Ref: CTO 2016 013 [B] **Sheep and Goat Semen: UK Veterinary Certification**

CTO direction to biosecurity inspectors relating to the clearance of semen from sheep and goats from UK according to the approved United Kingdom's Department for Environment Food and Rural Affairs (DEFRA) veterinary certificate

Pursuant to section 27(1)(d)(iii) of the Biosecurity Act 1993 I, Howard Pharo, Deputy Chief Technical Officer, Ministry for Primary Industries, give the following directions for sheep and goat semen from the United Kingdom relating to whether to give clearance in accordance with the approved veterinary certificate from the United Kingdom's DEFRA. The approved veterinary certificate contains the following measures, different from those in the applicable *IHS: Semen and Embryos from Sheep and Goats* OVCAGERM.GEN (22 June 2015):

1. Removal of the requirement that tests (other than scrapie genotyping) be documented or attached to the certificate.

I consider the deletion as equivalent because DEFRA has confirmed that the certifying veterinarian will assess the tests before certification. In addition, MPI has communicated that an audit will be conducted in the future (as was indicated to the EU during the bovine germplasm negotiation).

2. The section title "Semen collection centre". The word "facility" has been replaced with the word "centre" throughout the document. According to the OIE, there are AI centres and semen collection facilities. The centres contain administration offices, semen labs and storage areas, and the pre-entry isolation facility.

I consider a centre equivalent to a facility as required by OVCAGERM.GEN.

3. The addition of clause 20.d. Donors were vaccinated with a vaccine against all known BTV serotypes in the United Kingdom, no less than 2 months and no more than one year before collection.

I consider 20.d to manage the risk with the equivalent outcome of the other BTV options in OVCAGERM.GEN.

4. An amendment to clause 21.i and ii. Donors were inspected for ticks and treated with an effective acaricide under direct veterinary supervision to ensure they are free from ticks before entering approved vector-proof premises; AND confirmed free of ticks by the authorised centre veterinary surgeon at the time of entry to the semen collection centre.

I consider 21.i. and ii. to be equivalent to the requirements of OVCAGERM.GEN, where only one inspection is required under "official vet supervision".

5. The amendment to 23. Before entering the semen collection centre, donors only lived in herds/flocks that included animals older than 5 years; and.

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I consider 23 to be equivalent to the requirements of OVCAGERM.GEN, where the requirement was that the donor has only lived in herds/flocks with animals older than 5 years. The risk is managed because animals enter the collection centre after the period of time when transmission is believed to occur (neonate) and would therefore be less likely to spread disease in the centre. In addition, the clauses subsequent to it have been adjusted to reference all flocks/herds (not just those before the collection flock/herd).

6. The amendment to clause 23. b. "The flocks/herds have remained free from ovine pulmonary adenomatosis based on the absence of clinical signs for at least 3 years prior to collection and no sheep/goat from a from a flock/herd of an inferior health status has been introduced during that period; and

(i) The donor was tested for ovine epididymitis (*Brucella ovis*)* using CFT, as described by the OIE manual, during the 30 days prior to collection, with negative results;

*Infection with *Brucella ovis* increases the risk of ovine pulmonary adenomatosis retrovirus being in semen;

I consider 23. b. to be equivalent to the requirements of OVCAGERM.GEN. The equivalence is described in detail in the attached decision document.

7. An amendment to clause 32.ii (tuberculosis). Donors were kept in herds free from bovine tuberculosis and tested annually with negative results with the test described in (i).

Clause 34.ii. requires that the herd is free of tuberculosis and there, I consider 34.ii. equivalent to the requirements of OVCAGERM.GEN, which requires that all animal in the collection centre are to be tested prior to entry.

The reason for directing clearance is that the biosecurity risks associated with this CTO direction have been assessed and are managed effectively.

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

DECISION DOCUMENT FOR COUNTRY-SPECIFIC VETERINARY CERTIFICATE

BACKGROUND:

This will be the first certificate to meet the requirements of OVCAGERM.GEN. It will allow importation of new genetics from the UK to improve the sheep and goat industries. Previously, new genetics have only originated from Australia.

During the negotiation, the attached letter and annex from the DEFRA CVO were provided. The annex provides information regarding the diseases in the IHS which are non-notifiable in the UK: Contagious caprine pleuropneumonia (CCPP), Crimean-Congo hemorrhagic fever (CCHF), and Wesselsbron disease. These diseases have never been recorded in the UK, but there is a passive surveillance system in place, as described in the letter.


CVO letter to Dr Stone.pdf


Annex.pdf

These diseases are still indicated in the veterinary certificate. In the case of CCHF, they are unable to satisfy the country freedom requirement due to lack of official notification and have agreed to require tick protection and treatment.

The following disease freedoms are in accordance with the OIE Code: FMD, bluetongue, Peste des Petis ruminants, Rift Valley fever, and sheep and goat pox.

DEFRA has indicated that all tests will be conducted in accordance with the OIE *Manual.* The tests are either specified in the certificate or they are indicated to be the ones recommended by the OIE (which have all been approved by MPI and will be listed in *MPI-STD-TVTL*).


testing in accordance with the

The following equivalences were granted:

1. Removal of the requirement that tests (other than scrapie genotyping) be documented or attached to the certificate.

DEFRA is not being required to provide evidence of test information (dates, type, and results). For bovine germplasm with the EU, this requirement was eliminated due to the confidence MPI has in the EU veterinary authorities. For this negotiation, like bovine germplasm, MPI will request the ability to perform an audit in the future. The ability to deem the deletion as an equivalence is therefore due to DEFRA's confirmation that the certifying veterinarian will assess the tests before certifying and MPI's future audit (as was indicated to the EU during the bovine germplasm negotiation).

2. The section title "Semen collection centre". The word "facility" has been replaced with the word "centre" throughout the document. According to the OIE, Artificial Insemination (AI) centres are different from semen collection facilities. The centres contain administration offices, semen labs and storage areas, and the pre-entry isolation facility.

The centres do not contain anything that significantly increases the risk compared to a standalone semen facility. MPI has therefore deemed the centre equivalent to the facility as required by OVCAGERM.GEN.

3. The addition of clause 20.d. Donors were vaccinated with a vaccine against all known BTV serotypes in the United Kingdom, no less than 2 months and no more than one year before collection.

MPI-STD-TVTL will indicate that vaccination must be with a live-attenuated vaccine. The live attenuated vaccines produce protective immunity after a single inoculation and is effective in preventing clinical BT disease. The virus is only considered likely to enter semen and embryos when the animal is viraemic (usually for 6-8 days, up to 54) and therefore if the vaccine is administered at least 2 months before collection, the viraemic period would not align with the collection period. Since the overall risk is considered very low, vaccination given at least 2 months before collection and no more than one year before collection, in a country which monitors for circulating strains and vaccinates appropriately. MPI has deemed 20.d to manage the risk with the equivalent outcome of the other BTV options in OVCAGERM.GEN.

4. An amendment to clause 21.i and ii (CCHF). Donors were inspected for ticks and treated with an effective acaricide under direct veterinary supervision to ensure they are free from ticks before entering approved vector-proof premises;
AND confirmed free of ticks by the authorised centre veterinary surgeon at the time of entry to the semen collection centre.

MPI has deemed 21 i and ii to be equivalent to the requirements of OVCAGERM.GEN, where only one inspection is required under "official vet supervision".

5. An amendment to clause 23 (OPA). Before entering the semen collection centre, donors only lived in herds/flocks that included animals older than 5 years; and.

MPI has deemed clause 23 to be equivalent to the requirements of OVCAGERM.GEN, where the requirement was that the donor has only lived in herds/flocks with animals older than 5 years. The risk is managed because animals enter the collection centre after the period of time when transmission is believed to occur (neonate) and would therefore be less likely to spread disease in the centre. In addition, the clauses subsequent to it have been adjusted to reference all flocks/herds (not just those before the collection flock/herd).

6. An amendment to clause 23. b. "The flocks/herds have remained free from ovine pulmonary adenomatosis based on the absence of clinical signs for at least 3 years prior to collection and no sheep/goat from a from a flock/herd of an inferior health status has been introduced during that period; and
(i) The donor was tested for ovine epididymitis (*Brucella ovis*)* using CFT, as described by the OIE manual, during the 30 days prior to collection, with negative results;
*Infection with *Brucella ovis* increases the risk of ovine pulmonary adenomatosis retrovirus being in semen;

Howard Pharo's risk assessment is provided in this email:

FW Pulmonary adenomatosis risk -

The primary concern is that the virus may enter semen when there is inflammation in the reproductive tract. The most likely cause of inflammation is ovine epididymitis, caused by *Brucella ovis*. A general requirement of the OIE Code includes routine testing for *Brucella ovis* in semen collection centres. The equivalence has been developed which reduce the premise freedom requirement to 3 years if the semen donor tests negative for

Brucella ovis during the 30 days before semen collection. MPI has therefore deemed 23 (b) to be equivalent to the requirements of OVCAGERM.GEN.

7. An amendment to clause 32.ii (tuberculosis). Donors were kept in herds free from bovine tuberculosis and tested annually with negative results with the test described in (i).

Clause 34.ii. requires that the herd is free of tuberculosis and there, MPI has deemed 34.ii. equivalent to the requirements of OVCAGERM.GEN, which requires that all animal in the collection centre are to be tested prior to entry.

ASSESSMENT OF RISK:

The outcome of the requirements in the UK veterinary certificate equivalently manage the biosecurity risks, as they are described in the IRA and managed by the IHS.

LEGAL:

MPI is required to approve any proposed veterinary certificate in accordance with OVCAGER.GEN issued 22 June 2015. This CTO direction and attached decision document, including all appendices serves as the formal record of negotiations with the UK DEFRA.

DECISION:

(a) MPI accepts the veterinary certificate for semen from the UK, which proposes equivalent measures as noted above;

(b) The CTO issues the attached direction under section 27(1)(d)(iii) of the Biosecurity Act 1993.

RECOMMENDATION:

That you:

(a) approve DEFRA's veterinary certificate and the following equivalences; and

(b) issue the CTO direction under section 27(1)(d)(iii) of the Biosecurity Act 1993.

Team Manager: Lucy Johnston pp

Sign and date: 18/04/16.

AGREED / ~~**NOT AGREED**~~

Signed at Wellington this 18th day of April 2016

Howard Pharo
Deputy Chief Technical Officer
Animals and Animal Products Directorate
Regulation & Assurance Branch
Ministry for Primary Industries