolation accommodation described in (a), have belonged to a herd which is officially tuberculosis free and officially brucellosis free in accordance with Directive 64/432/EEC. The animals may not previously have been kept in one or more herds of a lower status;

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(c) ►M3 have come from a herd free of enzootic bovine leucosis as defined in Directive 64/432/EEC, or have been produced by dams which have been subjected, with negative results, to an Agar Gel immunodiffusion test, carried out in accordance with Annex G of Directive 64/432/EEC, after removal of the animals from their 'dam' In the case of animals derived by embryo tansfer, 'dam' means the recipient of the embryo. ◄

If this requirement cannot be fulfilled, the semen may not be the subject of trade until the donor has reached the age of two years and has been tested in accordance with Chapter II. 1 (iii) with a negative result;

(d) before the period of isolation specified in (a), and within the previous 30 days, have been subjected to the following tests with negative results:

(i) an intradermal tuberculin test carried out in accordance with the procedure laid down in Annex B to Directive 64/432/EEC;

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(ii) a serum agglutination test carried out in accordance with the procedure described in Annex C to Directive 64/432/EEC and showing a brucella count lower than 30 IU of agglutination per millilitre, or a complement fixation test showing a brucella count lower than 20 EEC units per millilitre (20 ICFT units);

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(iii) a serological test for enzootic bovine leukosis carried out in accordance with the procedure laid down in Annex G to Directive 64/432/EEC;

(iv) a serum neutralization test or an Elisa test for infectious bovine rhinotracheitis/infectious pustular vulvo-vaginitis;

(v) a virus isolation test (fluorescent antibody test or immunoperoxidase test) for bovine viral diarrhoea. In the case of an animal less than six months of age the test must be deferred until that age is reached.

The competent authority may give authorization for the tests referred to in (d) to be carried out in the isolation accommodation, provided that the results are known before the commencement of the 30-day isolation period laid down in (e);

(e) during the period of isolation of at least 30 days specified in (a), have been subjected to the following tests with negative results:

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(i) a serum agglutination test complying with the procedure described in Annex C to Directive 64/432/EEC and showing a brucella count lower than 30 IU of agglutination per millilitre, or a complement fixation test showing a brucella count lower than 20 EEC units per millilitre (20 ICFT units);

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(ii) either an immunofluorescent antibody test or a culture test for campylobacter foetus infection on a sample of preputial material or artificial vaginal washings; in the case of female animals a vaginal mucus agglutination test shall be carried out;

(iii) a microscopic examination and culture test for trichomonas foetus on a sample of vaginal washings or preputial washings; in the case of female animals a vaginal mucus agglutination test shall be carried out;

(iv) a serum neutralization test or an Elisa test for infectious bovine rhinotracheitis/infectious pustular vulvo-vaginitis.

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If any of the above tests should prove positive, the animal must be removed forthwith from the isolation accommodation. In the case of group isolation, the competent authority must take all necessary measures to re-establish the eligibility of the remaining animals for entry into the collection centre in accordance with this Annex.

2. All tests must be carried out in a laboratory approved by the Member State.

3. Animals may only be admitted to the semen collection centre with the express permission of the centre veterinarian. All movements, both in and out, must be recorded.

4. No animal admitted to the semen collection centre may show any clinical sign of disease on the day of admission. All animals must, without prejudice to paragraph 5, have come from isolation accommodation as referred to in paragraph 1 (a) which, on the day of consignment, officially fulfils the following conditions:

   (a) is situated in the centre of an area of 10 kilometres radius in which there has been no case of foot-and-mouth disease for at least 30 days;

   (b) has for at least three months been free from foot-and-mouth disease and brucellosis;

   (c) has for at least 30 days been free from those bovine diseases which are compulsorily notifiable in accordance with Annex E to Directive 64/432/EEC.

5. Provided that the conditions laid down in paragraph 4 are satisfied and the routine tests referred to in Chapter II have been carried out during the previous 12 months, animals may be transferred from one approved semen collection centre to another of equal health status without isolation or testing if transfer is direct. The animal in question must not come into direct or indirect contact with cloven-hoofed animals of a lower health status and the means of transport used must have been disinfected before use. If the movement from one semen collection centre to another takes place between Member States it must take place in accordance with Directive 64/432/EEC.

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6. However, until 1 July 1995 the Member States may admit to approved semen collection centres animals of the bovine species originating in herds which are free of brucellosis. In that case, the animals must, during the aforementioned period, be subjected to a complement fixation test showing a brucella count lower than 20 EEC units per millilitre (20 ICFT units) as provided for in (d) (ii) and (e) (i).

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CHAPTER II

ROUTINE TESTS AND TREATMENT WHICH MUST BE APPLIED TO ALL BOVINE ANIMALS IN AN APPROVED SEMEN COLLECTION CENTRE

1. All bovine animals kept at an approved semen collection centre mut be subjected at least once a year to the following tests and treatment:

   (i) an intradermal tuberculin test for tuberculosis, carried out in accordance with the procedure laid down in Annex B to Directive 64/432/EEC, with a negative result;

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   (ii) a serum agglutination test for brucellosis, carried out in accordance with the procedure described in Annex C to Directive 64/432/EEC, giving a count lower than 30 IU of agglutination per millilitre, or a complement fixation test showing a brucella count lower than 20 EEC units per millilitre (20 ICFT units);

   (iii) a screening test for enzootic bovine leucosis, carried out in accordance with the procedure described in Annex G to Directive 64/432/EEC, with a negative result;

▼M1

   (iv) for infectious bovine rhinotracheitis/infectious pustular vulvo-vaginitis, a serum neutralization test or an ELISA test with a negative result. However ►M3 ——————— ◄:

   — it is not necessary to carry out these tests on bulls which have already been subjected to such tests and have given a positive result to the serological test carried out in accordance with this Directive,

▼M1

— vaccination against these diseases may be practised on sero-negative bulls, either with one dose of a temperature-sensitive live vaccine administered intranasally or two doses of an inactivated vaccine separated by an interval of not less than three weeks and not more than four weeks; the vaccination must be repeated subsequently at intervals of not more than six months;

▼B

(v) either an immunofluorescent antibody test or a culture test for campylobacter foetus infection on a sample of preputial material or artificial vaginal washings; in the case of female animals a vaginal mucus agglutination test must be carried out. ►M1 However, bulls which are not used for the production of semen may be exempt from the antibody test or a culture test for campylobacter foetus infection, with the proviso that such bulls may not be re-admitted to semen production until they have been subjected to such a test or culture and given a negative result. ◄

2. All tests must be carried out in a laboratory approved by the Member State.

3. If any of the above tests should prove positive, the animal must be isolated and the semen collected from it since the last negative test may not be the subject of intra-Community trade.

Semen collected from all other animals at the centre since the date when the positive test was carried out shall be held in separate storage and may not be the subject of intra-Community trade until the health status of the centre has been re-established.

▼M3

These provisions shall not apply to sero-positive bulls which, prior to their first vaccination in accordance with this Directive at the insemination centre, gave a negative reaction to the serum neutralization test or the ELISA test for infectious bovine rhinotracheitis or infectious pustular vulvo-vaginitis.

Sero-positive bulls referred to in the second subparagraph of Article 4 (1) must be isolated since their semen may be the subject of intra-Community trade in accordance with the provisions for trade in semen from such bulls.

▼B

ANNEX C

CONDITIONS WHICH SEMEN COLLECTED AT APPROVED CENTRES MUST SATISFY FOR THE PURPOSES OF INTRA-COMMUNITY TRADE

1. Semen must be obtained from animals which:

(a) show no clinical signs of disease on the day the semen is collected;

▼M3

(b) (i) have not been vaccinated against foot-and-mouth disease during the 12 months prior to collection, or

(ii) have been vaccinated against foot-and-mouth disease during the 12 months prior to collection, in which case 5 % (with a minimum of five straws) of each collection shall be submitted to virus isolation test for foot-and-mouth disease with negative results;

▼B

(c) have not been vaccinated against foot-and-mouth disease within 30 days immediately prior to collection;

▼M3

(d) have been kept at an approved semen collection centre for a continuous period of at least 30 days immediately prior to the collection of the semen in the case of collections of fresh semen;

▼B

(e) are not allowed to serve naturally;

▼M3

(f) are kept in semen collection centres which have been free from foot-and-mouth disease for at least three months prior to collection of the semen and 30 days after collection or, in the case of fresh semen, until the date of dispatch and are situated in the centre of an area of 10 kilometres radius in which for at least 30 days there has been no case of foot-and-mouth disease;

(g) have been kept in semen collection centres which, during the period commencing 30 days prior to collection and ending 30 days after collection of the semen or, in the case of fresh semen, until the date of dispatch, have been free from those bovine diseases which are compulsorily notifiable in accordance with Annex E to Directive 64/432/EEC.

▼B

2. Antibiotics as listed below must be added to produce these concentrations in the final diluted semen:

not less than: 500 IU per ml streptomycin,
500 IU per ml penicillin,
150 µg per ml lincomycin,
300 µg per ml spectinomycin.

An alternative combination of antibiotics with an equivalent effect against campylobacters, leptospires and mycoplasmas may be used.

Immediately after their addition the diluted semen must be kept at a temperature of at least 5 ºC for a period of not less than 45 minutes.

3. Semen for intra-Community trade must:

▼M3

(i) be stored in approved conditions for a minimum period of 30 days prior to dispatch. This requirement shall not apply to fresh semen;

▼B

(ii) be transported to the Member State of destination in flasks which have been cleaned and disinfected or sterilized before use ►M1 and which have been sealed and numbered prior to dispatch from the approved storage facilities ◄.

▼B

ANNEX D

ANIMAL HEALTH CERTIFICATE

No: .....

Country of collection: .....

Competent authority: .....

Competent local authority: .....

I. **Identification of semen:**

.....

Number 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: .....

.....

.....

▼M1

IV. I, the undersigned veterinatian, certify that :

1. the semen described above was collected, processed and stored under conditions which comply with the standards laid down in Directive 88/407/EEC ;

2. the semen described above, was sent to the place of loading in a sealed container under conditions which comply with Directive 88/407/EEC and bearing the number ... ;

3. the semen described above was collected in a centre where all bulls gave a negative result to a serum neutralization test or an ELISA test for infectious bovine rhinotracheitis or infectious pustular vulvo-vaginitis carried out in accordance with Directive 88/407/EEC (1) ;

4. the semen described above was collected from bulls :

   (i) which gave a negative result to a serum neutralization test or an ELISA test for infectious rhinotracheitis or infectious pustular vulvo-vaginitis carried out in accordance with Directive 88/407/EEC (1) ; or

   (ii) which gave a positive result to the tests referred to at (i) but which had already given a negative reaction to these tests prior to a first vaccination in accordance with the Directive at the insemination centre (1) ; or

   (iii) which gave a positive result to a serum neutralization test or an ELISA test for infectious bovine rhinotracheitis or infectious pustular vulvo-vaginitis and have not been vaccinated in accordance with Directive 88/407/EEC (1) : and in which case the semen comes from a ►(1) collection ◄ which has been subjected, with a negative result, to an examination by inoculation or a virus isolation test (1) as referred to in the third subparagraph or Article 4 (1) of Directive 88/407/EEC in laboratory ... (2) ;

►(2) 5. the semen described above was collected from bulls :

   (i) which have not been vaccinated against foot-and-mouth disease within 12 months prior to collection(1);

   or,

   (ii) which have been vaccinated against foot-and-mouth disease with 12 months prior to collection, in which case the semen comes from a collection in which 5 % of each collection intended for trade (with a minimum of 5 straws) has been subjected, with negative results, to a virus isolation test for foot-and-mouth disease in ... laboratory (2); ◄

►(3) 6. the semen was stored in approved conditions for a minimum period of 30 days prior to dispatch (3). ◄

Done at .....

.....

(signature)

.....

(Name in block letters)

Seal

(1) Delete as necessary.
(2) Name of the laboratory specified in accordance with ►(4) Article 4 ◄ of Directive 88/407/EEC.
►(5) (3) May be deleted for fresh semen. ◄

►(1) (2) (3) (4) (5) M3