HEALTH CERTIFICATE FOREXPORT OF *IN VIVO*-DERIVED BOVID EMBRYOS [Specifically Bovine *(Bos taurus, Bos indicus, Bison bison*), Water buffalo (*Bubalus bubalis*), Yak (*Bos grunniens*)] FROM FOOT-AND-MOUTH DISEASE-FREE MEMBER STATES OF THE EUROPEAN UNION TO THE UNITED STATES OF AMERICA

Note: A separate certificate must be issued for each consignment of *in vivo* embryos. The original of this certificate must accompany the shipment.

1. EU Member State and competent authority:	2. Health certificate number:

A. ORIGIN OF EMBRYOS

3. Approval number of the embryo collection team_____

4. Name and address of the embryo collection team:	5. Name and address of the consignor:
6. Member State where embryos were collected:	7. Means of transport:

B. DESTINATION OF EMBRYOS

8.1. Name and address of the consignee:

8.2. Port of entry into the United States:

C. IDENTIFICATION OF THE EMBRYOS

9. Identification of straws/ vials (freeze code):

9.1 ID# on straws	9.2 ID# of dam/ ID# of sire	9.3 Breed of dam/ Breed of sire	9.4 Date of embryo collection	9.5 Number of straws/ vials	9.6 Indicate if sexed semen was used

10. Seal number of container(s):_____

D. HEALTH INFORMATION

Section A (to be signed by the Team Veterinarian**)**

11 I, the undersigned Team Veterinarian of the described embryo collection team, hereinafter "ECT," certify, either by direct examination or based on supporting documentation in my possession that has been separately attested to by an official veterinarian, that:

11.4 During the 12 months prior to the collection of embryos for export to the United States, there was no clinical or pathological evidence of brucellosis or tuberculosis (TB) found in the donor dams or on any premises on which the donor dams were located during that time.

11.5 During the 60 days prior to the collection of embryos for export to the United States, the donor dams were not corralled, pastured, or held with animals of lesser health status or under any restrictions which would make them ineligible as embryo donors for export to the United States.

11.6 During the 60 days prior to the collection of embryos for export to the United States, the donor dams were inspected at least once and appeared healthy and were found clinically free of contagious or communicable diseases.

11.7 Each of the donors were examined on the day of embryo collection and appeared healthy and were clinically free of contagious or communicable diseases.

11.8 The donor dams originated from herds officially free of tuberculosis and where no clinical cases of paratuberculosis occurred during the two years previous to the dams being used for embryo collection.

11.9 SELECT ONE

11.10 The embryos were either (retain the applicable part and **strike out** the other) collected prior to June 1, 2011; **OR**

11.11 The embryos were collected after June 1, 2011, from donors negative to two serum neutralization tests for Schmallenberg virus (using a 1:8 cutoff titer), with the first performed within 30 days prior to collection, and the second between 28 and 60 days after collection. Tests were performed in a laboratory approved by the national Competent Authority.

11.12 SELECT ONE for epizootic hemorrhagic disease (EHD).

- □ The animals originate from a Member State or region in the Member State where no cases of EHD have been reported within the previous 12 months, and where no serological evidence of EHD infection exists; **OR**
- □ The following serotypes of EHD exist:_____and animals were tested on two occasions by an agar gel immunodiffusion test (AGID) with negative results; **OR**
- □ Testing was by competitive enzyme-linked immunosorbent assay (C-ELISA) AND a whole-blood PCR test for all the above-listed serotypes of EHD, with negative results using blood samples taken prior to, and not less than 21 days following collection of the embryos (the two samples may not be taken more than 12 months apart). **OR**
- □ Testing was by competitive enzyme-linked immunosorbent assay (C-ELISA) AND a virus neutralization test (VNT) for all the above-listed serotypes of EHD, with negative results using blood samples taken prior to, and not less than 21 days following collection of the embryos (the two samples may not be taken more than 12 months apart).

11.13 SELECT ONE for Bluetongue virus, the donor animals were:

- □ Kept in a BTV free Member State or region of the Member State, where no cases of BTV have been reported within the previous 12 months and no serological evidence of BTV infection exists **OR**
- □ Tested negative by an ELISA test for the BTV group on blood serum during the pre-entry quarantine period, **OR**
- □ Tested with a whole blood PCR test for BTV group with one negative test at the beginning of the collection period **OR**
- □ Tested with a whole-blood virus isolation test for BTV group with one negative test at the beginning of the embryo collection period.

11.14 The semen used for *in vivo* embryo production was collected in the same Member State as that in which the embryos were conceived (except for semen imported from United States and/or Canada).

11.15 The semen used to fertilize the embryos for export to the United States was collected in an approved semen collection center (SCC), with a formal process of quarantine, observation, and testing as required by legislation in force, notably Annex B to Council Directive 88/407/EEC, as amended by Directive 2003/43/EC or in Regulation (EU) 2016/429 (Commission Delegated Regulation (EU) 2020/686) and was qualified for export to the United States. At the time of collection of the semen, the Member State was considered by the USDA to be free of foot-and-mouth disease, as listed in Title 9 Code of Federal Regulations, Part 94 and other official publications. OR bovid semen imported from the United States or Canada may be used; copies of the export health certificate (2) for this semen must accompany the shipment.

11.16 In addition, the semen was either (SELECT ONE)

□ Collected prior to June 1, 2011; **OR**

□ The semen in the consignment was collected after June 1, 2011, from donors that were negative to two serum neutralization tests for Schmallenberg virus (using a cutoff titer of 1:8), with the first performed within 30 days prior to collection, and the second between 28 and 60 days after collection. Tests were performed in a laboratory approved by the national Competent Authority, **OR**

□ Bovid semen used to fertilize the embryos for export to the United States was legally imported from the United States or Canada from U.S. origin and/or Canadian origin donors. Copies of the export health certificate (2) for this semen must accompany the shipment of embryos to the United States.

11.17 (Retain if applicable or strike out if not applicable) If embryos were fertilized with sexed semen:

11.17.1. The semen sexing facility used to sex the semen is located in the Member State where the semen was collected. The semen collection center is under the supervision of an approved Center Veterinarian and is regularly inspected and approved in accordance with EU Directive 88/407/EEC. in Regulation (EU) 2016/429 or in Regulation (EU) 2016/429 (Commission Delegated Regulation (EU) 2020/686). The sexing facility followed the United States Department of Agriculture approved "Cleaning and Disinfection Standard Operating Protocol" while processing this semen for export to the United States and is listed on the USDA website Approved EU and EFTA Bovine Semen Sexing Facilities | Animal and Plant Health Inspection Service (usda.gov) OR bovid semen imported from the United States or Canada may be used; copies of the export health certificate (2) for this semen must accompany the shipment.

11.17.2. The integrity of the semen shipment was maintained through the semen sexing process and no semen from other donors was mixed with semen during processing.

11.18 The embryos were collected using a closed collection system, and any instrument coming in contact with reproductive tract tissue or fluids was either new or equipment sterilized before use.

11.19 The embryos were washed at least 10 times and treated with trypsin in accordance with the latest edition of the Manual of the International Embryo Transfer Society. After the last wash, each embryo was examined microscopically over its entire surface at not less than 50x magnification.

11.20 The zona pellucida of each embryo was found to be intact and free from any adherent material subsequent to washing.

11.21 Embryos from different donors were not washed together.

11.22 The storage and shipping containers were clean, recently disinfected, and empty prior to use for this project, and only fresh liquid nitrogen has been used.

11. Date and place	12. Name and address of Team Veterinarian	13. Signature and stamp of Team Veterinarian (The signature and stamp must be a different color than that of the printed template text.)

Health certificate No_____

Section B (to be signed by the Official Veterinarian after the Center Veterinarian has signed)

14. I, the undersigned Official Veterinarian of Member States certify that:

14.1. The Member State_____ s considered by the USDA to be free from foot-and-mouth disease (FMD) as listed in Title 9 Code of Federal Regulations, Part 94, and other official publications, and was free of these diseases at the time of embryo collection.

14.2. The Member State_____is free from contagious bovine pleuropneumonia.

14.3. The donor dams were part of the national herd of the Member State for a minimum of 60 days prior to collection and were free from any movement or quarantine restrictions.

14.4. The embryos were collected from live cattle of documented health history and processed in accordance with the standards of the International Embryo Transfer Society (IETS) by an embryo collection team approved by the competent authority of the Member State in accordance with EU legislation in force, notably Council Directive 89/556/EEC, as amended.

14.5. All diagnostic testing of the donor dams and sires were conducted in laboratories approved by the National Veterinary Services to conduct such tests for export.

14.6. All media additives of animal origin were sourced from countries considered by the USDA to be free from FMD. Trypsin of porcine origin was sourced from countries considered by USDA to be free from FMD, classical swine fever and African swine fever as listed in 9 CFR Part 94 and other official publications. See USDA APHIS | Animal Health Status of Regions.

14.7. The embryos were maintained under lock and key or in the custody of the embryo collection team veterinarian until being sealed for direct transport to the United States.

14.8. The Team Veterinarian completing Section A of this certificate is authorized by the National Veterinary Service to perform this service.

15. Date and place	16. Name and address of Team Veterinarian	17. Signature and stamp of Team Veterinarian (The signature and stamp must be a different color than that of the printed template text.)