Ref: CTO 2018 026 [B]

Veterinary Certification for Sheep and Goat In-Vivo Derived Embryos from France

CTO direction as to equivalent measures in relation to sheep and goat in-vivo derived embryos from France, according to France's veterinary certificate.

Pursuant to section 27(1)(d)(iii) of the Biosecurity Act 1993 I, Howard Pharo, deputy chief technical officer at the Ministry for Primary industries, give the following directions for in-vivo derived sheep and goat embryos from France in relation to the *Import Health Standard for Semen and Embryos from Sheep (Ovis aries) and Goats (Capra hircus) (OVCAGERM.GEN)* issued 10 November 2016.

1. **Removal of the requirement that provide test information be documented or attached to the certificate 1.14 and sample handling and testing as per MPI-STD-TVTL 1.6. 2/3.**

   France will not be required to provide evidence of test information (dates, type and results). For bovine germplasms and sheep/goat semen this requirement was removed due to the confidence MPI has in the Veterinary Authorities in the Member States of the European Union.

   The Director General/CVO France has assured that all tests will be performed in accordance with MPI-STD-TVTL and the tests are listed in the proposed veterinary certificate.

2. **Bluetongue vaccination option**

   OVCAGERM.GEN does not contain a vaccination option for bluetongue disease.
   The French certificate proposes to vaccinate embryo donors with live attenuated bluetongue vaccine no less than 2 months and no more than one year before embryo collection.

   The MPI-STD-TVTL lists live attenuated vaccine for embryo donors against bluetongue disease. This option has been agreed between MPI and France for ovine/caprine semen certificates. The live attenuated vaccine produces protective immunity after a single inoculation and is effective in preventing clinical BT disease. The BT virus is only considered likely to enter semen and embryos during the viraemic phase and if the vaccine were to be administered at least 2 months before insemination, the embryo donors will not be viraemic during the collection period. In France where official monitoring of circulating strains and vaccinates occur, with vaccination given at least 2 months before embryo collection and no more than one year before collection, the overall risk can be considered very low. Corsica region of France has been excluded because appropriate monitoring of BTV strains does not occur.

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Vaccination of embryo donors with live attenuated bluetongue vaccine, no less than 2 months and no more than one year before embryo collection, effectively manages the risk of BTV infection in ovine and caprine embryos.

3. **Maedi-visna virus (MV)**

OVCAGERM.GEN requires MV country freedom or herd/flock freedom with segregation for 3 years from animals with inferior health status and testing donors with tests identified in the MPI-STD-TVTL.

The French embryo certificate proposes testing donors with either agar gel immunodiffusion test (AGID) or enzyme-linked immunosorbent assay (ELISA) with negative results, during the 21 day period prior to embryo collection, and trypsin treatment of embryos as per the IETS Manual. The AGID and ELISA tests are also nominated in the MPI-STD-TVTL for MV testing.

The OIE Manual states "*Due to the persistent nature of these infections, the establishment of positive antibody status is sufficient for the identification of virus carriers*". Moreover, AGID and ELISA tests have been recommended in the OIE Manual for individual animal freedom from infection prior to movement (*Chapter 2.7.2/3 OIE Manual*).

According to the OIE Manual the MV provirus DNA is carried in circulating monocytes and tissue macrophages and these infected cells may adhere to the zona pellucida of the embryo; a likely pathogen transfer pathway. The IETS recommends embryo processing, i. e. trypsin washing and microscopic examination of embryos to ensure only the embryos without any adherent material are selected thus reducing the risk of MV virus being transmitted to embryos.

Moreover, MV is listed in the Category 3 of the IETS pathogen list. Diseases/pathogens in the Category 3 are described as ""*....those for which preliminary evidence indicates that the risk of transmission is negligible provided that the embryos are properly handled between collection and transfer according to the IETS Manual, but for which additional in vitro and in vivo experimental data are required to substantiate the preliminary findings*".

Based on the above evidence, donor testing and embryo processing as given in the French embryo certificate effectively manage the risk of MV.

This direction takes effect from the date of signing and continues in effect until amended or revoked.