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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:

	Official Journal		
	No	page	date
► <u>M1</u> Council Directive 90/120/EEC of 5 March 1990	L 71	37	17.3.1990
► <u>M2</u> Council Directive 90/425/EEC of 26 June 1990	L 224	29	18.8.1990
► <u>M3</u> Council Directive 93/60/EEC of 30 June 1993	L 186	28	28.7.1993
► <u>M4</u> Council Regulation (EC) No 806/2003 of 14 April 2003	L 122	1	16.5.2003
► <u>M5</u> Council Directive 2003/43/EC of 26 May 2003	L 143	23	11.6.2003
► <u>M6</u> Commission Decision 2004/101/EC of 6 January 2004	L 30	15	4.2.2004
► <u>M7</u> Commission Decision 2006/16/EC of 5 January 2006	L 11	21	17.1.2006

Amended by:

► <u>A1</u> Act of Accession of Austria, Sweden and Finland	C 241	21	29.8.1994
(adapted by Council Decision 95/1/EC, Euratom, ECSC)	L 1	1	1.1.1995



**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 <sup>(1)</sup>,

Having regard to the opinion of the European Parliament <sup>(2)</sup>,

Having regard to the opinion of the Economic and Social Committee <sup>(3)</sup>,

Whereas provisions relating to animal health problems in intra-Community trade in bovine animals and swine appear in Directive 64/432/EEC <sup>(4)</sup>, as last amended by Regulation (EEC) No 3768/85 <sup>(5)</sup>; whereas in addition, Directive 72/462/EEC <sup>(6)</sup>, 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 supervised; whereas, in addition, in respect of countries on that list, specific

<sup>(1)</sup> OJ No C 267, 6. 10. 1983, p. 5.

<sup>(2)</sup> OJ No C 342, 19. 12. 1983, p. 11.

<sup>(3)</sup> OJ No C 140, 28. 5. 1984, p. 6.

<sup>(4)</sup> OJ No 121, 29. 7. 1964, p. 1977/64.

<sup>(5)</sup> OJ No L 362, 31. 12. 1985, p. 8.

<sup>(6)</sup> OJ No L 302, 31. 12. 1972, p. 28.

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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.

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This Directive shall not affect Community and/or national zootechnical provisions governing the organisation of artificial insemination in general and the distribution of semen in particular.

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#### *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;

**▼ M5**

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

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

**▼ M5**

- (a) it must have been collected and processed and/or stored if need be in a collection or storage centre or centres approved for the purpose in accordance with Article 5(1), with a view to artificial insemination and for the purposes of intra-Community trade;

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- (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***▼ M5**


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**▼ M3**

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.

**▼B***Article 5*

1. The Member State on whose territory the ►**M5** semen collection or storage 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 ►**M5** semen collection or storage 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 ►**M5** semen collection or storage centres ◀ shall be registered, each centre being given a veterinary registration number. Each Member State shall send a list of ►**M5** semen collection or storage 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 ►**M5** the procedure referred to in Article 18(2) ◀.

*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.
- (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 ► **M5** the procedure referred to in Article 18(2) ◀. That list may be supplemented or amended in accordance with ► **M5** the procedure referred to in Article 18(2) ◀.
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 wild-life 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*▼ **M5**

1. The lists of semen collection and storage centres from which Member States shall authorise the importation of semen originating in third countries shall be prepared and updated in accordance with this Article.

An establishment may be placed on such a list only if the competent authority of the third country of origin guarantees that the conditions referred to in paragraphs 2 and 3(b) to (e) are met.

The competent authorities of the third countries appearing on lists drawn up and updated in accordance with Article 8 shall guarantee that lists of semen collection and storage centres from which the semen may be dispatched to the Community are drawn up, kept up-to-date and communicated to the Commission.

The Commission shall provide the contact points designated by Member States with regular notifications concerning new or updated lists that it has received from the competent authorities of the third countries concerned in accordance with subparagraph 3.

If no Member State objects to the new or updated list within 20 working days of the Commission's notification, imports shall be authorised from establishments appearing on the list 10 working days after the day on which the Commission makes it available to the public.

Where written comments are made by at least one Member State or whenever it considers that amendments to a list are necessary in the light of relevant information such as Community inspection reports or the results of the controls carried out under Article 12, the Commission shall inform all Member States and include the matter on the agenda for the relevant sector at the next meeting of the Standing Committee on the Food Chain and Animal Health for decision in accordance with the procedure referred to in Article 18(2).

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The Commission shall arrange for up-to-date versions of all lists to be made available to the public.

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2. In deciding whether a ► **M5** semen collection or storage 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 ► **M5** semen collection or storage centres ◀ are subject.

3. A ► **M5** semen collection or storage 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 ► **M5** the procedure referred to in Article 18(2) ◀, 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 ► **M5** the procedure referred to in Article 18(2) ◀, 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:

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- (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 ►**M5** the procedure referred to in Article 18(2) ◀.

**▼M3***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 <sup>(1)</sup> 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****▼M2***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 <sup>(2)</sup>, 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.

**▼B***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).

<sup>(1)</sup> 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).

<sup>(2)</sup> OJ No L 224, 18. 8. 1990, p. 29.



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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 ► **M5** the procedure referred to in Article 18(2) ◀.

## CHAPTER V

**Final provisions**▼ **M5***Article 17*

Annex A shall be amended by the Council, acting by qualified majority on a proposal from the Commission, in particular to adapt it to advances in technology.

Annexes B, C and D shall be amended in accordance with the procedure laid down in Article 18(2).

*Article 18*

1. The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health set up by Regulation (EC) No 178/2002 <sup>(1)</sup>.

2. Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC <sup>(2)</sup> shall apply.

The period referred to in Article 5(6) of Decision 1999/468/EC shall be set at three months.

3. The Committee shall adopt its rules of procedure.

▼ **B***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.

*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.

<sup>(1)</sup> OJ L 31, 1.2.2002, p. 1.

<sup>(2)</sup> OJ L 184, 17.7.1999, p. 23.

▼ **M5***ANNEX A*

## CHAPTER I

**CONDITIONS FOR THE OFFICIAL APPROVAL OF CENTRES**

1. Semen collection centres must:
  - (a) be placed under the permanent supervision of a centre veterinarian authorised by the competent authority;
  - (b) have at least:
    - (i) animal housing, including isolation facilities;
    - (ii) semen collection facilities, including a separate room for the cleaning and disinfection or sterilisation 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 has no direct communication with the normal animal accommodation;
  - (f) be so designed that the animal accommodation is physically separated from the semen processing room and both are separated from the semen storage room.
2. Semen storage centres must:
  - (a) be placed under the permanent supervision of a centre veterinarian authorised by the competent authority;
  - (b) be so constructed or isolated that contact with livestock outside is prevented;
  - (c) be so constructed that the storage facilities can be readily cleaned and disinfected.

## CHAPTER II

**CONDITIONS RELATING TO THE OFFICIAL SUPERVISION OF CENTRES**

1. 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 that 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 for each animal;
  - (c) be regularly inspected by an official veterinarian, at least twice a year, in the context of standing checks on the conditions of approval and supervision;
  - (d) be so supervised that the entry of unauthorised persons is prevented. Furthermore, authorised 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) of Annex B,

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- 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 sterilised 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);

Deep-frozen embryos may also be stored in approved centres provided that:

- such storage is authorised 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 <sup>(1)</sup>,
  - the embryos are stored in separate storage containers in the premises for storing approved semen;
- (ii) collection, processing and storage of semen takes place only on the premises set aside for the purpose and under the strictest conditions of hygiene;
  - (iii) all instruments which come into contact with the semen or the donor animal during collection and processing are properly disinfected or sterilised prior to use, except for single-use instruments;
  - (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 containers and transport containers are either properly disinfected or sterilised before the commencement of each filling operation, except for single-use containers;
  - (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 of the semen, the breed and identification of the donor animal and the approval number of the centre can be readily established; each Member State shall communicate to the Commission and other Member States the characteristics and form of the marking used in its territory;
  - (viii) the storage unit must comply with specific conditions relating to the supervision of semen storage centres provided for in point 2.

2. Storage centres must:

- (a) be so supervised that a record is kept of all movement of semen (in and out the centre) and of the status of the donor bulls whose semen is stored there, and which must comply with the requirements of this Directive;
- (b) be regularly inspected by an official veterinarian, at least twice a year, in the context of the standing checks on the conditions of approval and supervision;
- (c) be so supervised that the entry of unauthorised persons is prevented. Furthermore, authorised visitors must be required to comply with the conditions laid down by the centre veterinarian;
- (d) employ technically competent staff suitably trained in disinfection procedures and hygiene techniques relevant to the control of the spread of disease;
- (e) be so supervised that:
  - (i) only semen collected at collection centres approved in accordance with this Directive is stored in approved storage centres, without coming into contact with any other semen.

In addition, only semen coming from an approved collection or storage centre and transported in conditions offering every possible health guarantee, having had no contact with any other semen, may be brought into an approved storage centre.

<sup>(1)</sup> OJ L 302, 19.10.1989, p. 1. Directive as last amended by Commission Decision 94/113/EC (OJ L 53, 24.2.1994, p. 23).

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Deep-frozen embryos may also be stored in approved centres provided that:

- such storage is authorised 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 containers in the premises for storing approved semen;
- (ii) storage of semen takes place only on the premises set aside for the purpose and under the strictest conditions of hygiene;
  - (iii) all instruments which come into contact with the semen are properly disinfected or sterilised prior to use, except for single-use instruments;
  - (iv) storage containers and transport containers are either properly disinfected or sterilised before the commencement of each filling operation, except for single-use containers;
  - (v) the cryogenic agent used has not been previously used for other products of animal origin;
  - (vi) 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 and the approval number of the collection centre can be readily established; each Member State shall communicate to the Commission and other Member States the characteristics and form of the marking used in its territory.

▼ **M5**

## ANNEX B

## CHAPTER I

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

1. For all bovine animals admitted to a semen collection centre the following requirements shall apply:

- (a) they must have been subjected to a period of quarantine of at least 28 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;
- (b) prior to their stay in the quarantine accommodation described in (a), they must have belonged to a herd which is officially tuberculosis free and officially brucellosis free in accordance with Directive 64/432/EEC. The animals shall not previously have been kept in a herd of a lower status;
- (c) they must come from a herd officially free of enzootic bovine leukosis as defined in Directive 64/432/EEC, or have been produced by dams which have been subjected, with negative results, to a test carried out in accordance with Annex D (Chapter II) to Directive 64/432/EEC, after removal of the animals from their dam. In the case of animals derived by embryo transfer, 'dam' means the recipient of the embryo;

If this requirement cannot be fulfilled, the semen shall 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(c) with a negative result;

- (d) within the 28 days preceding the period of quarantine specified in (a), they have been subjected to the following tests with negative results in each case, except for the BVD/MD antibody test mentioned in (v):
  - (i) for bovine tuberculosis, an intradermal tuberculin test carried out in accordance with the procedure laid down in Annex B to Directive 64/432/EEC;
  - (ii) for bovine brucellosis, a serological test carried out in accordance with the procedure described in Annex C to Directive 64/432/EEC;
  - (iii) for enzootic bovine leukosis, a serological test carried out in accordance with the procedure laid down in Annex D (Chapter II) to Directive 64/432/EEC;
  - (iv) for IBR/IPV, a serological test (whole virus) on a blood sample if the animals do not come from an IBR/IPV free herd as defined in Article 2.3.5.3. of the International Animal Health Code;
  - (v) for BVD/MD,
    - a virus isolation test or a test for virus antigen, and
    - a serological test to determine the presence or absence of antibodies.

▼ **M7**

The competent authority may give authorisation for the tests referred to in (d) to be carried out on samples collected in the quarantine station. In this case, the period of quarantine referred to in (a) may not commence before the date of sampling. However, should any of the tests listed in (d) prove positive, the animal concerned shall be immediately removed from the isolation unit. In the event of group isolation, the quarantine period referred to in (a) may not commence for the remaining animals until the animal which tested positive has been removed.

▼ **M5**

- (e) within the period of quarantine specified in (a), and at least 21 days after being admitted to quarantine (at least seven days after being admitted to quarantine to search for *Campylobacter fetus* ssp. *venerealis* and *Trichomonas foetus*), they have been subjected to the following tests with negative results in each case, except for the BVD/MD antibody test (see point (iii) below):

- (i) for bovine brucellosis, a serological test carried out in accordance with the procedure described in Annex C to Directive 64/432/EEC;
- (ii) for IBR/IPV, a serological test (whole virus) on a blood sample;

If any animals test positive, these animals shall be removed immediately from the quarantine station and the other animals of the same group shall remain in quarantine and be retested, with negative results, not less than 21 days after removal of the positive animal(s).

- (iii) for BVD/MD,

▼ **M5**

- a virus isolation test or a test for virus antigen, and
- a serological test to determine the presence or absence of antibodies.

Any animal (seronegative or seropositive) may only be allowed entry to the semen collection facilities if no sero-conversion occurs in animals which tested seronegative before entry into the quarantine station.

If sero-conversion occurs, all animals that remain seronegative shall be kept in quarantine over a prolonged time, until there is no more sero-conversion in the group for a period of three weeks. Serologically positive animals may be allowed entry into the semen collection facilities;

(iv) for *Campylobacter fetus* ssp. *venerealis*:

- in the case of animals less than six months old or kept since that age in a single sex group prior to quarantine, a single test on a sample of artificial vagina washings or preputial specimen;
- in the case of animals aged six months or older that could have had contact with females prior to quarantine, a test three times at weekly intervals on a sample of artificial vagina washings or preputial specimen;

(v) for *Trichomonas foetus*:

- in the case of animals less than six months old or kept since that age in a single sex group prior to quarantine, a single test on a sample of preputial specimen;
- in the case of animals aged six months or older that could have had contact with females prior to quarantine, a test three times at weekly intervals on a sample of preputial specimen.

If any of the above tests is 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 the Annex.

- (f) prior to the initial dispatch of semen from BVD/MD serologically positive bulls, a semen sample from each animal shall be subjected to a virus isolation or virus antigen ELISA test for BVD/MD. In the event of a positive result, the bull shall be removed from the centre and all of its semen destroyed.
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.

## CHAPTER II

**ROUTINE TESTS 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 must be subjected at least once a year to the following tests, with negative results:

▼ **M5**

- (a) for bovine tuberculosis, an intradermal tuberculin test, carried out in accordance with the procedure laid down in Annex B to Directive 64/432/EEC;
- (b) for bovine brucellosis, a serological test carried out in accordance with the procedure described in Annex C to Directive 64/432/EEC;
- (c) for enzootic bovine leukosis, a serological test carried out in accordance with the procedure described in Annex D (Chapter II) to Directive 64/432/EEC;
- (d) for IBR/IPV, a serological test (whole virus) on a blood sample;
- (e) for BVD/MD, a serological antibody which is applied only to seronegative animals;

Should an animal become serologically positive, every ejaculate of that animal collected since the last negative test shall be either discarded or tested for virus with negative results.

- (f) for *Campylobacter fetus* ssp. *venerealis*, a test on a sample of preputial specimen. Only bulls on semen production or having contact with bulls on semen production need to be tested. Bulls returning to collection after a lay-off of more than six months shall be tested not more than 30 days prior to resuming production;
  - (g) for *Trichomonas foetus*, a test on a sample of preputial specimen. Only bulls on semen production or having contact with bulls on semen production need to be tested. Bulls returning to collection after a lay-off of more than six months shall be tested not more than 30 days prior to resuming production.
2. All tests must be carried out in a laboratory approved by the Member State.
  3. If any of the above tests is 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 with the exception, for BVD/MD, of semen from every ejaculate which has been tested BVD/MD virus negative.

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 restored.

▼ **M5***ANNEX C***CONDITIONS WHICH SEMEN FOR INTRA-COMMUNITY TRADE OR IMPORTED INTO THE COMMUNITY MUST SATISFY**

1. Semen must be obtained from animals which:
  - (a) show no clinical signs of disease on the day the semen is collected;
  - (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 a virus isolation test for foot-and-mouth disease with negative results;
  - (c) have not been vaccinated against foot-and-mouth disease within 30 days immediately prior to collection;
  - (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;
  - (e) are not allowed to serve naturally;
  - (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 which are 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;
  - (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(I) to Directive 64/432/EEC.
2. Antibiotics as listed below must be added to produce these concentrations in the final diluted semen:
 

not less than:

  - 500 µg streptomycin per ml final dilution,
  - 500 IU penicillin per ml final dilution,
  - 150 µg lincomycin per ml final dilution,
  - 300 µg spectinomycin per ml final dilution.

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

Immediately after their addition the diluted semen must be kept at a temperature of at least 5 °C for a period of not less than 45 minutes.
3. Semen for intra-Community trade must:
  - (a) be stored in approved conditions for a minimum period of 30 days prior to dispatch. This requirement shall not apply to fresh semen.
  - (b) be transported to the Member State of destination in containers which have been cleaned and disinfected or sterilised before use and which have been sealed and numbered prior to dispatch from the approved storage facilities.



▼ **M6**

## ANNEX D

**MODELS OF CERTIFICATES FOR INTRACOMMUNITY TRADE**

## ANNEX D1

The following model of certificate is applicable to intra-Community trade of semen collected in accordance with Council Directive 88/407/EEC as amended by Directive 2003/43/EC

<b>HEALTH CERTIFICATE SEMEN OF DOMESTIC ANIMALS OF THE BOVINE SPECIES FOR INTRA-COMMUNITY TRADE COLLECTED IN ACCORDANCE WITH COUNCIL DIRECTIVE 88/407/EEC AS AMENDED BY DIRECTIVE 2003/43/EC</b>		
1. Member State of provenance and competent authority.		2. Health certificate No
A. ORIGIN OF SEMEN		
3. Approval number of the centre of provenance of the consignment: collection/storage <sup>(1)</sup>		
4. Name and address of the centre of provenance of the consignment: collection/storage <sup>(1)</sup>		5. Name and address of the consignor
6. Country and place of loading		7. Means of transport
B. DESTINATION OF SEMEN		
8. Member State of destination		9. Name and address of the consignee
C. IDENTIFICATION OF SEMEN		
10.1. Identification mark of the doses <sup>(2)</sup>	10.2. Number of doses	10.3. Approval number of the collection centre of origin
D. HEALTH INFORMATION		
I, undersigned official veterinarian, certify that		
11.1. The semen described above (a) was collected, processed and stored under conditions which comply with the standards laid down in Directive 88/407/EEC; (b) was sent to the place of loading in a sealed container under conditions which comply with Directive 88/407/EEC and bearing the number ....		

▼ **M6**

11.2. The semen described above was collected from bulls: <ul style="list-style-type: none"> <li>(i) which either have not been vaccinated against foot-and-mouth disease within 12 months prior to collection <sup>(1)</sup>; or</li> <li>(ii) which have been vaccinated against foot-and-mouth disease less than 12 months and more than 30 days prior to collection, and 5% of doses of semen of each collection, with a minimum of 5 straws, have been submitted to a virus isolation test for foot-and-mouth disease, carried out with negative results in the laboratory (.....) <sup>(3)</sup>, situated in or designated by the Member State of destination <sup>(1)</sup>;</li> </ul>		
11.3. The semen described above was stored in approved conditions for a minimum period of 30 days immediately following collection <sup>(4)</sup> .		
E. VALIDITY		
12. Date and place	13. Name and qualification of the official veterinarian	14. Signature and stamp of the official veterinarian

<sup>(1)</sup> Delete as necessary.  
<sup>(2)</sup> Corresponding to the identification of the donor animals and date of collection.  
<sup>(3)</sup> Name of the laboratory.  
<sup>(4)</sup> May be deleted for fresh semen.



## ANNEX D2

The following model of certificate is applicable from 1 January 2005 for intra-Community trade in stocks of semen collected, processed and/or stored before 31 December 2004 in accordance with the former conditions of Council Directive 88/407/EEC, and traded after that date in accordance with Article 2(2) of Directive 2003/43/EC

<b>HEALTH CERTIFICATE SEMEN OF DOMESTIC ANIMALS OF THE BOVINE SPECIES COLLECTED, PROCESSED AND STORED BEFORE 31 DECEMBER 2004, FOR INTRA-COMMUNITY TRADE AS OF 1 JANUARY 2005, IN ACCORDANCE WITH ARTICLE 2(2) OF COUNCIL DIRECTIVE 2003/43/EC</b>			
1. Member State of provenance and competent authority.		2. Health certificate No	
A. ORIGIN OF SEMEN			
3. Approval number of the centre of provenance of the consignment collection/storage <sup>(1)</sup>			
4. Name and address of the centre of provenance of the consignment: collection/storage <sup>(1)</sup>	5. Name and address of the consignor		
6. Country and place of loading	7. Means of transport		
B. DESTINATION OF SEMEN			
8. Member State of destination		9. Name and address of the consignee	
C. IDENTIFICATION OF SEMEN			
10.1. Identification mark of the doses <sup>(2)</sup>	10.2. Date of collection <sup>(3)</sup>	10.3. Number of doses	10.4. Approval number of the collection centre of origin
D. HEALTH INFORMATION			
I, the undersigned official veterinarian, hereby certify that :			
11.1. The semen described above was collected before the date of 31 December 2004 on a semen collection centre which was:			
(a) approved under the conditions laid down in Annex A, Chapter I, of Directive 88/407/EEC;			
(b) operated and supervised under the conditions laid down in Annex A, Chapter II, of Directive 88/407/EEC.			

## ▼ M6

<p>11.2. At the time the semen described above was collected, all bovine animals at the semen collection centre:</p> <ul style="list-style-type: none"> <li>(a) came from herds and/or were born to dams which satisfy the conditions of points 1(b) and (c) in Chapter I of Annex B to Directive 88/407/EEC;</li> <li>(b) have, within the 30 days preceding the quarantine isolation period, undergone, with negative results: <ul style="list-style-type: none"> <li>— the tests required by Annex B, Chapter I, 1.d(i),(ii),(iii) of Directive 88/407/EEC, and</li> <li>— a serum neutralization test or an ELISA test for infectious bovine rhinotracheitis/infectious pustular vulvo-vaginitis, and</li> <li>— a virus isolation test (fluorescent antibody test or immunoperoxidase test) for bovine viral diarrhoea, which in the case of an animal less than six months of age has been deferred until that age was reached.</li> </ul> </li> <li>(c) have satisfied the quarantine isolation period of 30 days and have been subjected with the required negative results to the following health tests: <ul style="list-style-type: none"> <li>— a serological test for brucellosis carried out in accordance with the procedure described in Annex C to Directive 64/432/EEC;</li> <li>— either an immunofluorescent antibody test or a culture test for campylobacter fetus infection on a sample of preputial material or artificial vagina washings, or, in the case of a female animal, a vaginal mucus agglutination test;</li> <li>— a microscopic examination and culture test for trichomonas foetus on a sample of preputial material or artificial vagina washings, or in the case of a female animal a vaginal mucus agglutination test.</li> </ul> </li> <li>(d) have undergone, at least once a year, with negative results, the routine tests referred to in points 1(a), (b) and (c) in Chapter I of Annex B to Directive 88/407/EEC.</li> </ul>
<p>11.3. At the time the semen described above was collected</p> <ul style="list-style-type: none"> <li>(a) all female bovine animals in the centre have undergone at least once a year a vaginal mucus agglutination test for campylobacter fetus infection with negative results, and</li> <li>(b) all bulls used for semen production have undergone with negative result either an immunofluorescent antibody test or a culture test for campylobacter fetus infection on a sample of preputial material or artificial vagina washings carried out within 12 months prior to collection.</li> </ul>
<p>11.4. The semen described above was collected from bulls standing in a semen collection centre in which</p> <ul style="list-style-type: none"> <li>(i) all bovine animals have undergone at least once a year with negative result a serum neutralisation test or an ELISA test for infectious bovine rhinotracheitis/infectious pustular vulvo-vaginitis <sup>(1)</sup>, or</li> <li>(ii) bovine animals not vaccinated against infectious bovine rhinotracheitis have undergone at least once a year with negative result a serum neutralisation test or an ELISA test for infectious bovine rhinotracheitis/infectious pustular vulvo-vaginitis, and testing for infectious bovine rhinotracheitis is not carried out on bulls which have received a first vaccination against infectious bovine rhinotracheitis at the insemination centre after they have been tested with negative result in a serum neutralisation test or an ELISA test for infectious bovine rhinotracheitis/infectious pustular vulvo-vaginitis and which since the first vaccination have been regularly re-vaccinated with an interval of not more than six months <sup>(1)</sup>.</li> </ul>
<p>11.5. The semen described above was collected from bulls:</p> <ul style="list-style-type: none"> <li>(i) which either have not been vaccinated against foot-and-mouth disease within 12 months prior to collection <sup>(1)</sup>; or</li> <li>(ii) which have been vaccinated against foot-and-mouth disease less than 12 months and more than 30 days prior to collection, and 5% of doses of the semen from each collection, with a minimum of five straws, have been submitted to a virus isolation test for foot-and-mouth disease, carried out with negative results in the laboratory (.....) <sup>(4)</sup> situated in or designated by the Member State of destination <sup>(1)</sup>.</li> </ul>

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11.6. The semen was stored in approved conditions for a minimum period of 30 days immediately following collection <sup>(5)</sup> .		
11.7. The semen described above was sent to the place of loading in a sealed container and bearing the number .....		
E. VALIDITY		
12. Date and place	13. Name and qualification of the official veterinarian	14. Signature and stamp of the official veterinarian

<sup>(1)</sup> Delete as necessary.

<sup>(2)</sup> Corresponding to the identification of the donor animals, the breed of the donor animals, the date of collection and the serological status of the donor animal in respect of infectious bovine rhinotracheitis and infectious pustular vulvo-vaginitis.

<sup>(3)</sup> The date of collection must be earlier than 31 December 2004.

<sup>(4)</sup> Name of the laboratory.

<sup>(5)</sup> May be deleted for fresh semen.