

Certificate for the approval in accordance with Council Directive 89/556/EEC¹ of a bovine embryo collection/production² team

<p>Name and address of the embryo collection/production⁽¹⁾ team</p> <p>Telephone Number</p>	
<p>Owner</p>	
<p>Person in charge</p>	
<p>Name and address of the responsible team veterinarian</p> <p>Telephone Number</p>	
<p>IETS Freeze Code</p>	
<p>Name and address of the competent official veterinarian</p> <p>I, the undersigned, certify that the embryo team detailed above has been inspected and found in compliance with the requirements of Council Directive 89/556/EEC.</p>	
<p>Name and address of the central competent authorities</p> <p>I, the undersigned, certify that the embryo team detailed above complies with the animal health requirements laid down in Council Directive 89/556/EEC for imports into the Union of embryos of animals of the bovine species.</p>	
<p align="center"><input type="checkbox"/> Initial Inspection</p>	<p align="center"><input type="checkbox"/> Re-inspection</p>
<p>Approval Date: [dd.mm.yyyy]</p>	
<p>Approval Number assigned to the team</p>	

¹ 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

² delete as appropriate or insert "and" instead of "/"

**EMBRYO COLLECTION TEAM (ECT) / EMBRYO PRODUCTION TEAM (EPT)
CHECKLIST FOR EXPORT OF BOVINE EMBRYOS
TO THE EUROPEAN UNION (EU)**

Date: _____

ECT/EPT Name: _____

ECT/EPT Address: _____

Name of Team Veterinarian: _____

International Embryo Transfer Society (IETS) Freeze Code: _____

1. TEAM VETERINARIAN:

- _____ a. Must be licensed in the State in which his/her Embryo Transfer Business (ETB) is located and certified by the American Embryo Transfer Association (AETA).
- _____ b. Must be Federally accredited in each State in which he/she issues a health certificate.
- _____ c. Accreditation and/or State veterinary license(s) #: _____
- _____ d. Must collect, process, and store the embryos, or supervise the technicians who do so.
- _____ e. Must ensure that technical personnel are trained and competent in embryo transfer methods and cleaning and disinfection techniques.
- _____ f. Must agree to on-site inspections of the ETB and non-financial records by APHIS at least twice a year.

2. PERMANENT FACILITY:

- _____ a. Must have a room or area physically separated from the donor handling area for the examination, processing, and freezing of embryos.
- _____ b. Must have a room or area physically separated from the embryo processing room for cleaning and sterilizing instruments and equipment used in embryo collection and processing.
- _____ c. Must have a lockable room or cabinet for storage of frozen embryos intended for export to the EU.

3. MOBILE FACILITY (if applicable):

- _____ a. Must have a separate area of the vehicle for examination, processing, and storage of embryos.
- _____ b. Must have a separate area of the vehicle to keep equipment and materials that have been in contact with donor animals.
- _____ c. Must have access to a permanent facility to sterilize equipment, maintain records, and for storage of embryos.

4. DONOR HANDLING AREA:

- _____ a. Embryos must be collected in an area isolated from other parts of the premises which is in good repair and easily cleaned and disinfected.

5. REQUIREMENTS FOR BOTH PERMANENT AND MOBILE LABORATORIES

- _____ a. Must have impervious work surfaces.
- _____ b. Must have a microscope capable of 50 x magnification.
- _____ c. Must have cryogenic equipment.
- _____ d. Floors and walls must be in good repair and be easily cleaned and disinfected.
- _____ e. Access by unauthorized personnel to the laboratory area must be prevented.

6. EMBRYO STORAGE

- _____ a. Embryos must be stored at suitable temperatures in premises approved for that purpose by APHIS.
- _____ b. Permanent facilities must include at least one lockable room or cabinet intended exclusively for storage of embryos intended for export to the EU.
- _____ c. Storage areas must be easily cleaned and disinfected.

7. EMBRYO COLLECTION AND PROCESSING

- _____ a. Embryos must be collected and processed without coming into contact with embryos not qualified for export to the EU.
- _____ b. Equipment that comes into contact with donor animals or that is used during embryo collection and processing must be disposable or reusable and sterilized.

- _____ c. All products of animal origin used to collect, process, and transport the embryos must be obtained from sources presenting no animal health risk or must be treated prior to use to prevent such risk.
- _____ d. Cryogenic agents must not have been in contact with other animal products or materials prior to use.
- _____ e. Embryos must be processed, including a trypsin wash, in accordance with the latest edition of the Manual of the International Embryo Transfer Society (IETS).
- _____ f. Embryos must be washed in groups of 10 or fewer by transferring them through ten changes of medium. Each of the ten washes must be of 100 fold dilutions, and a fresh sterile micropipette must be used to transfer the embryos to each of the washes. Only embryos from the same donor may be washed together.
- _____ g. After the last wash, each embryo must be examined microscopically over its entire surface at 50 x magnification to determine that the zona pellucida is intact and free from any adherent material. Only embryos with an intact zona pellucida may be frozen.
- _____ h. All frozen embryos must be labeled in accordance with IETS standards.
- _____ i. Each straw must be frozen as soon as possible, and the consignment placed in a new or sterilized tank and stored in a lockable room or cabinet under the control of the Team Veterinarian.

8. EMBRYO PRODUCTION TEAM (embryos derived by *in vitro* fertilization)
(if applicable)

- _____ a. Personnel must be trained in appropriate disease control and laboratory techniques, particularly in procedures for working in sterile conditions.
- _____ b. The EPT must have at its disposal a permanently-sited processing laboratory which must:
 - have adequate equipment and facilities, including a separate room for recovering oocytes from ovaries, and separate rooms or areas for processing oocytes and embryos, and storing embryos;
 - have laminar-flow facilities under which all oocytes, semen and embryos must be processed; however, the centrifugation of semen may be carried out outside the laminar-flow facility, as long as full hygienic precautions are taken;

- _____ c. where oocytes and other tissues are to be collected in an abattoir, it must have at its disposal suitable equipment for the collection and transport of the ovaries and other tissues to the processing laboratory in a hygienic and safe manner.

9. EMBRYO IDENTIFICATION AND RECORDKEEPING:

- _____ a. Records must be kept of the date of collection, name, breed, and registration number of the donor dam.
- _____ b. Records must be kept of the date of collection, name, breed, registration number, and the semen collection code of the donor sire.
- _____ c. All straws, goblets and canes must be labeled in accordance with IETS standards.
- _____ d. The number, evaluation, and disposition of the embryos collected at each flush must be recorded.
- _____ e. An inventory record of all embryos must be maintained for movement of all incoming and outgoing embryos, including their final destination, and kept for 12 months after disposition of the embryos.
- _____ f. Records must be kept of USDA seal numbers used to transport embryos.