Germinal Product Processing (GPP) Establishment- Bovine, Porcine, Ovine, Caprine, and Equine

*NOTE: This document is **only** for use with establishments that process germinal products for another EU-Approved establishment (e.g., sort/sex semen for a semen collection center other than the one the sorting/sexing equipment is approved under).*

Section 1: Germinal Product Establishment Information

***Name of Germinal Product Processing Establishment:**

***Physical Address of Germinal Product Processing Establishment:**

***Approval Number of the Germinal Product Processing Establishment (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.]*

NAAB Locator Number of GPP establishment if they will process bovine semen:

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

Name of Center Veterinarian:

USDA Accreditation Number of Center Veterinarian:

Date of inspection:

Germinal product species and type(s) processed at above Germinal Product Processing Establishment (check all that apply.):

___ Bovine ___ Semen ___ *in vivo* Embryos ___ *in vitro* Embryos ___ Oocytes

___ Porcine ___ Semen ___ *in vivo* Embryos ___ *in vitro* Embryos ___ Oocytes

___ Ovine ___ Semen ___ *in vivo* Embryos ___ *in vitro* Embryos ___ Oocytes

___ Caprine ___ Semen ___ *in vivo* Embryos ___ *in vitro* Embryos ___ Oocytes

___ Equine ___ Semen ___ *in vivo* Embryos ___ *in vitro* Embryos ___ Oocytes

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 center veterinarian understands that it is the responsibility of the center, not USDA-APHIS, to schedule the next inspection within the required timeframe (12 months, +/- 30 days). If the center does not request and obtain an inspection within the required timeframe, the center 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 Center 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 4 of Annex I to Delegated Regulation (EU) 2020/686

REQUIREMENTS FOR THE APPROVAL OF A GERMINAL PRODUCT PROCESSING ESTABLISHMENT ~~REFERRED TO IN ARTICLE 4~~

Germinal Product Processing Establishment Requirements from Part 4 of Annex I to Delegated Regulation (EU) 2020/686 [2023.02]

1. The responsibilities of the centre veterinarian, ~~referred to in Article 4(1)(a)(i)~~, shall be the following:

(a) the centre veterinarian shall ensure that:

(i) at the germinal product processing establishment records are kept in accordance with the requirements laid down in Article 8(1)(c);

[Article 8(1)(c)… approved germinal product establishments for bovine, porcine, ovine, caprine and equine animals shall keep and maintain records containing at least the following information:
…(c) in respect of a germinal product processing establishment or a germinal product storage centre:

(i) the type of germinal products either processed and stored or stored at the approved germinal product establishment with reference to the species of the donor animal;

(ii) the dates of movement of germinal products to and from the approved germinal product establishment with the reference to the documents which accompanied those germinal products;

(iii) the documents, including an animal health certificate and a self-declaration document, confirming that the health status of the donor animals whose germinal products are either processed and stored or stored at the approved germinal product establishment complies with the requirements of this Regulation;

(iv) the identification of germinal products that are either processed and stored or stored at the approved germinal product establishment.]

(ii) the entry of unauthorised persons is effectively prevented;

(iii) authorised visitors comply with the animal health and biosecurity requirements referred to in point (b)(i);

(iv) each straw or other package in which semen, oocytes or embryos are placed is clearly marked in accordance with the requirements laid down in Article 10;

[Article 10:
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.

2. In case of sex-sorting of semen at a germinal product processing establishment, the operator of the semen collection centre shall supplement the information referred to in paragraph 1 with information which permits the identification of the unique approval number of the germinal product processing establishment where that semen was sex-sorted.

3. Where a single straw or another package contains semen of bovine, porcine, ovine or caprine animals collected from more than one donor animal, the operator shall ensure that the information referred to in paragraph 1 permits the identification of all donor animals that have contributed to the dose of semen used for insemination.

4. By way of derogation from paragraph 1, where the semen of ovine or caprine animals is

(a) frozen in pellets, the operator may mark the goblet containing the semen pellets of a single donor instead of marking each individual pellet in that goblet;

(b) fresh or chilled semen, the operator may mark the goblet containing the semen tubes or straws of a single donor instead of marking each individual tube or straw in that goblet.

~~*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]]*

(v) the processing and storage of germinal products takes place only on the premises set aside for that purpose and under strict hygiene conditions;

(vi) all instruments which come into contact with the germinal products are cleansed and either disinfected or sterilised prior to use, except for new single-use instruments;

(vii) before the commencement of each filling operation, the storage containers and transport containers are cleansed and either disinfected or sterilised, except for new single-use containers;

(viii) cryogenic agents used for the preservation or storage of germinal products have not previously been used for other products;

(ix) the staff of the germinal product processing establishment have received adequate training:

— on disinfection and hygiene techniques to prevent the spread of diseases,

— for the purpose of processing germinal products, on laboratory techniques and particularly on procedures for working in sterile conditions;

(b) the centre veterinarian shall:

(i) lay down the animal health and biosecurity requirements for the operation of the germinal product processing establishment and the measures to ensure compliance with those requirements;

(ii) only accept into a germinal product processing establishment semen, oocytes or embryos collected, produced, processed and stored in an approved germinal product establishment, and transported under conditions that ensure that cross-contamination of semen, oocytes or embryos is prevented, as they have had no contact with germinal products which do not comply with the rules laid down in this Regulation.

2. The requirements for the facilities, equipment and operational procedures of a germinal product processing establishment, ~~referred to in Article 4(1)(b)(iv)~~, shall be the following:

(a) the germinal product processing establishment must have at least:

(i) a germinal products processing room, separated from the germinal products storage room referred to in point (ii) and the room used for cleansing equipment referred to in point (iii);

(ii) a germinal products storage room, which need not necessarily be on the same site, furnished with the necessary installation to store germinal products, and which is so constructed that it protects those germinal products and the installation from adverse weather and environment effects;

(iii) a separate room for the cleansing and disinfection or sterilisation of equipment;

(b) where processing is not limited to germinal products delivered from one approved germinal product establishment or is not limited to a germinal product of one type or of a single species, the germinal product processing establishment must have procedures in place to ensure that:

(i) the processing of each consignment of germinal products is separated in time; and

(ii) the equipment is cleansed and disinfected between the processing of different consignments;

(c) where storage is not limited to a germinal product of one type or of a single species,

(i) the germinal product processing establishment must have distinct storage containers assigned for each type and species of germinal product that is stored in the germinal products storage room referred to in point (a)(ii), and

(ii) the handling of stored germinal products of different types and species must be carried out by separate staff or at a different time;

(d) the germinal product processing establishment must be so constructed that, except the office rooms, it can be readily cleansed and disinfected;

(e) the germinal product processing establishment must be so constructed that unauthorised access of people is effectively prevented.