Proposal for a Council Directive amending Directive 88/407/EEC laying down the animal health requirements applicable to intra-Community trade in and imports of semen of domestic animals of the bovine species

(2003/C 20 E/22)

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(Submitted by the Commission on 25 September 2002)

EXPLANATORY MEMORANDUM

Council Directive 88/407/EEC lays down the animal health requirements applicable to intra-Community trade in, and imports of semen of domestic animals of the bovine species.

This Directive needs to be amended.

The purpose of this proposal is:

— to allow the storage of semen at other premises than the Artificial Insemination centre where semen was collected,

— to amend, in the light of the new scientific data available and the new provisions laid down in the Office International des Epizooties (OIE), the animal health conditions applicable to entry of bulls into AI centres, in particular concerning infectious bovine rhinothracheitis (IBR/IPV) and bovine viral diarrhoea (BVD/MD),

— to simplify, at the Community level, the procedure for the agreement and listing of AI centres in third countries. These lists are frequently modified on the basis of the information sent by the competent authorities of third countries (address, name, new establishment, etc.),

— to allow the Commission to amend, following the comitology procedure, the annexes of Directive 88/407/EEC as they cover technical points relating to approval of centres and conditions of admission of bulls onto centres.

The proposal has no financial impact on Community budget.

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 37 thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Parliament,

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

Having regard to the opinion of the Committee of the Regions,

Whereas:

(1) Directive 88/407/EEC [1] lays down the animal health requirements applicable to intra-Community trade in and imports of semen of domestic animals of the bovine species.

(2) In the light of the new scientific data available, it is necessary to amend the animal health conditions applying to entry of bulls into artificial insemination centres, in particular concerning infectious bovine rhinotracheitis/infectious pustular vulvovaginitis (IBR/IPV) and bovine viral diarrhoea/mucosal diarrhoea (BVD/MD).

(3) The procedure to establish the list of semen collection centres in third countries from which the importation of semen is authorised should be simplified.

(4) The same requirements for storage should apply to all establishments whether or not they are associated with a production unit.

(5) The necessary measures for the implementation of this Directive are of general scope within the meaning of Article 2 of Council Decision 1999/468 of 28 June 1999 laying down the procedures for the exercise of implementation powers conferred on the Commission, they should be adopted by use of the regulatory procedure provided for in Article 5 of that Decision,

[1] OJ L 194, 22.7.1988, p. 10.

HAS ADOPTED THIS DIRECTIVE:

Article 1

Directive 88/407/EEC is hereby amended as follows:

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

   '(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 and stored for use in artificial insemination;

   "Semen storage centre" means an officially approved and supervised establishment situated in the territory of a Member State or third country in which semen is stored for use in artificial insemination.'

2. Article 3(a) is replaced by the following:

   '(a) it must have been collected, processed and/or stored in a centre or centres approved in accordance with Article 5(1).'

3. Articles 4(1) and 4(2) are deleted.

4. In Articles 5, 9(2) and 9(3), the words 'semen collection centre(s)' are replaced by the words 'semen collection or storage centre(s)'.

5. Article 9(1) is replaced by the following:

   '1. The Commission shall establish the lists of semen collection and storage centres from which the Member States may authorise the importation of semen originating in third countries.

   The Commission shall inform the Member States of the modifications proposed by the third country concerned to the lists of centres.

   The Member States shall have ten working days, from receipt of the proposed modifications, to send any written comments to the Commission.

   Where no comments are received from Member States within the time limit laid down in the third sub-paragraph, the modifications to the lists shall be considered to have been accepted by the Member States and imports shall be authorised from such centres when the Commission notifies the competent authorities of the Member states and third country concerned that the modifications are published on the website of the Commission.

   Where written comments are made by at least one Member State, the Commission shall inform the Member States and include the point on 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.'

6. Article 17 shall be replaced by:

   'The Annexes to this Directive shall be amended in accordance with the procedure set out in Article 18, in particular to adapt them to advances in technology.'

7. Article 18 is replaced by:

   '*Article 18*

   1. Where the procedure referred to in this Article is to be used the Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health set up by Regulation 2002/178/EC shall act in accordance with the procedure laid down in Article 5 of Decision 1999/468/EC and in compliance with Article 7(3) thereof.

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

8. Article 19 is deleted.

9. In Articles 8, 9, 11 and 16, the words 'the procedure laid down in article 19' are replaced by the words 'the procedure referred to in article 18'.

10. Annexes A, B, C and D to Directive 88/407/EEC are replaced by the text in the Annex to this Directive.

Article 2

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

When Member States adopt those provisions, they shall contain a reference to this Directive or shall be accompanied by such reference on the occasion of their official publication. The Member States shall adopt the methods of making such reference.

2. Member States shall inform the Commission of the text of the essential provisions of national law, which they adopt in the area governed by this Directive.

Article 3

This Directive shall enter into force on the . . . following that of its publication in the *Official Journal of the European Communities*. Intra-community trade in and imports of semen certified according to the provisions and the model of certificate formerly in force shall be accepted for a period of six months after the date of publication of this Directive.

Article 4

This Directive is addressed to the Member States.

ANNEX

'*Annex A*

CHAPTER I

CONDITIONS FOR THE APPROVAL OF CENTRES

1. **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 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 shall have no direct communication with the normal animal accommodation;

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

2. **Semen storage centres must:**

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

(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 SUPERVISION OF CENTRES

1. **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 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)(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 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).

Also deep-frozen embryos may 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 flasks 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 implements(?) which come into contact with the semen or the donor animal during collection and processing are properly disinfected or sterilised 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 either properly disinfected or sterilised before the commencement of each filling operation, except for disposable 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 implemented on its territory;

(viii) the storage unit must comply with specific conditions relating to the supervision of semen storage centres provided in the following paragraph.

2. **The 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 Directive 88/407/EEC;

(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 Directive 88/407/EEC is stored in approved storage centres, without coming into contact with any other semen.

Also deep-frozen embryos may 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 flasks 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 implements which come into contact with the semen are properly disinfected or sterilised prior to use;

(iv) storage flasks and transport flasks are either properly disinfected or sterilised before the commencement of each filling operation, except for disposable 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 centre, can be readily established; each Member State shall communicate to the Commission and other Member States the characteristics and form of the marking implemented on its territory.

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 apply:

(a) they 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 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 one herds of a lower status;

(c) they have come from a herd officially 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 a test carried out in accordance with Annex D (Chapter II) of 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 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 don't 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.

The competent authority may give authorisation for the tests referred to in (d) to be carried out on samples collected in the quarantine accommodation, provided that the results are known before the commencement of the quarantine period laid down in (a);

(e) during the quarantine period specified in (a), they have been subjected after at least 21 days of quarantine to the following tests with negative results, except in the case of for BVD/MD antibody serological testing (see (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,

— a virus isolation test or a test for virus antigen, and

— a serological test to determine the presence or absence of antibodies.

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

If sero-conversion occurs, all the 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 subsp *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 test once 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:

(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 leucosis, 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* subsp *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.

Annex C

CONDITIONS WHICH SEMEN MUST SATISFY FOR THE PURPOSES OF INTRA-COMMUNITY TRADE

1. **Semen must be obtained from animals which:**

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

   (b) (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;

   (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 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(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, leptospires 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 flasks 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.

Annex D

HEALTH CERTIFICATE
FOR INTRA-COMMUNITY TRADE IN OF SEMEN OF DOMESTIC ANIMALS OF THE BOVINE SPECIES
IN ACCORDANCE WITH COUNCIL DIRECTIVE 88/407/EEC

1. Member State of provenance and competent authority	2. Health certificate No

A. ORIGIN OF SEMEN

3. Approval number of the centre of origin/provenance of the consignment: collection/storage (1)	
4. Name and address of centre of origin/provenance of the consignment: collection/storage (1)	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. Identification mark of the doses (2)	11. Number of doses	12. Approval number of the collection centre of origin

D. HEALTH INFORMATION

I, the undersigned official veterinarian, certify that:

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

(b) 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 . . . . . .;

(c) 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 within 12 months prior to collection, in which case 5 % (with a minimum of 5 straws) of each collection shall be submitted to a virus isolation test for foot-and-mouth disease in . . . . . laboratory) (3) with negative results (1).

(d) the semen was stored in approved conditions for a minimum period of 30 days prior to dispatch (4).

E. VALIDITY

13. Date and place	14. Name and qualification of the official veterinarian	15. Signature and stamp of the official veterinarian

(1) Delete as necessary.
(2) Corresponding to the identification of the donor animals and date of collection.
(3) Name of the laboratory specified in accordance with Article 4(3) of Directive 88/407/EEC.
(4) May be deleted for fresh semen.'