COMMISSION DECISION

of 10 June 1992

concerning animal health conditions and veterinary certification for the importation of bovine semen from Hungary

(92/386/EEC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community,

Having regard to Council Directive 88/407/EEC of 14 June 1988 laying down the animal health requirements applicable to intra-Community trade in, and imports of, deep-frozen semen of domestic animals of the bovine species [1], as last amended by Directive 90/425/EEC [2], and in particular Articles 10 and 11 thereof,

Whereas Hungary appears in the list, established by Commission Decision 90/14/EEC [3], of third countries from which Member States authorize importation of semen of domestic animals of the bovine species;

Whereas it appears that the animal health situation in Hungary is good and controlled by well-structured and organized veterinary services as regards diseases transmissible through semen;

Whereas the competent veterinary authorities of Hungary have confirmed that Hungary has for at least 12 months been free from rinderpest, foot-and-mouth disease, contagious bovine pleuro-pneumonia and bluetongue and that no vaccinations have been carried out against any of those diseases during that time;

Whereas the competent veterinary authorities of Hungary have undertaken to notify the Commission of the European Communities and the Member States by telex or telefax, within 24 hours, of the confirmation of the occurrence of any of the abovementioned diseases or of any change in vaccination policy concerning any of them or, within an appropriate period, of any proposed change in the Hungarian import rules concerning domestic animals or the semen or embryos thereof;

Whereas the competent veterinary authorities of Hungary have provided animal health guarantees in respect of bovine tuberculosis and brucellosis which are equivalent to those applicable within the Community;

Whereas the competent veterinary authorities of Hungary have undertaken to supervise officially the issue of certificates arising from this Decision and to ensure that all relevant certificates, derogations and laboratory findings on which certification may have been based remain on official file for at least 12 months following the dispatch of the semen to which they refer;

Whereas the competent veterinary authorities of Hungary have undertaken to approve officially semen collection centres for the export of bovine semen to the European Economic Community as required by Article 9 of Directive 88/407/EEC;

Whereas animal health conditions and veterinary certification must be adapted according to the animal health situation of the third country concerned;

Whereas the measures provided for in this Decision are in accordance with the opinion of the Standing Veterinary Committee,

HAS ADOPTED THIS DECISION:

Article 1

1. A Member State which does not practice vaccination against foot-and-mouth disease shall authorize the entry onto its territory of semen collected from bulls in an approved centre in which there are no bulls which have been vaccinated against that disease or from bulls in an approved centre in which all the bulls have been vaccinated in accordance with the provisions of paragraph 1 of Annex C to Directive 88/407/EEC but, in the latter case, may require that up to 10 % of each collection of such semen, with a minimum of five straws, be submitted, with negative result, to a virus isolation test for foot-and-mouth disease virus in a laboratory nominated by the importing Member State.

2. Member States shall authorize the importation from Hungary of bovine semen which conforms to the conditions set out in the certificate in Annex I A and, where relevant, the certificate in Annex I B to this Decision.

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[1] OJ No L 194, 22. 7. 1988, p. 10.
[2] OJ No L 224, 18. 8. 1990, p. 29.
[3] OJ No L 8, 11. 1. 1990, p. 71.

Article 2

This Decision shall come into effect 14 days after its notification to the Member States.

Article 3

This Decision shall be reviewed in the light of any relevant amendment to Council Directive 88/407/EEC.

Article 4

This Decision is addressed to the Member States.

Done at Brussels, 10 June 1992.

For the Commission

Ray MAC SHARRY

Member of the Commission

ANNEX I A

ANIMAL HEALTH CERTIFICATE

for the importation of bovine semen from Hungary

Certificate No: .....

Country of collection: Hungary

Competent authority:

I. **Identification of semen:**

Centre identity code: .....

Centre approval No: .....

Name of donor	Breed	Identity code	Date of birth	Date of collection	Number of doses

(Strike out unused entries. This certificate applies only to semen collected at a single approved collection centre.)

Marks on seal applied to transport container: .....

II. **Origin of semen:**

Address of semen collection centre: .....

.....

III. **Destination of semen:**

The semen will be sent from: .....
(place of sealing and loading)

to: .....
(country and place of destination)

by: .....
(means/identification of transport)

Name and address of consignor: .....

.....

Name and address of consignee: .....

.....

IV. Health information:

I, the undersigned official veterinarian, certify that:

1. Hungary has been free, during a period commencing at least 12 months before the first collection of the semen described above and finishing 30 days after the final collection of such semen, from cattle plague (rinderpest);

2. the approved semen collection centre in which the semen described above was collected:

   (a) has been approved, on the basis that it conforms to all the provisions of this paragraph, by the official veterinary authority of Hungary for the export of bovine semen to the European Community;

   (b) is situated at the centre of an area of 50 km radius in which, during a period commencing at least three months before the first collection of the semen described above and finishing 30 days after the final collection of such semen, there has been no evidence of foot-and-mouth disease, contagious bovine pleuro-pneumonia or vesicular stomatitis;

   (c) has been free, during a period commencing at least three months before the first collection of semen described above and finishing 30 days after the final collection of such semen, from foot-and-mouth disease and brucellosis;

   (d) has been free, during a period commencing at least 30 days before the first collection of the semen described above and finishing 30 days after the final collection of such semen, from rabies, anthrax, tuberculosis, enzootic bovine leukosis, or any evidence of infection with *Trichomonas foetus, Campylobacter foetus, Leptospira canicola, Leptospira pomona, Leptospira grippotyphosa, Leptospira hardjo* or *Leptospira icterohaemorrhagica;*

   (e) is inspected by an official veterinarian at least twice a year at which times all matters relating to the conditions set out in this certificate are considered and verified;

   (f) is under the permanent supervision of a centre veterinarian and is so supervised that:

      (i) animals are admitted only with the express permission of the centre veterinarian, all movements of animals, in or out, being recorded;

      (ii) a record is kept of the breed, date of birth, identification and health history of each bovine animal in the centre and of all diagnostic tests and the results thereof, all treatments and all vaccinations carried out on the animals kept therein;

      (iii) the entry of unauthorized persons is prevented and authorized visitors are required to comply with the conditions laid down by the centre veterinarian;

      (iv) only technically competent staff are employed, suitably trained in disinfection procedures and hygiene techniques relevant to the control of the spread of disease;

   (g) contains only bovine animals, except that other domestic animals strictly necessary for the normal operation of the centre may be admitted provided that they present no risk of infection to the bovine species and that they fulfil the conditions laid down by the centre veterinarian;

   (h) is so constructed that:

      (i) it has animal accommodation physically separated from the semen processing and semen storage rooms, which are physically separated from each other;

      (ii) it has an isolation facility for sick animals;

      (iii) it has a semen collection facility which has a separate room for the cleaning and disinfection or sterilization of equipment;

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

      (v) contact with outside livestock is prevented;

      (vi) the entire centre is capable of being readily cleaned and disinfected,

provided that, where the above conditions are fulfilled, an approved semen collection centre may share a site with one or more other semen collection centres;

3. the bulls and any teasers present in the approved semen collection centre during the period of collection and storage of the semen described above:

(a) were in the approved semen collection centre on, and continuously since, 1 January 1991, and have since their arrival been subjected to all the tests described, with the results provided for, at (d) below, and with negative result to a test for bovine viral diarrhoea as described at (c) (iv) and a test for trichomoniasis as described at (c) (v) below;

or

(b) were transferred from an approved semen collection centre without coming into contact with animals of a lesser health status and, where applicable, in transport which was thoroughly cleansed and disinfected before use;

or

(c) were admitted, on the authority of the centre veterinarian and showing no clinical signs of disease:

(i) having originated in herds deemed to be free of tuberculosis under the national tuberculosis eradication programme of Hungary and not having been held at any time in herds of lower status;

(ii) having originated in herds deemed to be free of brucellosis under the national brucellosis eradication programme of Hungary and not having been held at any time in herds of lower status;

(iii) having:

— originated in herds free for at least three years from any evidence for enzootic bovine leukosis, or

— been produced by cows which were subjected, within 30 days before the entry of their sons into the officially-approved isolation facility, to a serological test for enzootic bovine leukosis carried out in accordance with the procedure laid down in Annex G to Council Directive 64/432/EEC with negative result, or

— been subjected, within 30 days before entry into the officially-approved isolation facility or after having reached the age of two years, whichever is the later, to a serological test for enzootic bovine leukosis carried out in accordance with the procedure laid down in Annex G to Directive 64/432/EEC with negative result;

(iv) having been subjected, within 30 days before entry to the officially-approved isolation facility, to the following tests with negative result in each case:

— an official tuberculin test,

— an official serum agglutination test for brucellosis which is negative at less than 30 IU of agglutination per millilitre and a complement fixation test showing a brucella count lower than 20 EEC units per millilitre (20 ICFT units),

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

— a serum neutralization test or Elisa test for infectious bovine rhino-tracheitis/infectious pustular vulvo-vaginitis,

— a virus isolation test for bovine viral diarrhoea on blood samples in susceptible cell cultures subsequently subjected to a fluorescent antibody test or an immunoperoxidase test provided that, if at the time of its entry any bull was less than six months old, the test was delayed until the animal reached that age,

granted that all or any of the above tests may have been carried out while the animals were in the officially-approved isolation facility provided that if the result of any test was other than negative the isolation period of 30 days for the other animals in the isolation facility was not considered to have commenced until after the animal concerned had been removed from the facility and, if applicable, the tuberculosis or brucellosis status of the facility had been restored;

(v) having, after the completion of the pre-isolation tests described in (iv) above, undergone a period of at least 30 days in an officially-approved isolation facility which was, at the date of their entry, at the centre of an area of 10 km radius in which there had been no evidence of foot-and-mouth disease, cattle plague (rinderpest), contagious bovine pleuro-pneumonia or vesicular stomatitis for at least 30 days, the facility having been free for at least three months from foot-and-mouth disease and brucellosis and for at least 30 days from rabies, anthrax,

tuberculosis and enzootic bovine leukosis and in which they were subjected to the following tests with negative result in each case:

— an official serum agglutination test for brucellosis which is negative at less than 30 IU of agglutination per millilitre and a complement fixation test showing a brucella count lower than 20 EEC units per millilitre (20 ICFT units),

— either an immunofluorescent antibody test or a culture test for *Campylobacter foetus* infection on a sample of preputial material or artificial vaginal washings, or in the case of female animals a vaginal mucus agglutination test,

— a microscopic examination and a culture test for *Trichomonas foetus* infection on a sample of preputial material or artificial vaginal washings, or in the case of female animals a vaginal mucus agglutination test,

— a serum neutralization test or Elisa test for infectious bovine rhino-tracheitis/infectious pustular vulvo-vaginitis,

provided that if the result of any test was other than negative the isolation period of 30 days was not considered to have commenced for the remaining animals until after the animal concerned had been removed from the facility and, where relevant, the brucellosis status of the facility had been restored,

and in which they were treated against *Leptospirosis* by the injection on two separate occasions, 14 days apart, of streptomycin or dihydrostreptomycin, or a mixture thereof, at a rate of 25 mg per kg of live body weight;

(d) were subjected at least once a year to the following tests with negative result in each case:

(i) an official tuberculin test;

(ii) an official serum agglutination test for brucellosis that is negative at less than 30 IU of agglutination per millilitre and a complement fixation test showing a brucella count lower than 20 EEC units per millilitre (20 ICFT units);

(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 Elisa test for infectious bovine rhino-tracheitis/infectious pustular vulvo-vaginitis, provided that, in respect of semen collected prior to 31 December 1992 and where the competent authority of the importing Member State has so indicated in writing, the semen of bulls positive to either of these tests may be accepted provided a virus isolation and/or animal inoculation test for the above disease complex has been carried out on such semen with negative result, in this latter case the test having been carried out on the ..... at the ..... laboratory;

(v) either an immunofluorescent antibody test or a culture test for *Campylobacter foetus* infection on a sample of preputial material or artificial vaginal washings, except that no test under this heading is required in the case of animals which are not being used for the production of semen provided that such a test is carried out before semen production is resumed;

(vi) a serological test for the canicola, pomona, grippotyphosa, hardjo and icterohaemorrhagica serotypes of *Leptospira,*

all the above tests (with the exception of the tuberculin test) being carried out in a laboratory approved for the purpose by the official veterinary authority of Hungary;

4. the semen described above was:

(a) collected, without the use of electro-ejaculation or electro-stimulation techniques, in an approved semen collection centre from bulls:

(i) which have been continuously on the territory of Hungary during a period commencing at least six months before the first collection of the semen described above and finishing on the date of its dispatch;

(ii) which, other than as provided for in a written derogation given in the terms of 3 (d) (iv) above, have not given a positive result to any of the tests referred to in this certificate;

(iii) which were not, while in the approved semen collection centre, used for natural service;

(iv) which were kept in the approved semen collection centre for a continuous period of at least 30 days immediately prior to the collection of the semen;

(v) which showed no clinical signs of disease at the time;

(vi) — standing in an approved semen collection centre in which there is no animal which has been vaccinated against foot-and-mouth disease (*), or

— standing in an approved semen collection centre in which all the animals susceptible to foot-and-mouth disease have been protected against that disease according to the provisions of paragraph 1 (b) (ii) of Annex C to Directive 88/407/EEC (*);

(b) processed in an approved semen collection centre:

(i) in which, during the collection of the semen described above, no semen was processed other than semen from bulls in approved centres or semen from bulls having the same health status as bulls in approved centres, provided that in the latter case such processing took place with separate equipment and at different times to the processing of semen from approved centres and that the processing facility was thoroughly cleansed and disinfected before being again used for the processing of semen from bulls in approved centres;

(ii) in conditions of the strictest hygiene, all implements and equipment coming into contact with the donor bulls or with the semen being properly disinfected or sterilized, as appropriate, before use;

(iii) using additives, diluents or extenders in which any products of animal origin were obtained from sources which presented no animal health risk or which were so treated prior to use that such risk was prevented;

(c) protected by the addition of the following antibiotics in such quantities as were necessary to produce the indicated 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,

and immediately afterwards held at a temperature of not less than 5 °C (41 °F) for a period of not less than 45 minutes,

or

not less than:

— 50 µg per ml tylosin,

— 250 µg per ml gentamycin,

— 150 µg per ml lincomycin,

— 300 µg per ml spectinomycin,

contact between the antibiotic and the undiluted semen being maintained for at least three minutes at the temperature at which they were mixed and the semen and the non-glycerol fraction of the diluent being held at a temperature of not less than 5 °C (41 °F) for at least two hours;

(d) put into individual containers (straws) each marked with the date of collection, the breed and identity of the donor bull and the identity of the approved centre of collection, provided that such information, or any part of it, may have been marked in code where a full translation of such code has been made available to the competent authority of the importing Member State, and provided that there is a clear correspondence between the marking on each straw and the identification incorporated in this certificate;

(e) submitted to a virus isolation test for foot-and-mouth disease virus in accordance with the provisions of Article 1 of Commission Decision 92/386/EEC at the ..... laboratory;
(delete if not applicable);

(f) stored, in containers which have been thoroughly cleansed and disinfected or sterilized, as appropriate, before use and using cryogenic agents which have not previously been used for any other product of animal origin, in the approved semen collection centre under the supervision of the centre veterinarian for a period of not less than 30 days prior to dispatch;

(g) not exported after the date of a positive test on any bull in the centre, other than a test for infectious bovine rhino-tracheitis/infectious pustular vulvo-vaginitis as provided for in a written derogation given under the terms of 3 (d) (iv) above, and before the health status of the centre has been re-established;

(*) Delete whichever does not apply.

(h) dispatched in containers which have been thoroughly cleansed and disinfected or sterilized, as appropriate, before use and using cryogenic agents which have not previously been used for any other product of animal origin and which have been sealed under the supervision of the official veterinarian prior to dispatch from the approved semen collection centre.

Done at ....., on .....
(place) (date)

Stamp

Signature .....

Name in block letters .....

Official title .....

ANNEX I B

SUPPLEMENTARY CERTIFICATE

for the transfer of semen from one container to another for shipment from Hungary to the European Economic Community

I, the undersigned official veterinarian, certify that:

the semen to which the certificates and seals indicated below refer was transferred, in an approved semen collection centre and under my direct supervision, from the containers in which it was received, seals intact, to the container in which it is to be dispatched to the European Economic Community.

Centre of origin	Certificate No	Seal No

The transfer was carried out at: .....

.....

Approval No: .....

The seal applied to the shipment container carries the marks: .....

The certificates in respect of all the semen in the container are attached.

Done at ....., on .....
(place) (date)

Stamp

Signature .....

Name in block letters .....

Official title .....