Semen and Embryos from Sheep (Ovis Aries) and Goats (Capra hircus)

OVCAGERM GEN

10 November 2016
TITLE
Import Health Standard: Semen and Embryos from Sheep (Ovis Aries) and Goats (Capra hircus)

COMMENCEMENT
This Import Health Standard comes into force on 10 November 2016

ISSUING AUTHORITY
This Import Health Standard is issued under section 24A of the Biosecurity Act 1993.

Dated at Wellington this 10th day of November 2016.

Howard Pharo
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(acting under delegated authority of the Director-General)

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**Schedule 1 – Document History**  

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Introduction

This introduction is not part of the Import Health Standard, but is intended to indicate its general effect.

Purpose

This IHS specifies the minimum requirements that must be met when importing semen and embryos from sheep (Ovis aries) and goats (Capra hircus).

Background

The Biosecurity Act 1993 (the Act) provides the legal basis for excluding, eradicating and effectively managing pests and unwanted organisms.

Import Health Standards issued under the Act set out requirements to be met to effectively manage biosecurity risks associated with importing goods. They include requirements that must be met in the exporting country, during transit, and during importation, before biosecurity clearance can be given.

A guidance document accompanies this IHS providing information on how the requirements may be met

Who should read this Import Health Standard?

This IHS applies to importers of semen and embryos from sheep (Ovis aries) and goats (Capra hircus).

Why is this important?

It is the importer’s responsibility to ensure the requirements of this IHS are met. Consignments that do not comply with the requirements of this IHS may not be cleared for entry into New Zealand and/or further information may be sought from importers. Consignments that do not comply with the requirements of this IHS may be re-shipped or destroyed under the Act or tested/treated in accordance with this IHS prior to release or equivalence determined. Importers are liable for all associated expenses.

See guidance document for more information about importer responsibilities

Equivalence

The Chief Technical Officer (CTO) may approve measures under section 27(1)(d) of the Act, different from those set out in this IHS that may be applied to effectively manage risks associated with the importation of these goods.

See guidance document for more information about equivalence and permits.

Document History

Refer to Schedule 1.

Other information

This is not an exhaustive list of compliance requirements and it is the importer’s responsibility to be familiar with and comply with all New Zealand laws.

See guidance document for more information about inspection and verification of consignments.
Part 1: Requirements

1.1 Application

(1) This import health standard (IHS) applies to:
   a) semen from sheep (Ovis aries) and goats (Capra hircus) that is frozen and not genetically modified; and
   b) embryos from sheep (Ovis aries) and goats (Capra hircus) that are frozen, not genetically modified, in vivo derived and non-cloned.

(2) This IHS applies to imports of semen and embryos from all countries.

1.2 Outcome

(1) The outcome this IHS is seeking to achieve is the effective management of biosecurity risks associated with eligible consignments of semen and embryos from sheep (Ovis aries) and goats (Capra hircus).

(2) The biosecurity risk organisms associated with semen and embryos from sheep (Ovis aries) and goats (Capra hircus) that are managed by the requirements of this IHS are:
   a) Bluetongue virus
   b) Capripox virus
   c) Foot and mouth disease virus
   d) Jaagsiekte sheep retrovirus
   e) Maedi-visna virus
   f) Peste des petits ruminants virus
   g) Rift Valley fever virus
   h) Wesselsbron disease virus
   i) Brucella melitensis
   j) Leptospira serovars
   k) Mycoplasma capricolum subsp capripneumoniae
   l) Mycoplasma agalactiae
   m) Mycobacterium caprae
   n) Chlamydophila spp.
   o) Coxiella burnetii
   p) Scrapie.

1.3 Incorporation by reference

(1) The following international standards are incorporated by reference in this IHS under section 142M of the Act:

(2) The following MPI material is incorporated by reference in this IHS under section 142M of the Act:
1.4 Definitions

(1) For the purposes of this standard and the attached guidance document, terms used that are defined in the Act have the meanings set out there. The Act is available at the following website: http://www.legislation.govt.nz/.

(2) See Schedule 2 for additional definitions that apply.

1.5 Exporting country systems

(1) Semen and embryos to which this IHS applies may only be imported from a country where the Competent Authority has provided the following evidence to the satisfaction of the CTO:
   a) The verifiable animal health status of ovine and caprine populations in the exporting country or zone, with respect to biosecurity risk organisms of concern.
   b) The national systems/programmes and standards in the exporting country for regulatory oversight of livestock and semen and embryo collection.
   c) The capabilities and preferences of the exporting country’s Competent Authority with respect to achieving equivalent outcomes to requirements stated in the IHS.

(2) Once satisfied with the exporting country systems, MPI and the Competent Authority may commence negotiation of a country-specific veterinary certificate.

MPI reserves the right to perform an in-country or desk-top audit at any time, including prior to the first shipment of semen or embryos.

See guidance document for more information about exporting country systems and certification.

1.6 Diagnostic testing, vaccination, and treatment

(1) Any laboratory conducting any pre-export or surveillance testing where required by this IHS must be approved by the Competent Authority of a country approved to export to New Zealand.

(2) Laboratory samples must be collected, processed, and stored in accordance with the recommendations in the Code and/or the Manual or as described in the MPI Approved Diagnostic Tests, Vaccines, Treatments and Post-Arrival Testing Laboratories for Animal Import Health Standards (MPI-STD-TVTL).

(3) Diagnostic test(s) used must be listed in and carried out in accordance with MPI-STD-TVTL.

(4) All products and vaccinations administered to meet the specific disease requirements in Part 2 must be administered according to the manufacturer’s instruction in a country approved to export to New Zealand. All vaccinations were either the final dose of a primary course or the recommended booster to complement the primary course.

(5) All product names, manufacturers, active ingredients (where applicable), dose and date of treatment must be recorded on the veterinary certificate.

(6) All vaccine names, whether they are inactivated or modified live virus, and the virus types and strains included in the vaccine must be recorded on the veterinary certificate.
See guidance document for more information about diagnostic tests and vaccination.

1.7 Embryo collection team and flock/herd requirements

(1) At the time of collection of embryos for export to New Zealand, the embryo collection team must be approved by and registered with the Competent Authority to collect, process, and store embryos for export.

(2) The Competent Authority must have knowledge of and authority over the embryo collection flock/herd until completion of collection and testing required by this IHS.

1.8 Semen collection facility requirements

(1) The semen collection facility must meet the conditions specified in the Code Chapter on general hygiene in semen collection and processing centres.

(2) The semen collection facility must be:
   a) approved for export by the Competent Authority.
   b) subject to regular inspection, at least every 12 months, by an Official Veterinarian.
   c) under the supervision of a semen collection facility veterinarian approved by the Competent Authority.

(3) The name and approval number of the semen collection facility must be recorded on the veterinary certificate.

(4) Donors may be transferred from one approved semen collection facility to another of equal health status without isolation or testing if all of the following requirements are met:
   a) Donors must be examined, by the approved semen collection facility veterinarian, and show no clinical sign of disease on the day of entry into the facility.
   b) Transfer must be direct.
   c) Transfer must not be through a bluetongue or Rift Valley fever infected zone, or donors must be protected from insect attack during transit.
   d) Donors must not come into direct or indirect contact with animals of a lower health status.
   e) The means of transport must be disinfected before use.

1.9 Donor health status

(1) Embryo donors must not be situated in a herd/flock that is subject to veterinary restrictions for the identified risk organisms managed in Part 2 of this IHS for at least 28 days before the first embryo collection until completion of donor testing, where required by this IHS.

(2) Semen donors must be isolated for at least 28 days at a place specifically approved for this purpose by the Competent Authority prior to admission to the semen collection facility. During this time semen donors must not be used for natural mating and must be isolated from animals not of equivalent health status.

(3) The approved embryo collection team veterinarian or semen collection facility veterinarian must ensure that the donor is free from clinical evidence of infectious diseases transmissible in semen or embryos on the day of collection.

(4) Where a specific requirement for a risk organism is met by pre-collection testing, embryo donors must be isolated from other sheep or goats not of an equivalent tested health status, from the time of the pre-collection test until completion of embryo collection for export to New Zealand.
(5) Where a specific requirement of this IHS for a risk organism is met by monitoring for clinical signs for a specified time after collection, the semen or embryos must be stored for that amount of time prior to export.

1.10 Collecting and processing

(1) Embryos must be collected and processed in accordance with the recommendations in the Code Chapter on collection and processing of in vivo derived embryos from livestock.

(2) Semen must be collected and processed in accordance with the current recommendations of the Code Chapter on collection and processing of small ruminant semen, unless indicated otherwise in Part 2 of this IHS.

(3) Embryos must have an intact zona pellucida and be free of adherent material after the final wash when examined over its entire surface at not less than 50X magnification. If any micro-manipulation is done that causes a breach of the zona pellucida, it must be done according to the procedures described in the Code and IETS Manual.

(4) All media and solutions used to produce embryos must be either sterilised by approved methods set out in the IETS Manual or commercially prepared. They must be handled in such a manner as to ensure that sterility is maintained. All biological products of animal origin used in the media and solutions must be free from pathogenic organisms including pestiviruses.

(5) Antibiotics recommended by the Code or IETS Manual and listed in MPI-STD-TVTL must be added to embryo collection, processing, washing and storage media and to the semen diluent in accordance with the Code. The names of antibiotics added and their concentration must be stated on the veterinary certificate.

1.11 Storage

(1) The cryogenic or cooling agent used in the freezing process, storage, and transport must not have been used previously in association with any other product of animal origin.

(2) Dry ice and associated equipment to process semen pellets must be managed to prevent contamination with semen of donors not of equivalent tested health status.

(3) Semen and embryos must be in straws or sanitised containers which are sealed and tamper-evident, and clearly and permanently marked to identify the donor and the date(s) of collection. If a code is used for this information, its decipher instructions must accompany the consignment. The marking must, in accordance with the Code, conform to the international standards of the IETS or to the international standards of the International Committee for Animal Recording. See guidance document for more information about semen containers.

(4) Semen and embryos must only be stored with semen or embryos that have been collected and processed in accordance with the Code. Containers must be held in a storage place approved by the Competent Authority of the exporting country until the time of export.

(5) Semen and embryos may be stored in a third country (other than the country of origin) if the third country has met the requirements of section 1.5 of this IHS. The consignment of semen and embryos must be accompanied by:

   a) a declaration from the Competent Authority of the third country, linking the semen and embryos from the country of origin to the semen and embryos being exported to New Zealand and confirming that the semen and embryos have been stored as required by the IHS, at a facility approved by the Competent Authority; and either

      i) the veterinary certificate (current version) certified by the country of origin to export to New Zealand; or
ii) A letter from the country of origin’s Competent Authority indicating that the semen and embryos meets New Zealand’s current import requirements.

1.12 Transport

(1) Transport containers must be disinfected and free of contamination. When the transport container is not new, the disinfectant, its active chemical and date of disinfection must be recorded on the veterinary certificate.

(2) The transport container in which semen and embryos is transported to New Zealand must be sealed, by either the semen facility or embryo collection team veterinarian or an Official Veterinarian, using tamper-evident seals. The seal number must be recorded on the veterinary certificate.

(3) Where semen or embryos are transferred from one transport container to another, the date of transfer, approved collection facility or flock/herd, reason for transfer, and name of veterinarian involved in the transfer must be recorded on the veterinary certificate.

1.13 Permit to import

(1) A permit to import is required. Applications must be submitted to MPI prior to importation.

(2) The importer must supply the following information to obtain a permit:
   a) The name and address of exporter
   b) The date of proposed importation
   c) Name and address in New Zealand to which the semen and embryos is to proceed following biosecurity clearance
   d) Port of arrival

(3) Permit to import semen and embryos application forms can be found on the MPI website.

(4) Completed applications can be submitted to Animal Imports animalimports@mpi.govt.nz.

1.14 The documentation that must accompany goods

(1) The semen and embryos must arrive in New Zealand with:
   a) A permit to import (copy acceptable).
   b) A veterinary certificate, that must include all of the following:
      i) A unique consignment identifier
      ii) Species, donor animal identification, quantity (semen/embryos)
      iii) Dates of collection
      iv) Collection facility name or embryo collection herd/flock name, date of donor entry
      v) Name and address of importer (consignee) and exporter (consignor)
      vi) Certification and endorsements that the requirements outlined in Part 1 and Part 2 of this IHS have been met
      vii) Transport container seal number and disinfection information
      viii) Name, signature, and contact details of the Official Veterinarian
      ix) All diagnostic tests, including test type, date of sampling, and results must be clearly linked to each donor and in the form of either a tabulated summary or copies of laboratory reports
      x) All products and vaccines administered to meet specific disease import requirements, including the generic name, active ingredient, dose rate, and date of treatment
      c) Original laboratory reports; copies of laboratory reports endorsed by the Official Veterinarian; or a tabulated summary of laboratory results endorsed by the Official Veterinarian must include:
         i) Unique identification for each animal, consistent with the veterinary certificate
ii) dates of sample collection
iii) test type
iv) test result.

(2) A country-specific veterinary certificate must accompany the consignment where equivalent measures have been negotiated and approved by a CTO under section 27(1)(d) of the Act. See guidance document for more information about equivalence and country-specific veterinary certificates.

(3) All documents must:
   a) be original, unless otherwise stated
   b) accompany the imported goods
   c) be in English or have an English translation that is clear and legible
   d) be endorsed on every page by the Official Veterinarian with their original stamp, signature and date or be endorsed in the space allocated and all pages have paper based alternative security features

(4) Documentation copies must be sent to the Biosecurity Inspector at the airport/port of arrival at least one working day in advance of importation.

1.15 Biosecurity Clearance

(1) A biosecurity clearance, under section 26 of the Act 1993, may be issued when the semen and embryos from sheep and goats meet all the requirements of this IHS, provided the applicable requirements in section 27 of the Act are met.
Part 2: Specified Requirements for Identified Risk Organisms

Note: requirements are for semen and embryo donors unless otherwise specified.

(1) The Competent Authority of the exporting country is required to issue a signed, stamped and dated veterinary certificate containing declarations regarding the following diseases:

2.1 Bluetongue virus (bluetongue)

(1) Donors must:
   a) be resident in a BTV free country or zone in accordance with the requirements of the Code, for at least the 60 days prior to and during collection; or
   b) be resident during the seasonally free period in a BTV seasonally free zone in accordance with the requirements of the Code, for at least the 60 days prior to collection; or
   c) be resident in a vector-proof facility for at least the 60 days prior to collection and the facility must be regularly inspected and certified as being free from Culicoides spp. throughout the period when the donors are resident; or
   d) be subjected to a BTV test in accordance with the Code requirements and listed in MPI-STD-TVTL, with negative results.

2.2 Foot and mouth disease virus (FMD)

(1) Semen and embryo imports must comply with the FMD recommendations for ruminant semen\(^1\) in the Code.

2.3 Jaagsiekte sheep retrovirus (ovine pulmonary adenomatosis)

(1) Semen donors must be resident since birth in countries where ovine pulmonary adenomatosis has not been recognised by the Competent Authority; or

(2) Semen donors have only lived in herds/flocks that include animals older than 5 years; and
   a) The herd/flock has remained free from ovine pulmonary adenomatosis based on the absence of clinical signs for at least the 5 years prior to collection and no sheep/goat from a flock/herd of inferior health status has been introduced during that period; or

(3) Semen donors must be subjected to an ovine pulmonary adenomatosis examination or test in accordance with MPI-STD-TVTL, with negative results.

2.4 Maedi-visna virus (MV)

(1) Donors must be resident since birth in countries where MV has not been recognised by the Competent Authority; or

(2) Donors must only reside with herds/flocks where MV has neither clinically nor serologically been diagnosed and where animals of inferior health status have not been introduced during the 3 years before collection for New Zealand; and
   a) Semen donors must comply with the Code Chapter on collection and processing of small ruminant semen; or

\(^1\) The OIE Code does not currently provide FMD measures for ovine or caprine in vivo embryo trade; however MPI requires the semen measures be applied to embryo imports.
b) Embryo donors must be subjected to a MV test in accordance with MPI-STD-TVTL.

2.5 Peste des petits ruminants virus (PPR)

(1) Donors must be resident in a PPR free country or zone in accordance with the Code for at least 21 days prior to and during collection; or

(2) Embryo donors must comply with the Code recommendations for embryos of small ruminants from PRR infected countries; or

(3) Semen donors must comply with the Code recommendations for semen of small ruminants from PPR infected countries; and either
   a) Donors vaccinated against PPR must have been vaccinated between 21 and 120 days prior to semen collection; or
   b) Unvaccinated donors must be tested for PPR in accordance with MPI-STD-TVTL.

2.6 Rift Valley fever virus (RVF)

(1) Donors must be resident in a RVF free country or zone in accordance with the Code for at least the 30 days prior to collection; or

(2) Donors from RVF infected countries or zones must comply with the Code recommendations for semen and in vivo derived ruminant embryos; or

(3) Donors must be held in a vector-proof facility for at least 30 days prior to and during collection and never show clinical signs of RVF. The facility must be inspected regularly and mosquito-free throughout the period when donors were resident.

2.7 Capripox virus (sheep and goat pox)

(1) Donors must be resident in a sheep and goat pox free country in accordance with the Code for at least the 21 days prior to collection; or

(2) Donors from sheep and goat pox infected countries must comply with the Code recommendations for semen from sheep and goats.

2.8 Wesselsbron disease virus (Wesselsbron disease)

(1) Donors must be resident in a country recognised by the Competent Authority as free from circulating Wesselsbron disease virus for at least the 21 days prior to collection; or

(2) Donors must be resident in an establishment where Wesselsbron disease has not been recognised for at least the 21 days prior to collection; or

(3) Donors must be tested for Wesselsbron disease in accordance with MPI-STD-TVTL.

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2 There are currently no Code sheep and goatpox recommendations for ovine/caprine embryo importation; however MPI requires the semen measures be applied to embryo imports.
2.9 *Brucella melitensis* (caprine and ovine brucellosis)

(1) Donors must be resident in a country, zone, or flock/herd that is officially free from caprine and ovine brucellosis in accordance with the Code; or

(2) Embryo donors must comply with the caprine and ovine brucellosis recommendations for importation of embryos/ova of sheep and goats in the Code; or

(3) Semen donors must comply with the caprine and ovine brucellosis recommendations for importation of semen of sheep and goats in the Code.

2.10 *Leptospira* serovars (leptospirosis)

(1) Antibiotics must be added to semen and embryos in accordance with the Code, IETS Manual, and MPI-STD-TVTL.  

See guidance document for more information about antibiotics effective against leptospirosis.

2.11 *Mycoplasma capricolum* subsp. *capripneumoniae* (contagious caprine pleuropneumonia)

(1) For goats only:
   a) Donors must be resident in a country that is free from contagious caprine pleuropneumonia (CCPP) in accordance with the Code; or
   b) For at least the 45 days prior to collection, donors did not reside in a CCPP infected zone, in accordance with the Code, and were not resident in a herd where CCPP had been officially reported during that time; and either
      i) Aliquots of semen or embryos/oocytes or collection/washing fluids from each collection must be subjected to a CCPP test in accordance with MPI-STD-TVTL, with negative results; or
      ii) Donors must be subjected to CCPP test in accordance with the OIE Code and Manual.

2.12 *Mycoplasma agalactiae* (contagious agalactia)

(1) Donors must be resident in a country recognised by the Competent Authority as free from contagious agalactia for at least the 6 months prior to collection; or

(2) Donors must be:
   a) resident for at least the 6 months prior to collection only at a premises where no case of contagious agalactia is officially reported during that time; and
   b) tested for *Mycoplasma agalactiae* in accordance with the Manual and MPI-STD-TVTL.

2.13 *Mycobacterium caprae*

(1) For goats only:
   a) Donors must be resident in a country recognised by the Competent Authority as free from tuberculosis in goats for at least the 3 years prior to collection; or
   b) Semen donors must comply with the Code Chapter on collection and processing of small ruminant semen; or
c) Embryo donors must be subjected to a single comparative tuberculin test for tuberculosis prior to entry to the collection flock/herd, with negative results; and
i) All animals in the embryo collection flock/herd must be tested prior to entry and at least annually, with negative results.

2.14 *Chlamydia abortus* (enzootic abortion of ewes)

(1) Donors must be resident in a country recognised by the Competent Authority as free from enzootic abortion of ewes (EAE) for at least the 2 years prior to collection; or

(2) Donors must comply with the *Code* Chapter on EAE for the importation of sheep and goat semen and embryos.

2.15 *Coxiella burnetii* (Q fever)

(1) Donors must never have been confirmed positive for Q fever; and either
   a) Donors must be subjected to a test for Q fever in accordance with *MPI-STD-TVTL*, with negative results; or
   b) Semen or embryos/oocytes or collection/washing fluids from each collection must be subjected to a Q fever test in accordance with *MPI-STD-TVTL*, with negative results.

2.16 Scrapie

(1) For goats only:
   a) Donors must be resident in a scrapie free country in accordance with the *Code*; or
   b) Donors must be resident in an establishment that has been maintained free from scrapie from commencement until conclusion of collection, in accordance with the *Code* recommendations for a scrapie free establishment; or
   c) Embryos must comply with the *Code* recommendations for importation of *in vivo* derived goat embryos from countries or zones not considered free from scrapie.

   *Note: Semen donors must satisfy either a) or b).*

(2) For sheep semen only:
   a) Semen donors must be resident in a scrapie free country in accordance with the *Code*; or
   b) Semen donors must be resident in an establishment that has been maintained free from scrapie from commencement until conclusion of collection, in accordance with the *Code* recommendations for a scrapie free establishment; or
   c) Semen donors must have the scrapie resistant genotypes – ARR/ARR, ARR/AHQ, ARR/ARH or ARR/ARQ. Laboratory evidence of the genotype is required.

   *Note: Section 1.10 of this IHS manages the risk for sheep embryos.*
# Schedule 1 – Document History

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Schedule 2 – Definitions

Approved embryo collection team

An embryo collection team demonstrated by the Competent Authority as having met the recommendations as described in the Code.

Competent Authority

The Veterinary or other Governmental Authority of an OIE Member, that has the responsibility and competence for ensuring or supervising the implementation of animal health and welfare measures, international veterinary certification and other standards and recommendations in the Code in the whole territory.

Donor(s)

Female animal(s) from which embryos are collected, or male animal(s) from which semen was collected.

Embryo collection flock/herd

The flock/herd the embryo donor is resident in at the time of embryo collection.

Inspection

A visual examination by an MPI Inspector to detect the presence of pests and contamination. An inspection does not require magnification but may require additional lighting if the inspection is carried out at night or within a building.

MPI

Ministry for Primary Industries

Official Veterinarian

A veterinarian authorised by the Competent Authority of the country to perform certain designated official tasks associated with animal health and/or public health and inspections of commodities and, when appropriate, to certify in conformity with the provisions of the Code Chapter for certification procedures.

OIE

The World Organisation for Animal Health

Permit to import

A permit issued by the Director General of MPI pursuant to section 24 (D)(2) of the Act.

Semen collection facility

The place where semen is collected from an animal. A semen collection facility may be within an artificial insemination centre.

The Code

The OIE Terrestrial Animal Health Code as found on the OIE website.
The IETS Manual

The International Embryo Transfer Society (IETS) Manual as found on the IETS website.

The OIE Manual

The OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals as found on the OIE website.

Vector

An insect or any living carrier that transports an infectious agent from an infected individual to a susceptible individual or its food or immediate surroundings. The organism may or may not pass through a development cycle within the vector.

Vector-proof

For the purposes of this IHS vector-proof refer to a PEI facility which provides maximum protection from insect vectors. This should be a building, ideally a compartment within a building, which should be vector screened and have risk management strategies to protect animals and the facility from any potential vector.

Veterinary certificate

A certificate, issued in conformity with the provisions of the Code Chapter for certification procedures, describing the animal health and/or public health requirements which are fulfilled by the exported commodities.