No:

EXPORT OF OVINE/CAPRINE SEMEN TO THE UNITED STATES OF AMERICA

NOTES FOR THE GUIDANCE OF VETERINARIANS AND EXPORTERS

Associated Documents: 7852EHC, 7852SPT, 7852NFGI

1. <u>Scope of the Certificate</u>

This certificate covers the export of ovine/caprine semen to the United States of America. The certificate refers to exports from either Great Britain or Northern Ireland. Ovine semen collected in both Northern Ireland and Great Britain and exported under one certificate is not permitted. The ovine semen must be collected in the same region of export (either Great Britain or Northern Ireland).

As a minimum, for exports from Great Britain the requirements in Directive 92/65/EEC and in the case of scrapie, Annex VIII of assimilated Regulation No 999/2001 need to be complied with. In the certificate references to `legislation applicable in Great Britain' refers to these legislations. For exports from Northern Ireland, the requirements in Regulation (EU) 2020/686 and in the case of scrapie, Annex VIII of Regulation (EU) No 999/2001 need to be complied with. In the certificate references to `legislation applicable in Northern Ireland' refers to these legislations.

The requirements in Directive 92/65/EEC or Regulation (EU) 2020/686 will have been met if the semen collection centre (SCC) is currently approved by APHA/DAERA and the Scrapie requirements can be met under the guidelines at paragraph 6 below.

In addition, USA requirements as in 7852EHC need to be met, especially in relation to tuberculosis and brucellosis which requires, as an option, for the donor animals to be isolated for at least 120 days and tested twice for these prior to the end of the isolation period, if whole flock/herd testing is not possible. For donor animals isolated for 120 days, TB testing 30-120 days after semen collection is also required. In order to demonstrate compliance with these as well as the additional USA (scrapie and Schmallenberg virus related) requirements where these are complied with outside the SCC, support certification (7852SPT) is available. 7852SPT provides documentary evidence to the centre veterinarian that the tuberculosis/brucellosis and scrapie/schmallenberg requirements have been met at the flocks (for sheep) or herds (for goats) of residence; and that the donor's health status has not been compromised during transport to/from the SCC. Please note, TB and brucellosis clearance does not extend to co-located cattle in the same premises. In relation to scrapie, 7852SPT also confirms that the parents of the donor have not been affected by scrapie and that the donor has never resided on holdings on which scrapie was confirmed during their residence on those holdings.

Please note, for EU origin donor animals, there is also an **7852/8746 SPT-SUP** that can be used as documentary evidence alongside the GB EHC (or ITAHC for NI) to confirm residency and scrapie compliance of EU origin donor animals to support certification of their germinal products collected in GB/NI to USA. It must be signed and certified by the EU owner and EU government vet and/or EU OV. The 7852SPT must still be completed in the UK as well.

Furthermore, please note, both 7852SPT and 7852/8746 SPT-SUP are internal support documents to facilitate export certification. They are not required to accompany the 7852EHC to USA. The 7852SPT and 7852/8746 SPT-SUP must be completed prior to export certification as the APHA/DAERA countersigning vets may request it to facilitate their certification of section B of the 7852EHC. There is also a pre-export scrapie declaration form to complete when submitting an export application online to ensure additional scrapie checks are performed by APHA/DAERA prior to export.

It is essential that the centre vet has evidence that the donor is fully compliant with the relevant scrapie, tuberculosis and brucellosis requirements prior to entry into the centre, to ensure there is no risk of animals being found to be non-compliant at a later stage and therefore adversely affecting the health status of the other animals in the centre. This should be done by having these health assurances checked and confirmed by APHA/DAERA on the 7852SPT.

In instances where an 7852SPT has not been obtained at this stage, then other documentary evidence of compliance must have been obtained prior to entry and be available for scrutiny.

It may be possible to request APHA/DAERA to certify the relevant section on an 7852SPT presented after the donors have entered, but in these cases the date of signature of the 7852SPT by APHA/DAERA will demonstrate that this request was made retrospectively so the other evidence mentioned above, will still be required for audit purposes.

2. Signatories - certification by the Centre Veterinarian and Official Veterinarian

The health certificate must be signed at sections 12-14, for Section A of Part D by the Centre Veterinarian (i.e. Authorised Veterinary Surgeon at the Semen Collection/Storage Centre). An APHA/DAERA veterinarian must complete/sign the certificate at paragraphs 16-18, Section B of Part D.

Please note: For exports from a Semen Storage Centre, it would be acceptable for the Semen Storage Centre veterinarian to complete the final export health certification (Section A) with the certificate issued by the Semen Collection Centre veterinarian provided as support for the attestations in Section A. As long as the semen was certified by the Semen Collection Centre veterinarian at the time the semen was moved to the approved Semen Storage Centre and has not been stored with semen of lesser health status while at the approved storage facility.

In addition, please note: Section B of Part D of 7852EHC suggests it can be signed by an Official Veterinarian. However, in the case of exports to USA, an Official Veterinarian is considered to be a veterinarian employed by the Department, so you must approach CIT, Carlisle or the local office of the Animal Plant and Health Agency (APHA) or, in the case of Northern Ireland, the Department of Agriculture, Environment and Rural Affairs (DAERA), Dundonald House, Belfast, to arrange countersignature.

APHA/DAERA veterinarian should affix their SP stamp to the certificate in the normal manner. The veterinarian should retain a copy for record keeping purposes, and should also forward a copy to APHA CIT, or in the case of Northern Ireland to DAERA, Dundonald House, Belfast, within seven days of signing.

All requests for countersignature must be submitted to the Centre for International Trade - Carlisle (CITC) at least two working days in advance of the requested date/time of countersignature using Request for APHA Veterinarian Countersignature of an Export Health Certificate (ET145) application.

The ET145 application can be submitted to CITC:

- as an attachment, at the same time you complete an online application for certification, on the Export Health Certificates (EHC) Online service, or
- by email to processingteam@apha.gov.uk

Upon receipt of your ET145 application CITC will liaise with an APHA Veterinarian at your preferred countersigning office/area to make arrangements for countersignature to take place and notify you of the arrangements made.

The health certificate must be signed and stamped in any ink colour $\ensuremath{\textbf{OTHER THAN}}$ $\ensuremath{\textbf{BLACK}}.$

Some requirements in Section B will require support certification from the centre veterinarian - e.g. 15.4 and 15.9 to 15.14. List of FMD and rinderpest free countries/regions recognised by APHIS can be found here: https://www.aphis.usda.gov/regionalization-evaluation-services/region-health-status

Note, Rinderpest was declared eradicated in 2011 globally.

Paragraphs 15.5 and 15.6 - Tests carried out by APHA laboratories in Great Britain or by AFBI in Northern Ireland are deemed to be in accordance with the WOAH (formerly known as OIE) manual and the corresponding statements can be certified; if necessary, the APHA/DAERA veterinarian may ask to see copies of the test results and confirm with the laboratory that the report is genuine.

The APHA/DAERA veterinarian should also cross-check some of the content (straws etc) in the shipping container with the consignment details on the certificate. If in order, the seal (but see below) should be applied by, or under the supervision of, the APHA/DAERA veterinarian. The requirement for 'continuous supervision' of the semen by an official veterinarian while in storage at 15.12 can be certified on the basis that the SCC/SSC is regularly inspected under Directive 92/65/EEC in GB (or under Regulation (EU) 2020/686 in NI) by an APHA/DAERA veterinarian and visited by an APHA/DAERA veterinarian every time there is need to countersign 7852EHC for exports to USA.

3. Import Permit

The import conditions of the United States of America require that an official Import Permit must be obtained from the U.S. Department of Agriculture (USDA). Please note that such a permit may be cancelled at any time depending on the current disease status of the exporting country. The procedure for applying for an import permit and copies of the US's latest requirements can be found at: https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/animal-and-animal-product-import-information/animal-health-permits/ct animal health permits home

Exporters / certifying vets must cross check the latest requirements against 7852EHC and notify CIT if discrepancies are found.

4. Notifiable disease clearance

Centre veterinarians may certify paragraphs 10.4, 10.7a) & c), 10.9 b) first option if applicable and 10.9 c) first option of the certificate based on a 618NDC authorisation. It is very unlikely semen collected in the UK during the period 15/01/2001 to 17/12/2002 - when the UK was not free of FMD in accordance with 9 CFR Part 94 - would be compliant.

Please note, regarding 10.9 b) first option (**BTV freedom**) or 10.9 c) first option (**EHD freedom**), the donor animals must be resident in a BTV/EHD free country or zone for at least 12 months (or since birth) prior to and during semen collection. GB/NI must be free of BTV/EHD (i.e. no evidence of serological infection exists) for 12 months prior to and during semen collection.

For imported animals, this may include a 12-month residency prior to collection in multiple countries/zones, including GB/NI, that are (or were) BTV/EHD free. USDA APHIS require the country/zone(s) to be BTV/EHD free (i.e. no evidence of serological infection exists) for 12 months prior to donor animal movement to GB/NI and GB/NI must also be free of BTV/EHD for 12 months prior to and during semen collection.

Origin of ruminant products in semen extenders

Paragraphs 11.5 and 15.9 refer: The list of countries which are free of FMD and rinderpest according to the CFR can be found at: https://www.aphis.usda.gov/regionalization-evaluation-services/region-healthstatus

Note, Rinderpest was declared eradicated in 2011 globally.

Centre vets can sign these paragraphs if they are using a semen extender which does not contain ruminant products.

5. Compliance with Directive 92/65/EEC or Regulation (EU) 2020/686

For semen collection in Great Britain, the SCC/SSC must be approved in accordance with Directive 92/65/EEC and listed on the gov.uk website: https://www.gov.uk/government/publications/livestock-and-equine-semen-collection-centres

For semen collection in Northern Ireland, the SCC/SSC must be approved in accordance with Regulation (EU) 2020/686 and listed on the EU website: https://ec.europa.eu/food/animals/semen-oocytes-embryos/ovine-caprine_en

6. Scrapie Requirements

- 6.1 Paragraph 10.7 refers. If the centre veterinarian is not the veterinarian overseeing the holdings where the rams had resided on since birth, due enquiries must be made to enable sub-paragraphs a) and b) of paragraph 10.7 to be certified. 7852SPT has been created for this and the procedure described at paragraph 6.2 below should be followed to complete it. Sub-paragraph c) requires confirmation that the donors continue to be free of clinical signs of scrapie at the time the semen is being certified for export, so arrangements must be made to get this assurance (that the donor continues to be healthy if still alive or did not die of scrapie). The 618NDC will confirm that the donor animal has not been recorded as having died from scrapie prior to export of the semen.
- 6.2 Paragraphs 10.7 a) and b) must be corroborated by conducting a thorough search of Defra's Scrapie Notification Database (SND), and <u>additionally</u> compliance with the requirements of Annex VIII of the TSE Regulations (e.g. via membership of the Scrapie Monitoring Scheme (if the donors are not ARR/ARR)). For caprine animals, scrapie monitoring and genotyping is not required provided the semen complies with the US requirements and is collected and stored completely separate to EU qualified donor animals and germinal products. Further advice maybe sought from APHA/DAERA.

SND checks:

In **Great Britain**, the owner/exporter **and** an authorised Official Veterinarian (OV) appointed to the appropriate panel for export purposes by Defra, the Scottish Government or the Welsh Government, or who holds the appropriate Official Controls Qualification (Veterinary) (OCQ(V)) authorisation OCQ(V)EX or OCQ(V)TB, must complete form 7852SPT for submission to Carlisle CIT.

In Northern Ireland, the owner/exporter and an Authorised Veterinary Inspector (AVI) appointed as an OV to the appropriate export panel for export purposes by the DAERA, must complete form 7852SPT for submission to DAERA.

Close liaison with the Centre Veterinarian is required to ensure that the movement of the other donor rams to the Semen Collection Centre can be coordinated since an all-in / all-out procedure may be necessary; the OV may choose to use the Centre Veterinarian to submit requests for clearances, in which case the Centre Veterinarian must submit 7852SPTs for all the donors (from which semen is intended for certification) to CIT/DAERA. CIT/DAERA would then arrange for the details (CPHH, Name and address of holdings of birth and residence, and if necessary (e.g. if the dam of the donor is not available or it is dead), identity details of the dams of the donors to be sent to APHA, Weybridge, preferably collated and by e-mail. APHA, Weybridge will check for confirmed cases of Scrapie on the holdings where the donor rams have resided in. If confirmed cases are identified, further search will be made on the Scrapie Notification Database to determine if the Scrapie was confirmed during the time that the donors were resident on the holding and whether they are the progeny of any dam/sire confirmed with scrapie. If satisfactory, an APHA/DAERA veterinarian will then complete paragraph III of the 7852SPTs. The submission

of the form(s) to CIT/DAERA must be made in good time to allow the search to be completed before paragraph 10.7 a) and b) could be signed.

7. <u>Clinical Examination</u>

Paragraph 10.7 c) refers: Clinical examination of the donor animals is required on the day the semen for export is collected, and also to ensure compliance with Council Directive 92/65/EEC (as amended) in Great Britain or Regulation (EU) 2020/686 in Northern Ireland.

8. Laboratory/Tuberculin Tests and isolation of donors prior to movement/transport to the SCC (pre-entry quarantine) and following their return

Paragraphs 10.8 and 10.9 refer: Samples should always be submitted to a government or government authorised laboratory in good time to allow reports to be received in advance of the export date. For example, tests can be performed at APHA Weybridge or AFBI (or Pirbright Institute for BTV/EHD testing). If in doubt as to the length of time a test is likely to take, Centre Veterinarians should seek the advice of the relevant laboratory. (The footnotes in the certificate indicate the test options available for 10.8 for B. melitensis/abortus and ovis, the CFT is the test of choice, but note the different cut-offs.)

All samples and tests must be taken/carried out by or under the supervision of the Centre Veterinarian or delegated to an authorised Official Veterinarian (OV) appointed to the appropriate panel for export purposes by Defra, the Scottish Government or the Welsh Government or DAERA, or who holds the appropriate Official Controls Qualification Veterinary) OCQ(V)EX and OCQ(V)TB authorisation.

Isolation / Pre-entry quarantine and Tests for tuberculosis/ Brucellosis and contagious epididymitis:

Being seasonal breeders, most donor rams are unlikely to be permanent residents of the SCC. In which case, the first or third option at Paragraph 10.8 will need to be certified. The **first option**, requires the flock of origin of the donor rams to be tested twice, 60 days apart, the first test within 12 months prior to entering the SCC and the second test during the 30 days preentry isolation.

It is impractical to test the whole flock, so an alternative is to certify the third option for donor animals isolated for 120 days from the flock of origin in the holdings/farms/SCC before intended first collection of semen in SCC. This requires a sub-population of donor ram/s to be created by isolating it/them for at least 120 days and test/sample them twice - the first at the start of the 120 day pre-entry isolation and the second at least 60 days later and within 30 days prior to the intended first collection of semen. The centre veterinarian may delegate the approval and supervision of the isolation/quarantine units on holdings/farms/SCC to an OV appointed to the appropriate panel for export purposes by Defra, the Scottish Government or the Welsh Government or DAERA, or who holds the appropriate Official Controls Qualification (Veterinary) (OCQ(V)EX and OCQ(V)TB) authorisation. The OV must ensure the criteria/instructions in 7852NFGI are met and the appropriate requirements in 7852SPT certified on this basis. The OV must include the address of the SCC and date of entry into the SCC if the 120 day isolation period is to continue in the SCC. Also, a tuberculin test is required 30 - 120 days after collection of semen for donor animals originating from such subpopulations.

For tuberculosis, donor animals must be subjected to a single intradermal test using bovine tuberculin, with negative results (negative means no increase in skin thickness and no oedema when the test is read at 72 hours).

Instructions/guidance for carrying out the test can be found at http://ahvla.defra.gov.uk/External OV Instructions/TB Sheep Instructions/Skin Test/index.htm. It must be noted that any positive bovine reaction in

accordance with the UK interpretation (i.e. a reaction of more than 2mm) must be reported to APHA/DAERA. However, a comparative (using both bovine and avian PPD / tuberculins) test may be carried out (and the avian reaction ignored for export purposes) to inform how the reaction is interpreted for domestic purposes: if the positive bovine reaction is equal to or less than the avian reaction then it does not require reporting to APHA/DAERA; if otherwise it should be reported to APHA/DAERA.

For brucellosis/contagious epididymitis, tests for both B. melitensis/abortus and B. ovis are required.

The appropriate statements in 7852SPT must be certified on the above basis. This also requires certification that no clinical, microbiological, or serological evidence of brucellosis and bovine tuberculosis has been found at the flocks/herds on which the donors were isolated during the 24 months prior to movement to the SCC.

Pre- and Post-collection tests for Schmallenberg Virus

A serum neutralisation test (SNT) is required. APHA Weybridge refer to the SNT as the VNT (virus neutralisation test) on current lab submission forms, this can be confirmed with the laboratory when required. The submission form accompanying the samples to the laboratory must specify the test as well as the cut-off which is 1:16. The post collection test may be carried out at the SCC or the donor animal may be returned after collection to a holding/farm, in which case it must be isolated / supervised by an OV in accordance with the criteria/instructions in 7852NFGI, and the appropriate statements in 7852SPT must be certified on this basis.

Transport of donors to and from the SCC

It is important to ensure that the health status of the donors is not compromised during movement to the SCC and also from the SCC if the post collection testing is to be carried out on a holding/farm. The centre veterinarian/OV must ensure the transporter certifies the appropriate statements in 7852SPT.

Herd level clinical freedom of Maedi Visna (MV) or Caprine Arthritis Encephalitis (CAE)

Paragraph 10.10 refers to the donor animals originating from premises where MV/CAE have not been clinically detected in the last three years prior to collection. This also includes no contact with animals with the clinical disease prior to collection of the semen to be exported. The health attestation refers to clinical detection/evidence but not test/serological evidence.

The appropriate statement in 7852SPT must be certified on the above basis by the owner/farmer and endorsed by the OV, to support the centre vet to certify 10.10 in section A of the EHC.

9. <u>Sealing of shipping container</u>

Paragraph 15.13 refers. This requires the shipping container to be sealed with an official seal (to reflect the USDA requirement that the seal has to be a 'government seal'). As the UK (Defra) does not have any government seals for Animal Health purposes, this should be taken to mean a seal with a unique identification number/code which when applied will ensure the integrity of the contents in the shipping container. The seals intended for shipments to the USA must be discussed with, and approved by, an APHA/DAERA veterinarian. Such seals can then be accepted as 'official/government' seals. The seals must be applied by, or under the supervision of, the certifying APHA/DAERA veterinarian.

10. Disclaimer

The DEFRA disclaimer (Form 372DMR) will be issued to the exporter with this certificate for his/her information. The certificate is provided on the basis of information available at the time and may not necessarily comply fully with the requirements of the importing country. It is the exporter's responsibility to check the certificate against any relevant import permit or any advice provided by the competent authority in the importing country. If these do not match, the exporter should contact the International Animal Health Division via the appropriate address in the link given below.

https://www.gov.uk/government/organisations/animal-and-plant-healthagency/about/access-and-opening#centre-for-international-trade-carlisle