Embryo Collection Team (ECT)-
Bovine, Porcine, Ovine, Caprine, and Equine
(for teams that collect *in vivo* derived embryos or oocytes for export)

Section 1: Germinal Product Establishment Information

***Name of Embryo Collection Team:**

***Physical Address of Embryo Collection Team:**

***Approval Number of the Embryo Collection Team (Approval number is assigned by Riverdale Staff if this is the initial inspection.):**

*Note: Above items with (*) must match **exactly** the information published on the EU's TRACES NT list: Establishment Lists - TRACES NT (europa.eu) [Select "United States (US)" for the Country field at the top; then select "Germinal Products" for the Chapter.]*

Active International Embryo Transfer Society (IETS) Freeze Code: E___

ISO Code: US *(no additional answer required)*

Name of Team Veterinarian:

USDA Accreditation Number of Team Veterinarian:

Is Team Veterinarian certified by the American Embryo Transfer Association (AETA)? (Required for bovine and ovine/caprine ECTs): ___YES ___NO

Date of inspection:

Species: ___Bovine ___Porcine ___Ovine ___Caprine ___Equine

Central Competent Authority: USDA APHIS- Veterinary Services; 4700 River Road, Riverdale, MD 20737 *(no additional answer required)*

Section 2: Attestation of Compliance and Acknowledgement of Inspection Scheduling Responsibility:

The above germinal product establishment has been inspected and complies with requirements referred to in Article 82(2) of and Delegated Regulation (EU) 2020/692. (Described in Section 3)

The team veterinarian understands that it is the responsibility of the team, not USDA-APHIS, to schedule the next inspection within the required timeframe (12 months, +/- 30 days). If the team does not request and obtain an inspection within the required timeframe, the team may be removed from the EU's list and any stocks of germinal products stored under this approval will irrevocably lose EU-eligibility.

Name of Team Veterinarian [type or print]: _____

Signature: _____

Name of Inspecting USDA Veterinary Medical Officer [type or print]: _____

Signature: _____

After this inspection document has been completed and signed, APHIS-VS FiOps needs to submit information about the inspection via MS Forms to APHIS-VS in Riverdale:

https://forms.office.com/g/RMU9fw5gZr

This information can be submitted by the inspecting VMO or the VETS office, depending on local policy. The signed documents should also be filed as per local policy.

Section 3: Requirements referred to in Article 82(2) of and Delegated Regulation (EU) 2020/692, attested to above.

Notes:

- Some requirements may not apply to all species as noted within the text.
- *Italicized text* is referenced legislation and is linked within in the document to its reference.
- ~~Lined-out text~~ is part of the quoted legislation, but can be ignored for clarity

Article 82(2) of and Delegated Regulation (EU) 2020/692:

2. Consignments of germinal products shall only be permitted to enter the Union from approved germinal product establishments referred to in paragraph 1 that comply with the following requirements set out in Annex I to Delegated Regulation (EU) 2020/686:

(a) Part 1 of that Annex, in respect of a semen collection centre;

(b) Part 2 of that Annex, in respect of an embryo collection team;

(c) Part 3 of that Annex, in respect of an embryo production team;

(d) Part 4 of that Annex, in respect of a germinal product processing establishment;

(e) Part 5 of that Annex, in respect of a germinal product storage centre.

Part 2 of Annex I to Delegated Regulation (EU) 2020/686

REQUIREMENTS FOR THE APPROVAL OF AN EMBRYO COLLECTION TEAM ~~REFERRED TO IN ARTICLE 4~~

1. The responsibilities of the team veterinarian of an embryo collection team, ~~as referred to in Article 4(1)(a)(ii),~~ shall be the following:

(a) the team veterinarian shall be responsible for all embryo collection team operations, including, amongst others, the following:

(i) the verification of the identity and health status of donor animals;

(ii) the clinical examination and surgery of donor animals;

(iii) the disinfection and hygiene procedures, including procedures ensuring the transport of embryos to the laboratory in a hygienic and safe manner;

(iv) record-keeping in accordance with the requirements laid down in Article 8(1)(b);

[Article 8(1)(b)
…approved germinal product establishments for bovine, porcine, ovine, caprine and equine animals shall keep and maintain records containing at least the following information:

(b) in respect of an embryo collection team, an embryo production team or an embryo collection and production team:

(i) the species, breed, date of birth and identification of each donor animal from which oocytes or embryos were collected;

(ii) the health status, the results of clinical and diagnostic tests and the laboratory techniques used, treatments and vaccinations carried out on donor animals of oocytes or embryos;

(iii) the date and place of oocytes or embryos collection, examination, and processing;

(iv) the identification of oocytes or embryos and details of their destination;

(v) where micromanipulation is being performed on the embryos, the details of micromanipulation techniques used which involve penetration of the zona pellucida or, in case of equine embryos, the embryonic capsule;

(vi) the origin of semen used for artificial insemination of donor animals or to fertilise oocytes for in vitro production of embryos]

(v) the marking of straws and other packages where oocytes or *in vivo* derived embryos are placed in accordance with the requirements set out in Article 10(1) and (5);

[Article 10(1) and (5)
(1)… shall mark each straw or other package in which semen, oocytes or embryos, whether or not separated into individual doses, are placed, stored and transported, in such a way that the following information can be readily established:

(a) the date of collection or production of those germinal products;

(b) the species and identification of the donor animal(s);

(c) the unique approval number of the germinal product establishment of collection or production, processing and storage of those germinal products;

(d) any other relevant information.

(5) ~~By way of derogation from paragraph 1(c), the operator shall ensure that the marking of each straw or other package in which semen, oocytes or embryos are placed, stored and transported, is carried out in such a way that it permits the identification of:~~

~~(a) in the case of semen of ovine and caprine animals which has been collected at the establishment where the donor animals are kept as referred to in Article 13, the unique registration number of that establishment; or~~

~~(b) in the case of germinal products of bovine, porcine, ovine, caprine or equine animals which have been collected or produced at a confined establishment referred to in Article 14, the unique approval number of that confined establishment.~~ [Note: point (5) is not currently relevant to any U.S. establishments]]

(vi) the training of members of the embryo collection team on disinfection and hygiene techniques to prevent the spread of diseases;

(b) the team veterinarian shall lay down the animal health and biosecurity requirements for the operation of the embryo collection team and the measures to ensure compliance with those requirements, including the testing of samples within a quality control scheme.

2. The facilities, equipment and operational procedures of the embryo collection team, ~~as referred to in Article 4(1), point (b)(ii)~~, shall comply with the following points (a) and (b):

(a) the embryo collection team must have at its disposal a laboratory where oocytes or *in vivo* derived embryos can be examined, processed and packaged with adequate equipment, and that laboratory must be either:

(i) a permanently located laboratory, which must have the following:

— a room where oocytes of *in vivo* derived embryos can be processed which is physically separated from the area used to handle the donor animals during collection,

— a room or area for cleansing and sterilising instruments used for oocytes or *in vivo* derived embryo collection and processing, except when using only new single-use equipment,

— a room for the storing of oocytes or *in vivo* derived embryos;

or

(ii) a mobile laboratory, which must:

— have a specially equipped part of the vehicle consisting of two separate sections: one section for the examination and processing of oocytes or *in vivo* derived embryos, which must be the clean section; and another section for accommodating equipment and materials used in contact with the donor animals,

— use only new single-use equipment, unless the sterilisation of its equipment and the provision of fluids and other products necessary for the collection and processing of oocytes or *in vivo* derived embryos is carried out at a permanently located laboratory.

The laboratories referred to in points (i) and (ii) must be designed and have a layout so as to prevent the cross-contamination of oocytes or *in vivo* derived embryos, and team operations shall be carried out in a manner that prevents such cross-contamination;

(b) the embryo collection team must have at its disposal storage premises which comply with the following conditions:

(i) they comprise at least one lockable room for the storage of oocytes or *in vivo* derived embryos;

(ii) they must be easy to cleanse and disinfect;

(iii) they must have permanent records of all incoming and outgoing oocytes or *in vivo* derived embryos;

(iv) they must have storage containers for oocytes or *in vivo* derived embryos.