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

NOTES FOR THE GUIDANCE OF VETERINARIANS AND EXPORTERS

Associated Documents: 8746EHC, 8746SPT, 8746NFGi

1. **Scope of the Certificate**

This certificate covers the export of in vivo derived ovine/caprine embryos and oocytes to the United States of America. **The certificate refers to exports from either Great Britain or Northern Ireland.** Ovine/caprine embryos/oocytes collected in both Northern Ireland and Great Britain and exported under one certificate is not permitted. The ovine/caprine embryos/oocytes 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 retained Regulation (EU) No 999/2001 need to be complied with. 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. 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 Approved Embryo Collection Team 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 8746EHC need to be met, especially in relation to tuberculosis and brucellosis which requires that the donors (and sires where natural service or fresh semen is used) have been subjected, with negative results, to tests during the timeframes indicated - the first within 30 days prior to collection and the second between 30 and 120 days after collection. 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 collection unit, support certification (8746SPT is available). **8746SPT** provides documentary evidence to the Team Veterinarian that the tuberculosis/brucellosis and maedi-visna requirements have been met at the flocks/herds of residence of the donor. In relation to scrapie, 8746SPT 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 8746SPT must still be completed in the UK as well.

Furthermore, please note, both 8746SPT and 7852/8746 SPT-SUP are internal support documents to facilitate export certification. They are not required to accompany the 8746EHC to USA.

2. **Signatories - certification by the Team Veterinarian and Official Veterinarian**

The health certificate must be signed covering paragraphs 10-14 in Section A of Part D by the Team Veterinarian (i.e. Authorised Ovine Embryo Collection Team Veterinarian). An APHA/DAERA veterinarian must complete/sign the certificate at paragraphs 15-18, Section B of Part D.

Please note: Section B of Part D of 8746EHC 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 APHA Centre for International Trade – Carlisle (CITC), or, in the case of Northern Ireland, the Department of Agriculture, Environment and Rural Affairs (DAERA), Dundonald House, Belfast, to arrange countersignature.

The 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 CIT, Carlisle, 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 APHA 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 **OTHER THAN BLACK**.

Some requirements in Section B will require support certification from the EC veterinarian – e.g. 15.9, 15.10, 15.11, 15.12 and 15.15.

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 globally in 2011.

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 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/ampoules 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 embryos/oocytes by an official veterinarian while in storage at 15.12 can be certified on the basis that the Ovine Embryo Collection Team 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 8746EHC 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

8746EHC and notify CIT/DAERA if discrepancies are found.

4. **Notifiable disease clearance**

The EC veterinarian may certify paragraphs 10.2.8 (Brucellosis and TB), 11.2.1.4.1 (BTV), 11.2.1.5.1 (EHD) based on a 618NDC authorisation.

Please note, regarding 11.2.1.4.1 (BTV) or 11.2.1.5.1 (EHD) 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 collection. GB/NI must be free of BTV/EHD (i.e. no evidence of serological infection exists) for 12 months prior to and during 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 collection.

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

For embryos collection in GB, the Embryo Collection (EC) Team 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-embryo-collection-approved-premises/ovine-and-caprine-embryo-collection-and-production-teams

For embryos collection in NI, the Embryo Collection Team must be approved in accordance with Regulation (EU) 2020/686 and listed on the EU website/TRACES: https://ec.europa.eu/food/animals/embryos-oocytes-embryos/ovine-caprine_en

6. **Scrapie Requirements**

6.1 Paragraph 11.1 refers - If the EC veterinarian is not the veterinarian overseeing the holdings where the donors had resided on since birth, due enquiries must be made to enable sub-paragraph 11.1.2 of paragraph 11.1 to be certified. 8746SPT has been created for this and the procedure described at paragraph 6.2 below should be followed to complete it. Sub paragraph 11.1.1 can be crossed out as the UK is not yet officially recognised by APHIS as scrapie free or with an equivalent scrapie flock certification program.

6.2 Paragraph 11.1.2 must be corroborated by conducting a thorough search of Defra's *Scrapie Notification Database (SND)*, and additionally 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 and/or ARR/ARQ and/or ARQ/ARQ genotype. 11.1.2.1 refers to parent genotyping so that the resulting embryo is AARR or AAQR genotype. The laboratory reports confirming the parents (dam and sire) genotypes must accompany the 8746EHC to USA. One parent must be ARR/ARR and the other parent has to be either ARR/ARR or ARR/ARQ or ARQ/ARQ, so that in such a way the embryos produced will be **AARR** or **AAQR** genotype. Testing maybe performed at official laboratories, such as SRUC and APHA laboratories. The reports must include a reference and explanation of the relevant codons. If the parents are not of such genotypes or for all caprine embryos, 11.1.2.2 should be certified.

SND checks:

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 and OCQ(V)TB, must complete form 8746SPT for submission to Carlisle CIT.

Close liaison with the EC Veterinarian is required to ensure that the movement of the other donors to the Embryo/Oocyte Collection Unit can be co-ordinated

since an all-in / all-out procedure may be necessary; the OV may choose to use the EC Veterinarian to submit requests for clearances, in which case the EC Veterinarian must submit 8746SPTs for all the donors (from which embryos are intended for certification) to CIT. CIT would then arrange for the details: CPH, Name and address of holdings of birth and residence, and if necessary (e.g. if the sire and dam of the donor are not available or are dead), identity details of the sires and 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 donors 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 8746SPT. The submission of the form(s) to CIT must be made in good time to allow the search to be completed before paragraph 11.1 could be signed.

7. **Clinical Examination**

Paragraphs 10.2.3 and 10.2.5 refers - Clinical examinations of the donor animals are required during the 30 days prior to collection and again on the day of embryo collection to ensure compliance with Council Directive 92/65/EEC (as amended) in GB or Regulation (EU) 2020/686 in NI.

8. **Embryo/oocyte processing**

Paragraph 11.3.3. refers to in vivo embryos only. If export is of oocytes only, it can be deleted.

9. **Semen used for embryo production**

Paragraph 10.2.2 refers to semen that has been collected at approved semen collection centres and used for artificial insemination. If natural service has been performed, 10.2.2 can be crossed out.

Please note, if frozen semen is used it must comply with the conditions in the ovine/caprine semen to USA EHC (7852EHC). If fresh semen or natural service is used, then such semen must be compliant with the relevant conditions in the ovine/caprine embryo to USA certificate (8746EHC).

10. **Laboratory/Tuberculin Tests and isolation of donors prior to movement/transport to the Embryo Oocyte Collection Unit (EOCU) and following their return**

Paragraph 11.2 refers - Samples should always be submitted to a government or government authorised laboratory (APHA Weybridge or AFBI) in good time to allow reports to be received in advance of the export date. If in doubt as to the length of time a test is likely to take, EC Veterinarians should seek the advice of the relevant laboratory. From the test options available for 11.2.1.1 and 11.2.1.2 for *B. melitensis/abortus* and *B.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 EC 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 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:

Tuberculosis Paragraph 11.2.1.3 refers - For export purposes, donor animals must be subjected to two intradermal tests at least 60 days apart, using bovine tuberculin, with negative results (negative means no increase in skin thickness and no oedema when the test is read at 72 hours). The first test being within 30 days prior to collection and the second test between 30-120

days after collection.

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 / tuberculin) 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 8746SPT must be certified on the above basis, by the appointed OV, to support certification of the relevant attestations (e.g. 10.2.6, 10.2.7, 10.2.8, 11.2 testing options) in 8746EHC.

Pre- and Post-collection tests for Schmallenberg Virus

Paragraph 11.2.1.6.2 - 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 EOCU 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 8746NFGI, and the appropriate statements in 8746SPT must be certified on this basis.

Transport of donors to and from the Embryo/oocyte Collection Unit (EOCU)

It is important to ensure that the health status of the donors is not compromised during movement to the EOCU and also from the EOCU 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 8746SPT.

11. **Sealing of shipping container**

Paragraph 15.4 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 US 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.

12. **OOCYTE/EMBRYO COLLECTION AREA - at Embryo/oocyte Collection unit (EOCU), on farm or another location approved by the ET Veterinarian**

Paragraph 10.1.2 refers - Goat and sheep embryos and oocytes are eligible for exportation to the United States if they were conceived, collected, processed, and stored prior to exportation at an embryo collection unit approved by the ET veterinarian. The embryo/oocyte collection may be carried out on the premises where the donor dam's herd of origin is kept, and/or at any other location, provided that the following USA requirements are met (as referred to in the USDA APHIS Import Protocol), which must be verified and approved by the ET veterinarian before collection begins:

a) **Animal holding and breeding area(s).** The EC facility has an area or areas for holding the donor dams and for breeding them (either by natural breeding or artificial insemination).

b) **Embryo collection area.** The EC facility has a room or outdoor area for collection of embryos/oocytes that contains a device or devices for restraining goats and sheep during embryo/oocyte collection. If the EC area is a room, then the floor, walls, and ceiling are impervious to moisture (i.e. waterproof and can withstand repeated cleaning and disinfection). If the EC area is an outdoor area, then the area has a floor that is impervious to moisture and is constructed of materials that can withstand repeated cleaning and disinfection. If the outdoor area also has walls or a roof, the walls or roof also are impervious to moisture (i.e. waterproof) and constructed of materials that can withstand repeated cleaning and disinfection.

c) **Embryo processing area.** The EC team utilizes an enclosed room (which may be a separate mobile facility) that is used only for processing embryos/oocytes. The walls, floor, and ceiling of the room are impervious to moisture (i.e. waterproof) and constructed of materials that can withstand repeated cleaning and disinfection. The room contains a work surface for handling the embryos/oocytes, such as table or countertop that is impervious to moisture. The room also contains a microscope with a minimum of 50x magnification and equipment for freezing the embryos.

d) **Embryo/Oocyte storage area.** The EC area has a lockable storage tank that is used only for storing frozen embryos/oocytes intended for exportation to the United States.

e) **Area for cleaning and disinfection or sterilizing equipment.** The EC team utilizes an enclosed room for cleaning and disinfecting or sterilizing equipment used for the artificial insemination or for the collection, processing, or storage of embryos/oocytes. The walls, floor, and ceiling of the room are impervious to moisture (i.e. waterproof) and constructed of materials that can withstand repeated cleaning and disinfection.

13. **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-health-agency/about/access-and-opening#centre-for-international-trade-carlisle