

MAFRA Notification No. 2015-9

In accordance with Article 34 Clause 2 of the Livestock Epidemics Prevention and Control Act (LEPCA) and Article 35 of the enforcement regulation of the said Act, this is to establish the import health requirements for the U.S. bovine embryos as follows.

February 3, 2015
Minister of Agriculture, Food, and Rural Affairs

Import Health Requirements for U.S. Bovine Embryos

MAFRA (Quarantine Policy Division): 044-201-2076 (Tel.)

Article 1 (Purpose) the purpose of these import health requirements (IHRs) is to stipulate information necessary for the inspection of the U.S. bovine embryos exported to Korea including the animal health status and inspection details in the U.S., etc., in accordance with Article 34 and Clause 2 of the LEPCA and Article 35 of the enforcement regulation of the LEPCA.

Article 2 (Definition of terms) definitions of the terms used in these IHRs are as follows:

1. Donor dam: A cow used for fertilization and collection of embryos that meets the conditions of chapter 4.7 of the current edition of the OIE Terrestrial Animal Health Code.
2. Donor sire: A bull for producing semen needed for artificial insemination that meets the conditions of chapter 4.7 of the current edition of the OIE Terrestrial Animal Health Code.
3. Bovine embryo (hereinafter referred to as “embryo”): An embryo produced in accordance with chapter 4.7 of the current edition of the OIE Terrestrial Animal Health Code and which is viable when it is transferred to a recipient dam, but not including an embryo that has been transferred to a recipient dam previously, that has been derived by in vitro fertilization, or that has been manipulated by sex identification, splitting, and cloning, etc., which may cause damage on the zona pellucida.
4. Embryo collection facility: A cattle breeding farm or an artificial insemination center that meets the conditions of chapter 4.7 of the current edition of the OIE Terrestrial Animal Health Code where the embryos are fertilized, collected, processed, and stored in accordance with these IHRs.
5. Government veterinary officer: A veterinary officer belonging to the U.S. veterinary authority.

6. Designated veterinarian: A veterinarian approved by the U.S. veterinary authority who is wholly responsible for the sanitary management of the donor dams and the embryo collection facility, and for collection, processing, and storage of embryos.
7. Embryo collection team: A team to perform the collection, processing, and storage of embryos that meets the conditions of chapter 4.7 of the current edition of the OIE Terrestrial Animal Health Code and these IHRs.

Article 3 (Disease requirements) there should be no outbreaks of foot and mouth disease for 1 year, rinderpest and contagious bovine pleuropneumonia for 2 years, lumpy skin disease and bovine Akabane disease for 3 years, and rift valley fever for 4 years prior to shipping, and no vaccination against these diseases should be conducted. However, for the diseases the Minister of Agriculture, Food, and Rural Affairs of Korea recognizes that the U.S. government is performing effective stamping-out policies, the required period for no outbreaks may be shortened in accordance with the OIE standards.

Article 4 (Export suspension, etc.) when there are outbreaks of the diseases mentioned in Article 3 above or when animals suspected to be infected with the diseases are found in the U.S., the U.S. government should suspend the export of the embryos immediately. The U.S. government should consult with the Korean government in advance when it wishes to resume the export.

Article 5 (Embryo collection facility requirements) the embryo collection facilities should be selected by the U.S. government and notified to the Korean government, and they should meet the following conditions:

- A. The embryo collection facility should be located in a State where there were no outbreaks of vesicular stomatitis for 2 years prior to the date of selection by the U.S. government.
- B. The embryo collection facility should receive regular sanitary inspection and supervision by the U.S. veterinary authority.
- C. There should be no confirmed case of the diseases provided in the Appendix from 6 months before the initial collection of the embryos until 30 days after the final collection of the embryos.
- D. The embryo collection facility should be safely equipped in such a manner as to prevent the contact with the outside livestock or wild animals.

Article 6 (Embryo collection team requirements) the embryo collection team should meet the following conditions:

- A. The embryo collection team should include at least one designated veterinarian, and should be trained in sanitation and disease control.

B. The embryo collection team should be supervised by a designated veterinarian on all matters regarding the collection of the embryos including handling of donor dams and disinfection and sanitary management of the embryo collection facility, etc.

C. The embryo collection team should record the breed, date of birth, individual identification, medical history, farm of origin, status of movement, details of tests and their results, treatment, vaccination, and collection status of embryos or semen of each animal in the embryo collection facility.

D. Cattle that can be introduced into the embryo collection facility should meet the sanitary level equivalent to that of the donor dam, and the embryo collection team should record their entry and exit status.

E. Biosecurity measures that are satisfactory for the issuance of the health certificate for exporting embryos should be in place in the embryo collection farm, and the embryo collection team should be composed of those who have been approved by the designated veterinarian or a government veterinary officer.

Article 7 (Donor dam requirements) the donor dams should meet the following conditions:

A. The donor dams should be born and raised in the U.S. or imported into the U.S. at least 60 days prior to the embryo collection.

B. The donor dams should be from farms where there were no confirmed cases of tuberculosis and brucellosis according to the standards set by the OIE.

C. The donor dams should be from cattle breeding farms where there were no confirmed cases of bovine genital campylobacteriosis, bovine viral diarrhea, infectious bovine rhinotracheitis/infectious pustular vulvovaginitis/infectious pustular balanoposthitis, Johne's disease, bovine leptospirosis, trichomoniasis and anaplasmosis for 6 months prior to the introduction into the embryo collection place.

D. The donor dams should be marked in such a manner as to be individually identified.

E. The donor dams should be tested by the U.S. veterinary authority according to the test methods and standards for the diseases shown in the Appendix within the time frame of 3 months prior to and 30 days after the embryo collection, and the test results should be negative. Nevertheless, if the U.S. government certifies that the donor dams were not used for natural mating, the tests for bovine genital campylobacteriosis and trichomoniasis can be omitted.

Article 8 (Embryo collection and processing requirements) the collection and processing of embryos should meet the following conditions:

- A. All donor dams in the embryo collection facility should be inspected by a veterinarian of the embryo collection team on the day of the embryo collection, and no clinical signs of communicable animal diseases should be found.
- B. The collection and processing of the embryos should be done as recommended by IETS.
- C. The embryos should be Grade A or B whose entire surface of the zona pellucida is intact and free of adherent foreign materials as a result of the microscopic examination (at not less than 50X magnification) done in accordance with the procedures recommended by IETS under the supervision of the U.S. government veterinary officer.
- D. Artificial insemination or natural breeding to produce embryos should be performed under the supervision of a designated veterinarian.
- E. Embryos should be fertilized and produced using the semen that meets the U.S. government's disease management requirements for the semen for producing embryos or Korea's import health requirements for bovine and porcine semen.
- F. Only one embryo should be stored in an ampoule or a straw.
- G. Antibiotics added to the solutions used for collection, washing, and storage of embryos should be approved by the U.S. government, and should not exceed the allowed level generally accepted.
- H. Ampoules or straws storing embryos should be labeled with information on the collection date, individual identification of the donor sire and the donor dam, the embryo number, and the approval number of the embryo collection team according to the standards set by IETS, and sealed under the supervision of a designated veterinarian or a government veterinary officer.
- I. Embryos should be contained in liquid nitrogen containers which have been washed and disinfected or sterilized using refrigerant that has not been used for materials of animal origin, and they should be stored at an embryo collection facility, etc., under the supervision of a government veterinary officer or a designated veterinarian until they are exported to Korea.

Article 9 (Embryo transportation, etc.) embryos should be sealed under the supervision of a designated veterinarian or a government veterinary officer before being taken out of the embryo collection facility, and should be transported in such a manner as to prevent contamination by and spread of communicable animal disease pathogens.

Article 10 (Veterinary health certificate) a U.S. government veterinary officer should issue a veterinary health certificate that includes the following information when exporting embryos:

- A. Information stipulated in Articles 3, 5, 7, and 8 above
- B. Addresses and names, or company names, of the exporter and the importer
- C. Names and addresses of the semen collection facility and the embryo collection facility
- D. Registered name, breed, tattoo/ID number, and the date of the introduction into the embryo collection facility of the donor dam and the donor sire of each embryo
- E. Dates of collecting embryos and semen, number of total embryos, number and label of ampoules or straws
- F. Methods, dates, and results of tests stipulated in Article 8-E, and the name of the laboratory
- G. Number of the seal and the label attached to the liquid nitrogen container
- H. Date and place of shipping, name of the vessel or flight information
- I. Date and place of the issuance of the veterinary health certificate, and name /title and signature of the issuer

Article 11 (Return or destruction) when communicable animal diseases are found during the import inspection of the embryos arrived in Korea, when the diseases mentioned in Article 3 occur in the U.S., or when vesicular stomatitis mentioned in Article 5-A occurs in the State where the embryo collection facility is located, the relevant shipment may be returned or destroyed.

Article 12 (On-site audit) in case it is deemed necessary in relation to the enforcement and application of these IHRs, Korean government veterinary officers may conduct on-site audits of the U.S. embryo collection facilities, and the U.S. government should fully cooperate in the audit. During the audit, the approval of the embryo collection facilities that are in violation of these IHRs may be cancelled.

Additional Clause

Article 1 (Enforcement date) this notice will be effective upon publication.

Article 2 (Reconsideration Deadline) this notice should be reconsidered for possible measure of cancellation, revision, etc. by February 2, 2018 per “Regulation on the Issuance and Management of Orders and Established Rules” (Presidential Order No. 248), taking into consideration of other regulations established after this notice is issued and changes to the conditions of the reality.

[Appendix]

Test Methods and Standards by Disease

Name of Disease	Test Methods and Standards
Tuberculosis	Tuberculin intradermal test or bovine interferon gamma assay: Negative
Johne's Disease	CF test (1:8) or ELISA test: Negative
Bovine leptospirosis	<p>Microscopic Agglutination Test (MAT): Negative at less than 50% at 1:100 (L. pomona, L. hardjo, L. icterohaemorrhagiae)</p> <p>OR</p> <p>Clinical Test: Negative; AND Treatment with two injections of oxytetracyclin (25mg/live body weight (kg)) or tetracycline type (at optimum dose) administered with an interval of 14 days (The 2nd treatment should be given within 24 hours of the start of the embryo collection)</p>
Bovine genital campylobacteriosis	Agent identification: Negative OR meets the requirements of 7.E.
Trichomonosis	<p>Immunofluorescent antibody test on preputial cavity or vaginal irrigation solution: Negative OR</p> <p>Agent identification: Negative OR meets the requirements of 7.E.</p>
BVD	<p>Fluorescent antibody test: Negative OR</p> <p>Immunoperoxidase test: Negative OR</p> <p>PCR: Negative</p>
IBR/IPV/IPB	<p>SN Test: Negative at 1:2 dilution; <i>or</i> increase of less than four-fold in antibody titer on SN test taken twice with an interval of 3 – 5 weeks: The increase in the antibodies should not be more than 4 times.</p> <p>OR</p> <p>Enzyme trypsin treatment on the embryos per IETS Manual</p>
Anaplasma marginale	<p>CAT (Card Agglutination Test): Negative OR CF (Complement Fixation): Negative</p>

