Intra-Union Trade in Ovine/Caprine Ova/Embryos

Notes for Guidance of Certifying Veterinarians and Exporters
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1. **Key Documents**

The following key documents must be read and understood prior to completing and signing the Intra-trade Animal Health Certificate (ITAHC) for ovine/caprine ova/embryos.

- Ovine-Caprine-Ova-Embryos-NFG
- Ovine-Caprine-Semen-Embryos-SUP
- Ovine-Caprine-NDR
- Ovine-Caprine-Ova-Embryos-CKL

In the case of embryos, the semen used for fertilisation must meet the requirements of Council Directive 92/65/EC (as amended). A fully completed Ovine-Caprine-Semen-CKL for the semen in question will provide this evidence, provided that the semen has been stored in an EU approved store prior to insemination.

2. **Notifiable Disease Clearance (NDC)**

Official Veterinarians may certify the following paragraph of Ovine-Caprine-Semen-Embryos-SUP on behalf of the Department provided a written authority to do so has been obtained from Centre for International Trade (CIT) – Exports, Carlisle on form SUP NDC:

**Part II.3**

The SUP NDC can be requested using Ovine-Caprine-NDR

3. **Scope**

This Intra trade Animal Health Certificate (ITAHC) must be used for the export of ovine/caprine ova/embryos to another Member State.

There are two different ITAHCs available for export, as follows:

Part A (model health certificate IVA from Decision 2010/470/EU, as amended by Decision 2014/802/EU to enable embryos carrying at least one ARR allele to be certified if collected after 1 January 2015): This is for ova / embryos collected after 31 August 2010. Any collections after 1 July 2013 must be in accordance with the revised scrapie requirements. Any collections made after 1 January 2014 will need to be certified in accordance with the revised scrapie requirements, which if made on or after 1 January 2015 could be ARR heterozygote embryos.

Whilst this guidance focuses on Part A, the requirements that donor females had to comply with for germplasm collected before 1 September 2010 (i.e. before the amendments introduced by Decision 2010/470/EU came into force on 1 September 2010) are the same, Part B can be signed on a similar basis. Furthermore, the guidance focuses on in-vivo derived embryos as most embryos traded are so derived. It is assumed that the Team Veterinarian and the certifying Official Veterinarian is/are conversant with the procedures advocated by the International Embryo Transfer Society (IETS).

From 1 July 2013, the scrapie requirements for intra-Union trade in breeding sheep/goats as set out in Annex VIII of Regulation (EC) No 999/2001 (as amended)) were aligned more closely
with the recommendations of the OIE. However, for semen and embryos, they were essentially the same i.e. the embryos could either be ARR/ARR homozygote or in the case of collections after 1 January 2015, ARR heterozygote OR the donors belong to a holding with at least a Controlled or Negligible Risk status for classical scrapie.

Germplasm collected under the revised scrapie requirements (which will be obligatory from 1/1/2014) should be certified using 2010/470 as amended by 2014/802 certificate. Part B certificate is for germplasm collected before 01/09/2010 and remains unchanged.

**Bluetongue**

Great Britain is officially free from bluetongue from 05 July 2011 so does not have to meet the additional requirements set out in Commission Regulation (EC) No 1266/2007. However, in the case of semen, ova and embryos collected between 3 August 2007 and 05 July 2011, the donors need to be tested and certified as they would have been collected whilst GB was in a restricted zone. The bluetongue NFG provide further detail.

4. **Certification by an Official Veterinarian**

The final certificate may be signed by an OV appointed by the Department for Environment, Food and Rural Affairs, the Scottish Government or Welsh Government who is on the appropriate panel for export purposes. OVIs should affix the OV stamp to the certificate in the normal manner in any ink colour other than black. A copy of the signed certificate must be faxed to the CIT – Exports, Carlisle on the day of issue. (e.g. the TRACES pre-certificate as in paragraph 12 below, or the Ovine-Caprine-Ova-Embryo-CKL) from the Team Veterinarian. The Team Veterinarian and the Collection Team must be approved in accordance with Council Directive 92/65/EEC. Exports of ovine/caprine ova and embryos to other Member States are harmonised under conditions laid down in Council Directive 92/65/EEC (as amended). Certifying veterinarians must be conversant with the provisions of the Directive.

The ova/embryos MUST be collected from sheep and goats from holdings that meet the requirements of Council Directive 91/68/EEC. The requirements concerning classical scrapie would have been met if the holding of origin complies with point 1.3.(a) to (f) of Part I of Chapter A of Annex VIII to Regulation (EC) No. 999/2001 e.g. by being registered in the SAC Consulting: Veterinary Services at Inverness, (part of the Premium Sheep & Goat Health Scheme (PSGHS) - OR the donor animals have an ARR/ARR prion protein genotype or the embryo contains at least one ARR allele if collected after 1 January 2015.

The final certificate may be signed if all the answers in the checklist Ovine-Caprine-Ova-Embryos-CKL are "YES". The checklist must be valid on the day of collection of the ova or embryos.

5. **Health requirements of donor animals – Point II.3 and II.4 of ITAHC refer**

The health requirements can be considered met if the animals admitted on to the centre are accompanied by a valid support certificate Ovine-Caprine-semen-embryos-SUP. The guidance below also applies to the completion of the support certificate.
6. Classical Scrapie Requirements – Point II.3 of ITAHC and Part II paragraph 4 of the SUP refers

Paragraph II.3 provides 4 options

The 2\textsuperscript{nd} option is not available from 1 January 2015 and 3\textsuperscript{rd} option is not applicable for exports from the UK.

Guidance for options 1 and 4 is provided below:

**Holdings** with Negligible or Controlled Risk of Classical Scrapie (1\textsuperscript{st} option refer) are listed as such through membership of the SAC Consulting: Premium Sheep and Goat Health Schemes (part of Scotland’s Rural College (SRUC) – hereinafter referred to as the SAC SMS (Scrapie Monitoring Scheme). They do not have to be kept continuously on such holdings since birth; rather, they need to be resident for at least 7 years (if negligible risk) or 3 years (if controlled risk). Member States (MSs) with a negligible risk of classical scrapie (currently Austria, Finland and Sweden) or with an approved national scrapie control programme in place (currently Denmark) would accept semen from donors animals which belong to a holding with a Controlled Risk of Classical Scrapie.

SAC SMS Negligible Risk status provides robust evidence that the holding complies with the requirements at point 1.2. (a) to (f) and (i) OR point 1.3 (a) to (f) of Section A of Chapter A of Annex VIII to Regulation (EC) No 999/2001.

**Option 4:** ARR/ARR homozygote OR ARR heterozygote embryo
This option can be certified if the embryos are of the ARR/ARR prion protein genotype or in the case of collections on or after 1 January 2015, the contain at least one ARR allele as defined in Annex I to Commission Decision 2002/1003/EC and their holding of origin is not subject to any official – e.g. CSFS - restrictions for scrapie. If such restrictions are in place, movement of such sheep, including for trade, will not be allowed.

The genotyping must be either carried out at a government laboratory (APHA) or SAC / SRUC OR the individual sheep for intra-Union trade must have a genotyping certificate issued under the National Scrapie Plan (NSP) or the Compulsory Scrapie Flocks Scheme (CSFS) by a laboratory which is* / was* authorised by the government to carry out genotyping under the plan/scheme. Any such genotyping certificates issued under the scheme/plan before it/they closed remain valid, but the OV must ensure that the identification of the animal as recorded on the genotyping certificate correlates with the official ear tag on the animal as recorded on the ITAHC; if only the electronic identification number is recorded on the genotyping certificate, then the OV must scan and check the electronic identification of the sheep to confirm correlation between the certificate, the sheep and the official ear tag number on the ITAHC. Unless genotyping was carried out officially under the NSP or CSFS, all blood samples for genotyping must be taken by a veterinary surgeon.

6.1 Other Health Requirements

Paragraph II.1 and 2 of ITAHC and Part II Paragraph 3 of SUP refers.

The other health requirements to be met are those applicable to the intra-Union movement of breeding sheep and goats as set out in Articles 3, 4 and 5 of Council
Directive 91/68/EEC. These can be considered met if the animals admitted on to the centre are accompanied by a valid support certificate Ovine-Caprine-semen-embryos-SUP.

7. Official Identification

Paragraph 2 of Part II of Ovine-Caprine-Semen-Embryos-SUP refers.

Donor animals must be double identified by two ear-tags or two means of identification, both bearing the same unique identification number consisting of “UK” followed by the flock/herd number of the natal holding and the individual animal ID number, for example UK 123456 00001, where 123456 is the flock/herd number of the holding on which the animal was born. The numbers must be visible.

For animals born, or identified for the first time, after 31/12/2009, one of these means of identification must be electronic (electronic ID – EID), either an electronic eartag or bolus. EID numbers have a 12-digit format consisting of the unique 6-digit flock number (preceded by a zero), followed by a 5-digit animal number. UK EID tags will be yellow, and will have the unique letters and numbers printed visually on the tag. This information is programmed into the chip in the EID tag (or other EID device), so that when the EID tag is scanned with a reader, it will display the number printed on the tag, although ‘UK’ will display as ‘826’ - the internationally recognized code for the UK. If bolus, is used the match up must be black.

For animals identified before 31 December 2009 (where the likelihood is that they will not have been electronically identified), exporters are recommended to confirm with their importers in the MSs of destination that they are prepared to accept animals which are not electronically identified. Some Member States have introduced retrospective EID domestically and it is possible that the importer is not prepared to accept animals which are not electronically identified. If this is the case, electronic identifiers can be applied in accordance with the requirements laid down in the Sheep and Goats (Records, Identification and Movements) (England) Order 2009 as amended. Please refer to the Defra guidance for further information:

8. Collection and processing of in vivo derived embryos

In vivo derived embryos shall be conceived as a result of artificial insemination with semen meeting the requirements of Directive 92/65/EC (as amended) and shall be collected, processed and preserved in accordance with the following:

8.1. Embryos shall be collected and processed by an approved embryo collection team, without coming into contact with any other batch of embryos not complying with the requirements of this Directive.

8.2. Embryos shall be collected in a place, which is separated from other parts of the premises or holding where the embryo is collected and which shall be in good repair and constructed with materials which permit its effective and easy cleansing and disinfection.

8.3. Embryos shall be processed (examined, washed, treated and placed in identified and sterile straws, ampoules or other packages) in either a permanently sited laboratory or a mobile laboratory, which, as regards susceptible species, is situated in an area in which there has been no outbreak of foot-and-mouth disease for the past 30 days within a 10 kilometre radius.
8.4. All equipment used to collect, handle, wash, freeze and store embryos shall either be sterilised or properly cleansed and disinfected prior to use according to the IETS Manual, or be single-use equipment.

8.5. Any biological product of animal origin used in the media and solutions for collection, processing, washing or storage of embryos shall be free of pathogenic micro-organisms. Media and solutions used in the collection, freezing and storage of embryos shall be sterilised by approved methods according to the IETS Manual and handled in such a manner as to ensure that sterility is maintained. Antibiotics might be added, when appropriate, to collection, processing, washing and storage media according to the IETS Manual.

8.6. The cryogenic agents used for preservation or storage of embryos shall not be previously used for other products of animal origin.

8.7. Each embryo straw, ampoule or other package shall be clearly identified by labels according to the standardised system according to the IETS Manual.

8.8. The embryos shall be washed according to the IETS Manual and have an intact zona pellucida before and immediately after washing. The standard washing procedure shall be modified to include additional washes with the enzyme trypsin, according to the IETS Manual, when inactivation or removal of certain viruses is required.

8.9. Embryos from different donor animals shall not be washed together.

8.10. The zona pellucida of each embryo shall be examined over its entire surface area at not less than 40 × magnification and certified to be intact and free of adherent material.

8.11. Embryos of a batch that has successfully undergone the examination set out in point 8.10 shall be placed in a sterile straw, ampoule or other package marked in accordance with point 8.7 which shall be sealed immediately.

8.12. Each embryo shall, where appropriate, be frozen as soon as possible and stored in a place which is under the control of the team veterinarian.

8.13. Each embryo collection team shall submit for official examination for bacterial and viral contamination routine samples of non-viable embryos or ova, flushing fluids or washing fluids resulting from its activities according to the IETS Manual.

8.14. Each embryo collection team shall keep a record of its activities in respect of embryo collection for a period of two years after the embryos have been the subject of trade or import, including: (a) the breed, age and individual identification of the donor animals concerned; (b) the place of collection, processing and storage of embryos collected by the team; (c) the identification of the embryos together with details of the consignee of the shipment.

9. **Storage of embryos**

9.1. Each embryo collection and production teams shall ensure that the embryos are stored at suitable temperatures in an approved storage premises. Such a premises (which can be part of a semen storage centre) must be available to the team, and shall:

9.1.1 comprise at least one lockable room for the storage of ova and embryos;

9.1.2 be easy to cleanse and disinfect;

9.1.3 have permanent records of all incoming and outgoing ova or embryos;
9.1.4 have storage containers for ova and embryos which are stored in a place which is under the control of the team veterinarian and which is subject to regular inspections by an official veterinarian;

9.2. Frozen embryos shall, prior to dispatch, be stored in approved conditions for a minimum period of 30 days from the date of their collection or production.

10. **Transport of embryos**

10.1. Embryos to be subject for trade shall be transported to the Member State of destination in containers which have been cleansed and disinfected or sterilised before use, or are single-use containers, and which have been sealed and numbered prior to dispatch from the approved storage premises.

10.2. The straws, ampoules or other packages shall be marked in such a way that the number on the straws, ampoules or other packages coincides with the number on the ITAHC and with the container in which they are stored and transported.

11. **Completion of ITAHC**

Having completed all the checks, ensuring the ITAHC is fully completed and all the appropriate deletions and/or additions have been made, the Official Veterinarian must sign and stamp the ITAHC with the Official Veterinarian’s official stamp in ink of any colour other than black. The completed ITAHC will accompany the consignment to its final destination.

12. **Final certification by independent Official Veterinarian**

In cases where there may be a conflict of interest for the AVS, the final ITAHC must be certified by an independent Official Veterinarian (OV) appointed to Panel 1N. The Official Veterinarian (OV) must not have a conflict of interest.

13. **Cancellation or Changes to the Consignment Details following Certification**

Any amendments to Part I of the ITAHC, e.g. changes in identification numbers of animals in the consignment, must be clearly indicated so that the necessary changes can be made by the APHA office before electronic validation.

If the consignment is

- cancelled, or
- its date/time of departure has changed significantly, or
- a different vehicle is used, or
- amendments to identification of the consignment

the exporter must notify CIT-Exports, Carlisle by fax or email, giving details of changes, so that a replacement TRACES message can be sent.