

DEPARTMENT FOR ENVIRONMENT, FOOD AND RURAL AFFAIRS SCOTTISH GOVERNMENT

WELSH GOVERNMENT

DEPARTMENT OF AGRICULTURE ENVIRONMENT AND RURAL AFFAIRS, NORTHERN IRELAND

HEALTH CERTIFICATE FOR EXPORT OF OVINE AND CAPRINE IN VIVO DERIVED EMBRYOS AND OCCYTES FROM UNITED KINGDOM OF GREAT BRITAIN AND NORTHERN IRELAND TO THE UNITED STATES OF AMERICA

2. Health certificate No.

1. Country of Origin and Competent Authority:

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A. ORIGIN OF EMBRYOS/OOCYTES					
3. The name and address of the place where the embryos/oocytes were collected:					
Country where embryos/oocytes were collected:					
4. The name and address of the Embryo Collection Team: Approval Number:	5 The name and address of the approved artificial insemination centre where the semen was collected for the embryo production, if applicable:				
6.Name and address of the consignor:	7. Country and place of loading:				
	Means of transport:				
B. DESTINATION OF EMBRYOS/OOCYTES					
8. Name and address of the consignee:					

Port of Entry in the United States:

C. IDENTIFICATION OF EMBRY	YOS/OOCYTES
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9.1 Name of a)donor dam & b)donor sire (if applicable	9.2 Species & Breed of dam & sire	9.3 Age of dam & sire	9.4 Identificat ion Number of dam & sire	9.5 Number of ampoules/s traws	9.6 Date of collection	9.7 Identifica tion code(s) on straws/amp oules
0						
	XO					
9.8 Explanation of collection code(s):						

^{9.9} Seal number(s) of container(s)

D. HEALTH INFORMATION

Section A (to be signed in Section 14 by the Embryo Team Veterinarian):

I, the undersigned Embryo Collection Team Veterinarian certify that:

10.1. THE EMBRYO/OOCYTE COLLECTION TEAM

10.1.1. The embryos/oocytes were collected by an Embryo Collection (EC) Team that is approved by the Competent Veterinary Authority of (insert either Great Britain or Northern Ireland) and were collected, processed, identified, and stored in accordance with the recommendations set out in the World Organisation for Animal Health (WOAH) Terrestrial Animal Health Code and the International Embryos Transfer Society (IETS) Manual;

10.1.2. Goat and sheep embryos and oocytes were collected at EC unit(s) approved by the approved Embryo Team Veterinarian, located at the donor dam's herd of origin and/or at another dedicated location. The EC unit(s) met the relevant requirements in the USDA APHIS import strategy and policy protocol;

10.2. HEALTH ATTESTATION

10.2.1. The donor animals were part of the national herd of (insert either Great Britain or Northern Ireland) for a minimum period of 90 days prior to the collection of embryos/oocytes for export to the Unites States and the animals have been free of any import quarantine restrictions;

- 10.2.2. * If artificial insemination (AI) is used to conceive the embryos, the semen was collected in a semen collection center (SCC) in (insert either Great Britain or Northern Ireland), in accordance with the current WOAH Terrestrial Animal Health Code and is approved by the Competent Veterinary Authority and is eligible for export to the United States;
- 10.2.3. On the date of collection of embryos/oocytes, the donors were examined and found to be free from signs of infectious or contagious disease. If natural service or fresh semen is used, the sires were also examined;
- 10.2.4. During the 60 days prior to collection of embryos/oocytes for export to the United States, the donor dams were not corralled, pastured, or held with animals of a lesser health status or under any restrictions which would have made them ineligible for export to the United States. If natural breeding or fresh semen are used, this condition also applied to the sires;
- 10.2.5. During the 30 days prior to the collection of embryos/oocytes for export to the United States, the donor dams were inspected by the team veterinarian or appointed veterinarian and found to be clinically free of contagious diseases;
- 10.2.6. During the 12 months prior to the collection of embryos/oocytes for export to the United States, there was no evidence of enzootic abortion of ewes, bluetongue, brucellosis, or tuberculosis (TB) found in the donor dams or sires or in any herd which the donors were located during that time;
- 10.2.7. The donor animals do not come from premises, and have not been in contact with animals from premises where Maedi-Visna (in the case of sheep) or Caprine Arthritis Encephalitis virus (in the case of goats) has been clinically detected within the 3 years prior to the collection of embryos/oocytes to be exported;
- 10.2.8. All donor animals of embryos/oocytes collected for export to the United States resided in flocks/herds recognized by the Competent Veterinary Authority of (insert either Great Britain or Northern Ireland) as being officially free of brucellosis for at least 2 years prior to collection of embryos/oocytes for exportation to the United States; and where no clinical, microbiological, or serological evidence of TB or brucellosis was found during the 24 months prior to export of the embryos/oocytes to the United States;

11.1. SCRAPIE

- 11.1.1. * Sheep and goat embryos/oocytes were collected from donors located in, or originating from, regions recognized by APHIS as free of classical scrapie, or from a flock or herd having certified status in a scrapie flock certification program recognized by APHIS as acceptable; OR
- 11.1.2. * In vivo-derived sheep and goat embryos or oocytes were collected from donors located in, or originating from, regions or flocks not recognized by APHIS as free of classical scrapie, and the following conditions were also met:

- 11.1.2.1. * For in vivo-derived sheep embryos only: The embryos are of the genotype AAQR or AARR based on official testing of the parents of the embryos. Testing was performed at an officially approved laboratory, and laboratory reports are attached to the certificate; OR
- 11.1.2.2. \star For sheep embryos and oocytes not of the genotype AAQR or AARR, and for all goat embryos, in (insert either Great Britain or Northern Ireland), the donor animals:
 - 11.1.2.2.1. * have been kept since birth in flocks or herds where no case of scrapie had been confirmed during their residency; and
 - 11.1.2.2.2. * are permanently identified to enable a traceback to their flock or herd of origin, and this identification is recorded on the certificate accompanying the embryos/oocytes and linked to the embryo container identification; and
 - 11.1.2.2.3. * showed no clinical sign of scrapie at the time of embryo/oocyte collection; and
 - 11.1.2.2.4. * have not tested positive for, and are not suspect for, a transmissible spongiform encephalopathy; and
 - 11.1.2.2.5. are not under movement restrictions as a result of exposure to a transmissible spongiform encephalopathy;

11.2. **TESTING**

- 11.2.1. The donor dams (and sires where natural service or fresh semen is used) were tested for the following diseases within 30 days prior to collection and again between 30 and 120 days after collection:
 - 11.2.1.1. Brucella abortus/melitensis (both sheep and goats):
 - 11.2.1.1.1. * the FPA (a negative result is considered anything less than 20 millipolar above the negative control value); OR
 - 11.2.1.1.2. * the rose-bengal test/card test, /utilizing 8% Brucella abortus/ 3% Brucella melitensis lipopolysaccharide antigen; a negative result is the absence of any visible reaction); OR
 - 11.2.1.1.3. * the complement fixation test (Note: ewes that have been vaccinated with Brucella abortus S19 vaccine between 3 and 6 months of age are considered negative if the sera have no fixation reaction up to a titer of 30 ICFTU/ml when the animals are tested at an age of 18 months or older); OR

- 11.2.1.1.4. * the buffered plate antigen agglutination test (read for agglutination immediately after the 8-minute period is completed; a negative result is the absence of any visible reaction);
- 11.2.1.2. * Brucella ovis (in the case of sheep); the donor animals were:
 - 11.2.1.2.1. * tested negative by an enzyme-linked immunosorbent assay (ELISA) test in accordance with the WOAH Terrestrial Manual; OR
 - 11.2.1.2.2. * tested negative by a complement fixation test, (sera with no fixation reaction for a titer less than 50 ICFTU/ml are considered to be negative);
- 11.2.1.3. Tuberculosis¹The donor animals were subjected to two intradermal tests with negative results, the first test within 30 days prior to collection, and the second test between 30 and 120 days after collection, with at least 60 days in between tests;
- 11.2.1.4. Bluetongue virus (BTV); the donor animals were:
 - 11.2.1.4.1. * resident in a BTV free country or zone(s) for the previous 12 months (or since birth) prior to and during embryo/occyte collection; OR
 - 11.2.1.4.2. \star tested negative by an ELISA test for the BTV group on blood serum at the beginning of the collection period, and at least every 60 days after, with one test occurring 21-60 days after embryo/oocyte collection; OR
 - 11.2.1.4.3. * tested with a whole blood PCR test for BTV group with one negative test at the beginning and conclusion of the collection period, and at least every 28 days during the period of embryo/occyte collection; OR
 - 11.2.1.4.4. * tested with a whole-blood virus isolation test for BTV group with one negative test at the beginning and conclusion of the collection period, and at least every 7 days during the period of embryovoocyte collection;
- 11.2.1.5. Epizootic hemorrhagic disease (EHD):
 - 11.2.1.5.1. * The donor animals were resident in a EHD free country or zone(s) for the previous 12 months (or since birth) prior to and during embryo/oocyte collection; OR

- 11.2.1.5.2.1. * the animals were tested on two occasions by an agar gel immunodiffusion test (AGID) 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/oocytes (the two samples may not be taken more than 12 months apart);
 - 11.2.1.5.2.2. * the animals were tested on two occasions by competitive enzyme-linked immunosorbent assay (C-ELISA) AND by either a whole-blood PCR test or 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/oocytes (the two samples may not be taken more than 12 months apart).

11.2.1.6. Schmallenberg virus (SBV):

11.2.1.6.1. \star the embryos/oocytes for export to the United States was collected prior to June 1, 2011; OR

11.2.1.6.2. * were collected after June 1, 2011, from donors that were negative to two serum neutralization tests (using a 1:16 cutoff titer) for Schmallenberg virus, with the first performed within 30 days prior to collection, and the second between 28 and 60 days after collection.

11.3. EMBRYO/OOCYTE PROCESSING

- 11.3.1. After processing, the ampules/straws were stored in dedicated storage tanks containing embryos/oocytes for export to the United States at a storage facility designated by the Competent Veterinary Authority of (insert either Great Britain or Northern Ireland), and under lock and key until such time as they were placed in the shipping tank and sealed with government seals;
- 11.3.2. The embryos/oocytes were collected, processed and stored in accordance with recommendations provided in the current WOAH Terrestrial Animal Health Code;
- 11.3.3. * In the case of embryos to be exported², the embryos were determined, based on microscopic examination, to have an intact zona pellucida at the time the embryos were placed into its immediate container (straw or ampoule) for shipping.

12. Date and place	13. Name and	14. Signature and stamp
	qualification	of the Embryo Team
	of the Embryo Team	Veterinarian ³
	Veterinarian	

Section B (to be signed in Section 18 by the Official Veterinarian, after the Embryo Team Veterinarian has signed):

- I, the undersigned Official Veterinarian of (insert Great Britain or Northern Ireland where the embryos/oocytes were dispatched from) certify that:
- 15.1. The Embryo Collection team was last inspected by the Competent Veterinary Authority of (insert either Great Britain or Northern Ireland), on and did not report any outstanding violations;
- 15.2. The Embryo Team Veterinarian that completed Section A of this certificate is authorized by the Competent Veterinary Authority to perform this service;
- 15.3. The Embryo Team Veterinarian is not subject to any past or current disciplinary actions that would result in ineligibility to certify the health of the animals at the EC team, and meets all other requirements of the applicable legislation in (insert either Great Britain or Northern Ireland);
- 15.4. The donor animals for the embryos/oocytes to be exported to the United States have been part of the national flock/herd of (insert either Great Britain or Northern Ireland), where the embryos/oocytes were collected and are free from any movement or quarantine restrictions, according to Sections 10 and 11;
- 15.5. Any tests required under Sections 10 and 11 for ovine or caprine embryos/oocytes exported to the United States were performed by testing methods recognized by the World Organisation for Animal Health (WOAH) Manual of Diagnostic Tests and Vaccines for Terrestrial Animals, as acceptable for international trade,
- 15.6. The laboratory tests mentioned in Section 11 were carried out with negative results in a laboratory approved by the Competent Veterinary Authority;
- 15.7. (insert either Great Britain or Northern Ireland), is free of foot-and-mouth disease (FMD), rinderpest, contagious caprine pleuropneumonia, and Rift Valley Fever:
- 15.8. In (insert either Great Britain or Northern Ireland):
 - 15.8.1. scrapie is a compulsorily notifiable disease and an effective awareness, surveillance and monitoring system for scrapie is in place;
 - 15.8.2. scrapie affected sheep and goats are killed and completely destroyed;
 - 15.8.3. sheep and goats affected with scrapie are maintained under quarantine in a manner that will prevent disease spread until the animal is no longer living and the remains have been disposed of in a way that prevents disease spread;
 - 15.8.4. the feeding of sheep and goats with meat-and-bone meal or greaves derived from ruminants has been banned and the ban is effectively enforced in the whole region for the entire life of the animal; and the donors have not been in any other country/region with a less restrictive feeding policy prior to the collection of

embryos/oocytes for export;

- 15.9. Products of Animal Origin used in commercial embryo/oocyte flushing or handling media in (insert either Great Britain or Northern Ireland) where the embryos/oocytes were collected, were sourced from countries considered by USDA to be free from FMD and rinderpest as listed in 9 CFR Part 94 and other official publications;
- 15.10. Trypsin of porcine origin was sourced from countries considered by the USDA to be free from FMD, rinderpest, classical swine fever and African swine fever as listed in 9 CFR Part 94 and other official publications;
- 15.11. The embryos/oocytes to be exported to the United States were maintained under lock and key or in the custody of the Embryo Team veterinarian, and in dedicated storage tanks used for US eligible embryos/oocytes, until they were placed in the shipping container and sealed with official seals of (insert either Great Britain or Northern Ireland);
- 15.12. The entire shipment exported under this certificate has been maintained under continuous oversight of the Official Veterinarian until the conveyance is scheduled to depart for the United States;
- 15.13. The storage and shipping containers were examined by the veterinarian issuing the health certificate and found empty of embryos/oocytes and other biological materials prior to use for export of embryos/oocytes to the United States;
- 15.14. The shipping containers were sealed with an approved seal from the Competent Veterinary Authority, and the seal number(s) is (are) recorded in Box 9.9;
- 15.15. The embryos/oocytes are routed directly to the United States from (insert either Great Britain or Northern Ireland) in which it was collected with no stops on route other than those provided on the USDA import permit. This shipment may not transit a region considered by USDA APHIS to have FMD as noted on the USDA APHIS webpage: https://www.aphis.usda.gov/regionalization-evaluation-services/region-health-status

Notes: APHIS recognises separately the disease statuses of Great Britain and Northern Ireland as stipulated in the relevant section of the Federal Register (Vol. 86 No. 155).

- * Delete as appropriate
 - 1. Animals must be individually tested negative for bovine TB by an intradermal TB test using purified protein derivative Mycobacterium bovis tuberculin and read 72 hours following injection with intradermal tuberculin.
 - 2. The health attestation can be deleted if the consignment is of oocytes only.
 - 3. The signature and the stamp must be in a different colour from that of the printed text.