# Overseas Market Access Requirements Notification - Animal Products Act 1999

## Regulation and Assurance Branch, Animal and Animal Products Directorate, Ministry for Primary Industries

Ref: AE-EU-05
Date: 09 November 2015

**PART 2- BOVINE SEMEN TO THE EUROPEAN UNION**

## Statutory authority

Pursuant to section 60, section 60A and section 167 of the Animal Products Act 1999 I notify the following:

(i) the issue under section 60 of the Overseas Market Access Requirements Part 2 bovine semen to the European Union dated 16 November 2015;

(ii) the revocation and replacement of the Overseas Market Access Requirements Part 2 bovine semen to the European Union dated 12 August 2015;

This notice takes effect from the 16 November 2015.

Dated at Wellington this 10th day of November 2015.

Signed Howard Pharo
Manager Import and Export Animals
Animal and Animal Products Directorate
Regulation & Assurance Branch
(acting under delegated authority)

# Part 2 Bovine Semen

**Note: to be read in conjunction with Part 1: General**

## 2.1 Application

2.1.1 This Part applies to the semen of domestic bovine animals.

2.1.2 Frozen embryos may also be stored in the storage facilities of EU-listed collection centres provided that the facility is approved as an embryo collection/production team.

## 2.2 Facility requirements

2.2.1 A bovine semen collection centre must have a quarantine facility specifically approved for the purpose by MPI.

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| The requirements for the quarantine facility are audited during the approval of a pre-entry isolation facility when the semen centre is approved as an Export Approved Premises. |

2.2.2 Collection centres and quarantine facilities must be located outside Tb movement control areas, as specified by the National Pest Management Strategy for Bovine Tuberculosis.

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| Movement control areas are legally defined areas where there is a greater than normal risk of Tb infection and where extra Tb testing is compulsory prior to stock movement. |

2.2.3 Collection centres and quarantine facilities must be physically separated from neighbouring properties by a solid wall of a building, or by a distance of separation of at least five (5) metres.

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| Separation implies the centre has control of the five (5) metre separation area. |

2.2.4 Construction of collection, processing and storage facilities must be such that:

a. contact with livestock outside the centre is prevented

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| When paddocks are part of the centre, these should prevent unmanaged animal movements (be secure) and comply with the above. |

b. all rooms and facilities (except the office rooms) can be readily cleaned and disinfected

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| This is a constructional requirement; i.e. the lay-out and the materials used should allow for effective cleaning and disinfecting. In this context, office rooms imply the administration areas, including amenities. |

c. secure animal housing can be readily cleaned and disinfected, or managed effectively to prevent disease spread.

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| Where the centre and quarantine facility accommodation includes paddocks or areas that are not able to be readily cleaned and disinfected, the centre needs to have procedures to cover how this is managed effectively. |

2.2.5 Collection centres must have:

a. animal housing, including isolation facilities. The isolation facilities accommodation on the centre must not have direct communication with the normal animal accommodation

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| Direct communication means nose-to-nose contact. The normal animal accommodation refers to the non-isolation accommodation on the centre. |

b. semen collection facilities that may be open air, with non-slip flooring around the place of semen collection where required for the welfare of the animals
c. a separate room for the cleaning and disinfection or sterilisation of equipment
d. a physically separate semen processing room, which may be located off-site
e. a physically separate semen storage room, which may be located off-site.

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| Facilities located off-site should be operated with the same intensity of control as the EU listed collection centre. |

2.2.6 All areas and buildings within the perimeter of the collection centre or quarantine facility must be managed so that their status does not compromise the health status of the animals.

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| Waste areas and buildings used for storage (feed, tractor, etc.) should be kept tidy and have appropriate vermin control. |

## 2.3 Operational requirements

2.3.1 Semen collection centres must be under the permanent supervision of a centre veterinarian, approved by MPI as the competent authority.

2.3.2 Semen collection centres must be regularly inspected by a recognised person, at least twice a year, to verify the conditions of approval and supervision.

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| The verification would normally include records, standard operating procedures and internal audits, as well as compliance with the sanitary conditions regarding the collection, processing and storage of semen. Further inspections can occur in addition to the audits carried out twice a year. |

2.3.3 Collection, processing and storage of semen must be carried out hygienically and in separate facilities, designated for each respective purpose.

2.3.4 The centre veterinarian must inform the recognised person of any failure of compliance with these Export Requirements as soon as possible, and before affected semen is exported to the EU.

2.3.5 Animals of species other than those whose semen is to be collected must not be present at collection centres. Other domestic animals which are strictly necessary for the normal operation of the collection centre may nonetheless be admitted, provided that they present no risk of infection to those species whose semen is to be collected, and that they fulfil the conditions laid down by the centre veterinarian.

2.3.6 Semen must be obtained from donor animals which:

a. show no clinical signs of disease on the day the semen is collected

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| This excludes minor diseases which have no adverse effect on the requirements of these Export Requirements or cannot be transmitted through semen |

b. have not ever been vaccinated against foot-and-mouth disease
c. in the case of collections of fresh semen for export, have been kept at an approved semen collection centre for a continuous period of at least thirty (30) days immediately prior to the collection of the semen
d. have not been allowed to serve naturally

| This applies to the period from pre-quarantine testing to leaving the collection centre. |
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e. have been kept in semen collection centres which, during the period commencing thirty (30) days prior to collection and until the date of dispatch, were free from Tb and EBL.

2.3.7 Procedures and protocols must be in place for accommodation paddocks and shared facilities in the event of an incidence of any of the following diseases: any exotic disease of cattle, bovine Tb, EBL, infectious bovine rhinotracheitis/infectious pustular vulvo vaginitis (IBR/IPV), bovine viral diarrhoea/mucosal disease (BVD/MD), *Campylobacter fetus* subsp. *venerealis*, or *Trichomonas foetus*.

2.3.8 In the event of any significant disease occurrences as per 2.3.7 above, or any unfavourable test results, the centre veterinarian must inform the recognised person as soon as possible, including the status of any affected semen.

2.3.9 Feed and drinking water supplied must be so derived that it does not constitute an animal health risk.

2.3.10 Collection centres and quarantine facilities must have possum control measures, which must be located in the five (5) metre separation zone (as specified in clause 2.2.3).

2.3.11 Entry of unauthorised persons to the centre facilities must be prevented. Authorised personnel, including visitors, must comply with the conditions specified by the centre veterinarian.

2.3.12 Staff employed must be technically competent and suitably trained in disinfection procedures and hygiene techniques relevant to the control of the spread of disease.

2.3.13 All equipment which comes into contact with the semen or the donor animal during collection and processing must be disinfected or sterilised prior to use, except for single-use equipment which will be discarded after use.

2.3.14 Products of animal origin used in the processing of semen, including additives or diluents, must be obtained from sources which present no recognised animal health risk or are so treated prior to use that such risk is prevented.

2.3.15 Antibiotics as listed below must be added to produce concentrations in the final diluted semen of not less than:

- 500 µg streptomycin per ml final dilution
- 500 IU penicillin per ml final dilution
- 150 µg lincomycin per ml final dilution
- 300 µg spectinomycin per ml final dilution.

An alternative combination of antibiotics with an equivalent effect against campylobacters, leptospires and mycoplasmas can be used.

2.3.16 Immediately after the addition of antibiotics, the diluted semen must be kept at a temperature of at least 5°C for a period of not less than forty five (45) minutes.

| The contact time allows the antibiotics to continue to exert anti-microbial action before the semen is chilled to a temperature where the antibiotics may be ineffective. |
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2.3.17 Each individual dose of semen must be clearly marked in such a way that the date of collection of the semen, the breed and identification of the donor animal and the approval number of the centre can be readily established.

2.3.18 EU-eligible semen must not at any time come into contact with semen which is ineligible for the EU.

> This means that EU eligible semen should not be stored in the same room with semen or embryos that are ineligible for the EU.

2.3.19 Records must be kept of all bovine animals at the collection centre, giving details of:

a. the breed, date of birth and identification of each of the animals
b. any movement of animals entering or leaving the centre
c. a record of the health history, all diagnostic tests and results, and all vaccinations and treatments carried out on donor and teaser animals
d. the health status of the bull on the day of semen collection
e. the date of collection and processing of semen
f. the storage of semen
g. the destination of the semen.

2.3.20 Semen processed and stored in EU-listed collection, processing or storage facilities must have been collected in EU-listed collection centres. However, semen not collected in an EU-listed collection centre may be processed in EU-listed centres provided that:

a. this semen is produced from bovine animals which comply with all the animal health requirements specified in pre-quarantine testing in clause 2.5.1 of these Export Requirements
b. processing is carried out with separate equipment or at a different time from semen intended for the EU. Equipment used at different times must be cleaned and sterilised after each use
c. this semen is identifiable by a marking different than that provided for in clause 2.3.17. This semen cannot at any time come into contact with, or be stored with, semen intended for the EU.

2.3.21 Except for single-use containers, storage containers and transport containers must be either disinfected or sterilised before the commencement of each filling operation.

2.3.22 The cryogenic agent used must not have been previously used for other products of animal origin.

2.3.23 Semen must be transported to storage facilities under conditions which maintain the health status of the semen and without contact with any other semen.

2.3.24 Semen, other than fresh semen, must be stored in approved conditions for a minimum period of thirty (30) days prior to dispatch.

2.3.25 Frozen embryos may also be stored in the storage facilities of EU-listed collection centres or storage centres provided that:

a. the facility is approved by MPI as an embryo team for storage
b. the embryos comply with all EU requirements published in these Export Requirements
c. the embryos are stored in separate storage containers.

2.3.26 Semen must be exported in uniquely identified containers which have been cleaned and disinfected or sterilised before use, and which have been sealed with a uniquely numbered and tamper-proof seal prior to dispatch from the approved storage facility.

## 2.4 Procurement of donor and teaser animals

2.4.1 The donor bulls must have been born in New Zealand, or resided in New Zealand for at least six (6) months.

2.4.2 The donor and teaser animals must have spent their lifetime in herds that were:

a. officially Tb free (i.e. C2 or greater);
b. officially brucellosis free during the previous six (6) months
c. for EBL;
    i. the donors and teasers were produced by dams which have been subjected, with negative results, to an AGID or ELISA test after removal of the animals from their dam; or
    ii. if the requirements of (i) above cannot be fulfilled, the semen must not be the subject of trade until the donor has reached the age of two (2) years and has been tested using the ELISA with a negative result.

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| In the case of animals derived by embryo transfer, 'dam' means the recipient of the embryo. |

2.4.3 Movement of donor and teaser animals through pre-quarantine and quarantine, and onto the collection centre must be done on an "all in all out" basis.

## 2.5 Pre-quarantine testing

2.5.1 Within the twenty eight (28) days preceding the period of quarantine, the animals must have been subjected to the following tests with negative results in each case, except for the BVD/MD antibody testing:

a. for bovine Tb, the single intradermal test or the intradermal comparative test applied to the neck of the animal
b. for bovine brucellosis, a serological test
c. for EBL, a serological test
d. for IBR/IPV, a serological test on a blood sample if the animals do not come from an IBR/IPV free herd as defined by the OIE Code
e. for BVD/MD,
    i. a virus isolation test or a test for virus antigen, and
    ii. a serological test to determine the presence or absence of antibodies.

2.5.2 MPI may give authorisation for these pre-quarantine tests to be carried out on samples collected in the quarantine facilities, however, the period of quarantine referred to in clause 2.6.1 must not then commence before the date of sampling.

Should any of the tests, other than the BVD serological test, prove positive the animal concerned must be immediately removed from the quarantine facility. In the event of group isolation, the twenty eight (28) day quarantine period must not commence for the remaining animals until the animal which tested positive has been removed.

## 2.6 Quarantine testing

2.6.1 All bovine animals admitted to a semen collection centre must have been in quarantine for at least twenty eight (28) days in accommodation specifically approved for the purpose by MPI.

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| In the New Zealand situation, quarantine accommodation can be paddocks. |

2.6.2 Within the quarantine period, and at least seven (7) days after being admitted to quarantine, the animals must have been subjected to the following tests with negative results in each case;

a. for *Campylobacter fetus* subsp. *venerealis*:
   i. in the case of animals less than six (6) months old or kept since that age in a single sex group prior to quarantine, a single test on a sample of artificial vagina washings or a preputial specimen;
   ii. in the case of animals aged six (6) months or older that could have had contact with females prior to quarantine, three (3) tests at weekly intervals on a sample of artificial vagina washings or a preputial specimen.
b. for *Trichomonas foetus*:
   i. in the case of animals less than six (6) months old or kept since that age in a single sex group prior to quarantine, a single test on a preputial specimen;
   ii. in the case of animals aged six (6) months or older that could have had contact with females prior to quarantine, three (3) tests at weekly intervals on a preputial specimen.

2.6.3 Within the quarantine period and at least twenty one (21) days after being admitted to quarantine, the animals must have been subjected to the following tests with negative results in each case, except for the BVD/MD antibody test:

a. for bovine brucellosis, using a serological test
b. for IBR/IPV, a serological test on a blood sample
c. for BVD/MD,
   i. a virus isolation test or a test for virus antigen, and
   ii. a serological test to determine the presence or absence of antibodies.

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| Testing for BVD antibodies should still be carried out on animals that already tested positive at pre-quarantine testing. |

2.6.4 If any of the quarantine tests in 2.6.2 or 2.6.3 (apart from the BVD antibody test) are positive, the animal must be removed immediately from the quarantine facility and the other animals of the same group must remain in quarantine and be retested, with negative results, not less than twenty one (21) days after removal of the test-positive animal(s).

In the case of group isolation, the Recognised Person must take all necessary measures to re-establish the eligibility of the remaining animals for entry into the collection centre in accordance with these Export Requirements.

2.6.5 For BVD antibody testing, all animals (sero-negative or sero-positive) are allowed entry to the semen collection facilities after twenty eight (28) days if no sero-conversion has occurred in animals which tested sero-negative before entry into the quarantine facility.

If sero-conversion has occurred, serologically positive animals may be allowed entry into the semen collection facilities after twenty eight (28) days. All animals that remain seronegative must be kept in quarantine over a prolonged time, until there is no more sero-conversion in the group for a period of three (3) weeks before they are allowed entry into the semen collection facilities

2.6.6 Operators of quarantine facilities must inform the recognised person of any unfavourable test results as soon as possible, and before any animals are released from the facility.

## 2.7 Admission to collection centres

2.7.1 Animals must only be admitted to the semen collection centre with the express permission of the centre veterinarian. All inward and outward movements of animals must be recorded.

2.7.2 Animals must not show any clinical sign of disease on the day of admission.

2.7.3 All animals must, except for those that satisfy clause 2.7.4 below, have come directly from a quarantine facility which on the day of dispatch has for at least thirty (30) days been free from Tb and EBL.

2.7.4 Provided that the routine tests described in clause 2.8 have been carried out during the previous twelve (12) months, animals may be transferred from one approved semen collection centre to another of equal health status, without isolation or testing if the transfer is direct. The animals in question must not come into direct or indirect contact with cloven-hoofed animals of a lower health status, and the means of transport used must have been disinfected before use.

## 2.8 Routine testing at collection centres

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| Testing 'once a year' relates to an annual testing event of all the resident animals on the centre to confirm the disease status of the centre. |

2.8.1 All bovine animals (including teasers) kept at an EU-listed semen collection centre must be subjected at least once a year to the following tests, with negative results:

a. for bovine Tb, the single intradermal test or the intradermal comparative test applied to the neck of the animal
b. for bovine brucellosis, an EU approved serological test
c. for EBL, an EU-approved serological test
d. for IBR/IPV, a serological test on a blood sample
e. for BVD/MD, a serological antibody test which is applied only to sero-negative animals.

Should an animal become serologically positive, every ejaculate of that animal collected since the last negative test must be either declared ineligible for the EU or tested for virus with negative results.

2.8.2 All bulls on semen production or having contact with bulls on semen production, which are kept at an EU-listed semen collection centre, must be subjected at least once a year to the following tests, with negative results:

a. for *Campylobacter fetus* subsp. *venerealis*, a test on a preputial specimen
b. for *Trichomonas foetus*, a test on a preputial specimen.

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| This testing is required for bulls that are used as teasers, but is not required for steers. |

2.8.3 Before the semen is dispatched to the EU, at least twenty-one (21) days after the date of semen collection the donor bull must be subjected to the following tests, with negative results;

a. for IBR/IPV, a serological test on a blood sample
b. for BVD/MD, a serological antibody test which is applied only to sero-negative animals.

For semen collected after the 26 September 2012: Until negative test results as above are received, the semen must be held in a separate storage container. Upon

confirmation of EU eligibility of all the semen in the separate storage container, all of the semen may be moved into EU storage.

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| All semen in the separate storage container will be considered to be of the same health status i.e. either awaiting confirmation of EU eligibility, or confirmed EU eligible. |

2.8.4 Where an animal has not met clause 2.4.2.c (i) the semen must not be the subject of trade until the donor has reached the age of two (2) years and has been tested for EBL using the ELISA with a negative result.

2.8.5 Prior to the initial dispatch of semen from BVD/MD serologically positive bulls, a semen sample from each animal must be subjected to a virus isolation or virus antigen ELISA test for BVD/MD. In the event of a positive result, the bull and all its semen must be removed from the centre and the semen is ineligible for the EU.

2.8.6 If any of the tests listed in 2.8.1, 2.8.2 and 2.8.3 is positive, the animal must be isolated and any semen collected from it since the last negative test declared ineligible for the EU; the exception is for animals that sero-converted for BVD/MD [as per clause 2.8.1 (e)].

2.8.7 When a test is positive, semen collected from all other animals at the centre shall be held in storage and must not be exported to the EU until the health status of the centre has been restored.

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| For information regarding the process required for restoring the health status of the centre, the Animal Imports and Exports Group of MPI should be consulted. There are specific EU directives that contain conditions for bovine Tb and bovine brucellosis. |

## 2.9 Tb test methods

2.9.1 The tests for Tb must be one of the following:

a. the single intradermal test – a single injection of bovine tuberculin; or

b. the intradermal comparative test – one injection of bovine tuberculin and one injection of avian tuberculin given simultaneously.

2.9.2 The dose of tuberculin injected shall be:

- not less than 2,000 IU of bovine tuberculin
- not less than 2,000 IU of avian tuberculin.

2.9.3 The volume of each injection dose shall not exceed 0.2 ml.

2.9.4 Tuberculin tests shall be carried out by injecting tuberculin into the skin of the neck. The injection sites shall be situated at the border of the anterior and middle thirds of the neck.

When both avian and bovine tuberculin are injected in the same animal, the site for injection of avian tuberculin shall be about ten cm from the crest of the neck and the site for the injection of bovine tuberculin about 12.5 cm lower on a line roughly parallel with the line of the shoulder or on different sides of the neck; in young animals in which there is not room to separate the sites sufficiently on one side of the neck, one injection shall be made on each side of the neck at identical sites in the centre of the middle third of the neck.

2.9.5 The technique of tuberculin testing and interpretation of reactions shall be as follows:

Injection sites shall be clipped and cleaned. A fold of skin within each clipped area shall be taken between the forefinger and thumb and measured with callipers and recorded. The dose of tuberculin shall then be injected by a method that ensures that the tuberculin is delivered intradermally. A short sterile needle, bevel edge outwards, with graduated syringe charged with tuberculin, inserted obliquely into the deeper layers of the skin may be used. A correct injection shall be confirmed by palpating a small pea-like swelling at each site of injection.

The skin-fold thickness of each injection site shall be re-measured seventy two (72) hours (± 4 hours) after injection and recorded.

2.9.6 Interpretation of reactions:

The interpretation of reactions shall be based on clinical observations and the recorded increase(s) in skin-fold thickness at the sites of injection seventy two (72) hours after injection of tuberculin.

a. Single intradermal test:

   i. positive: if clinical signs such as diffuse or extensive oedema, exudation, necrosis, pain or inflammation of the lymphatic ducts in that region or of the lymph nodes are observed, or there is an increase of 4 mm or more in the thickness of the fold of skin at the injection site;

   ii. inconclusive: if no clinical signs (such as diffuse or extensive oedema, exudation, necrosis, pain or inflammation of the lymphatic ducts in that region or of the lymph nodes) are observed and if the increase in skin-fold thickness is more than 2 mm and less than 4 mm;

   iii. negative: only limited swelling is observed, with an increase of not more than 2 mm in the thickness of the fold of skin, without clinical signs such as diffuse or extensive oedema, exudation, necrosis, pain or inflammation of the lymphatic ducts in that region or of the lymph nodes.

   Animals inconclusive to the single intradermal test shall be subjected to another test after a minimum of forty two (42) days.

   Animals which are not negative to this second test shall be deemed to be positive to the test.

   Animals positive to the single intradermal test may be subjected to an intradermal comparative test if false positive reaction or interference reaction is suspected.

b. Intradermal comparative test:

   i. positive: a positive bovine reaction which is more than 4 mm greater than the avian reaction, or the presence of clinical signs;

   ii. inconclusive: a positive or inconclusive bovine reaction which is from 1 to 4 mm greater than the avian reaction, and the absence of clinical signs;

   iii. negative: a negative bovine reaction, or a positive or inconclusive bovine reaction but which is equal to or less than a positive or inconclusive avian reaction and the absence of clinical signs in both cases.

   Animals inconclusive to the intradermal comparative test shall be subjected to another test after a minimum of forty two (42) days. Animals, which are not negative to this second test, shall be deemed to be positive to the test.

| It is advised to use the intradermal comparative test. |
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## 2.10 Brucellosis test methods

2.10.1 The tests for brucellosis must be one of the following serological tests:

a. ELISA-Ab;

b. complement fixation test (CFT);

c. serum agglutination test (SAT).

## 2.11 EBL test methods

2.11.1 The tests for EBL must be one of the following serological tests:

a. agar gel immuno-diffusion test (AGID);

b. ELISA-Ab.

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| The test method used must comply with 64/432/EEC, and use the reference EU serum specified. |

## 2.12 IBR/IPV test methods

2.12.1 The test for IBR/IPV must be one of the following serological tests for whole virus:

a. ELISA-Ab;

b. virus neutralisation test (VNT).

## 2.13 BVD/MD test methods

2.13.1 The testing for BVD/MD must include the following:

a. virus isolation or ELISA-Ag for the detection of virus; and

b. a serological test using ELISA-Ab or VNT for determining the presence or absence of antibodies.

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| Semen can be tested for BVD/MD using virus isolation or ELISA-Ag. |

## 2.14 Campylobacter and Trichomonas test methods

2.14.1 The test for *Campylobacter fetus* subsp. *venerealis* and *Trichomonas foetus* must be the isolation and identification of the organisms by culture.

# Appendix 1: Risk Analysis *Guidance Information*

| **Purpose / Scope** |
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| To identify the risk organisms relating to disease transmission that are reasonably likely to occur, and ensure that appropriate controls are included in the centre work manual so that the semen meets the EU Export Requirements. |

**Identification of Biological Hazards from Inputs and Process Steps**

| Process step | Inputs | Hazard reasonably likely to occur | Justification | Control Measures | Reference |
|---|---|---|---|---|---|
| 1. Entry of donor bulls and teasers onto centre | Donor bulls and teasers | Tb, EBL, BVD, IBR, *Campylobacter*, *Trichomonas*<br><br>miscellaneous pathogens | Sporadic incidence of infection may occur | | (a) Entry conditions |
| | | | | • Resident in NZ 6 months, and come from herds of known disease status | 2.4 |
| | | | | • EU recognition of Tb free herds under the NZ Pest Management Strategy, see Commission Implementing Decision (EU) 2015/569 of 7 April 2015 | |
| | | | | • Tested during pre-quarantine and quarantine | 2.5, 2.6 |
| | | | | • Come from a quarantine facility free from Tb and EBL | 2.7.3 |
| | | | | • Animals show no clinical sign of disease on day of admission | 2.7.2 |
| | | | | • Express permission to enter centre | 2.7.1 |
| 2. Donor bulls and teasers resident on centre | Donor bulls and teasers | Tb, EBL, BVD, IBR, *Campylobacter*, *Trichomonas*<br><br>miscellaneous pathogens | Sporadic incidence of infection may occur | | (b) Centre facility and management conditions |
| | | | | • Routine testing carried out | 2.8 |
| | | | | • Donor bulls must show no clinical disease on the day semen is collected | 2.3.6 a. |
| | | | | • Facilities able to be cleaned and disinfected | 2.2.4 |
| | | | | • Isolation facilities available | 2.2.5 a. |

| Process step | Inputs | Hazard reasonably likely to occur | Justification | Control Measures | Reference |
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| | | | | • Procedures in place for endemic disease occurrence<br>• Semen held 30 days post collection to ensure donor health status not changed<br>• Post collection testing of donor bulls for IBR/IPV and BVD/MD | 2.3.7<br>2.3.24<br>2.8.3 |
| | Other animals | Tb, EBL, BVD, IBR, *Campylobacter*, *Trichomonas*<br>miscellaneous pathogens | Direct contact | • Excluded by physical separation (5 m boundaries)<br>• Only bovine animals are allowed on centre unless they are necessary for managing stock (e.g. dogs)<br>• Facilities able to be cleaned and disinfected | 2.2.3<br>2.3.5<br>2.2.4 |
| | Feed (pasture) | Tb, BVD, IBR, contamination with miscellaneous pathogens such as lepto | Pasture can be contaminated with Tb from possums<br>Feed contaminated by rodents, hedgehogs<br>Endemic disease occurrence | • Possum control<br>• Procedures in place for endemic disease occurrence<br>• Donor bulls must show no clinical disease on the day semen is collected<br>• Antibiotics added to semen | 2.3.10<br>2.3.7<br>2.3.6 a.<br>2.3.15 |
| | Supplementary feed | Tb, contamination with miscellaneous pathogens such as lepto | Feed can be contaminated with Tb from possums<br>Feed contaminated by rodents, hedgehogs | • Feed sourced from centre, or from property of known Tb free status<br>• Procedures in place for endemic disease occurrence<br>• Donor bulls must show no clinical disease on the day semen is collected<br>• Antibiotics added to semen | 2.3.9<br>2.3.7<br>2.3.6 a.<br>2.3.15 |
| | Water supply | None | Controlled water supply | • Water supply must not be an animal health risk | 2.3.9 |
| | Staff | BVD, IBR | Disease transmission may be | • Staff trained in disease and disinfection | 2.3.11, 2.3.12 |

| Process step | Inputs | Hazard reasonably likely to occur | Justification | Control Measures | Reference |
|---|---|---|---|---|---|
| | | | indirect | procedures | |
| | Visitors | BVD, IBR | Disease transmission may be indirect | • Authorised personnel only | 2.3.11 |
| | Vehicles | Tb, EBL, BVD, IBR, miscellaneous pathogens such as lepto | Disease transmission may be indirect | • Authorised access only | 2.3.11 |
| 3. Semen collection | Donor bulls and teasers | Tb, EBL, BVD, IBR, *Campylobacter*, *Trichomonas*<br><br>miscellaneous pathogens | Sporadic incidence of infection may occur | • Donor bulls must show no clinical disease on the day semen is collected<br>• Procedures in place for endemic disease<br>• Facilities able to be cleaned and disinfected<br>• Antibiotics added to semen | (c) Control of collection<br><br>2.3.6 a.<br><br>2.3.7, 2.8.3<br><br>2.2.4<br><br>2.3.15 |
| | Equipment | Tb, EBL, BVD, IBR, *Campylobacter*, *Trichomonas*<br><br>miscellaneous pathogens | Disease transmission may be indirect | • Equipment must be single use disposable, or disinfected prior to use | 2.3.13 |
| 4. Semen processing | Semen | Tb, EBL, BVD, IBR, *Campylobacter*, *Trichomonas*<br><br>miscellaneous pathogens | Disease may be present in semen | • Equipment must be single use disposable, or disinfected prior to use<br>• Antibiotics added to semen | (d) Control of processing<br><br>2.3.13<br><br>2.3.15 |
| | Equipment | None | Single use disposable, or disinfected prior to use | • Equipment must be single use disposable, or disinfected prior to use | 2.3.13 |
| | Media | Salmonella from eggs | Disease may be present on eggs | • Eggs sourced from poultry premises that do not represent an animal health risk | 2.3.14 |
| | Packaging | None | Single use disposable, or disinfected prior to use | • Equipment must be single use disposable, or disinfected prior to use | 2.3.13 |

| Process step | Inputs | Hazard reasonably likely to occur | Justification | Control Measures | Reference |
|---|---|---|---|---|---|
| 5. Storage | Packaging | None | Disinfected prior to use | • Storage and transport containers must be disinfected prior to use | (e) Control of storage 2.3.21 |
| | Cryogenic agent | None | New | • Must not have been used for other products of animal origin | 2.3.22 |

**Control measures**

**(a) Entry conditions**

Risks associated with donor bulls and teasers entering the centre is managed by:

- The donor bulls must be resident in NZ for 6 months, and come from herds of known disease status
- EU recognition of equivalence for Tb free herds under the NZ Pest Management Strategy, see Commission Implementing Decision (EU) 2015/569 of 7 April 2015
- Strict 28 day quarantine on an 'all in all out' basis
- Disease testing and health monitoring during pre-quarantine and quarantine
- All testing done to EU standards
- Come from a quarantine facility free from Tb and EBL
- Animals show no clinical sign of disease on day of admission to the centre
- Require the express permission of the centre veterinarian to enter the centre
- Other animals not associated with the centre are excluded from entry
- Bovine brucellosis not considered a risk organism as NZ has disease freedom.

**(b) Centre facility and management conditions**

Risks associated with donor bulls and teasers resident on the centre are managed by:

- Routine testing carried out

- Regular visual checks of resident animals
- Donor bulls show no clinical sign of disease on day of semen collection, records kept
- Facilities able to be easily cleaned and disinfected – non-porous surfaces on structures in direct contact with donors during collection (i.e. wood painted/sealed, concrete in good condition), flooring material in collection area either easily washable or able to be replaced (i.e. sand/bark), non-porous internal surfaces in processing areas, non-porous internal surfaces in storage areas with floor coverings able to be easily cleaned and disinfected or replaced (carpet can be used for safety reasons but must be able to be managed effectively). Other structures such as yards, building exteriors and fencing must be maintained in good repair so that they can be cleaned down or replaced as appropriate in the event of an endemic or exotic disease occurrence.
- Isolation facilities available for isolation of sick animals
- Procedures in place for endemic disease occurrence – when endemic disease occurs, animals isolated on centre or slaughtered/ removed from centre, EU export status assessed, any semen isolated back to last negative test, areas cleaned and disinfected, accommodation paddock has faecal matter removed/harrowed and paddock stand-down for minimum 21 days
- Procedures in place for exotic disease occurrence – if exotic disease occurs, MPI notified, EU notified, animals isolated on centre with possible destruction, EU exports suspended, any semen isolated/destroyed, all areas cleaned and disinfected, accommodation paddocks disinfected or topsoil removed
- Semen held in storage for 30 days post collection to ensure that the centre health status has not changed since the date of collection
- Post collection testing for IBR and BVD (sero-negative animals)
- Bovine brucellosis not considered a risk organism as NZ has disease freedom;

Other animals not directly associated with the centre are excluded from entry

- Excluded by physical separation (5 m boundaries)
- Only bovine animals are allowed on centre unless they are necessary for managing stock (e.g. dogs) and do not pose a disease risk
- Facilities able to be cleaned and disinfected;

Feed and supplementary feed

- Possum control in 5 m zone

- Normal farming practices discourage wildlife and vermin
- Supplementary feed sourced from centre pasture, or property of known Tb free status
- If commercially prepared feeds are used, they meet NZ manufacturing standards and do not contain ruminant protein
- Stored feed is protected from vermin
- Donor bulls must show no clinical disease on the day semen is collected
- Procedures in place for endemic disease
- Risk of diseases such as lepto additionally managed by use of vaccination/treatment programme, and antibiotics added to semen diluent/extender.

Water supply

- From secure water supply (town water, bore, or local supply)
- Use of back-flow preventers when reticulation shared with water troughs for non-EU cattle external to centre.

Risks associated with staff entering the centre is managed by:

- Staff trained in disease recognition, disease control, and disinfection procedures
- Use of clean protective clothing on entry to centre
- Limited contact off centre to animals that may pose a risk of indirect disease transmission.

Risks associated with visitors entering the centre is managed by:

- Authorised personnel only, and must be accompanied/supervised by staff when on centre
- Use of clean protective clothing on entry to centre
- Limited contact off centre to animals that may pose a risk of indirect disease transmission i.e. biosecurity stand-down period prior to visit.

Risks associated with vehicles entering the centre is managed by:

- Vehicle entry strictly controlled, authorised by centre veterinarian

- Limited to only vehicles necessary for centre operation i.e. motorbikes, tractors, service vehicles
- Vehicles cleaned and disinfected prior to entry
- Stock trucks excluded from entering centre – unloading ramps located on centre boundary.

**(c) Control of collection**

Risks associated with donor bulls and teasers managed by:

- Donor bulls must show no clinical disease on the day semen is collected
- Donor bulls and teasers adequately prepared – prepuce hair clipped, relevant areas free of obvious faecal material
- Donor bulls handled correctly during teasing and mounting to minimise risk of cross-contamination of semen/artificial vagina
- Procedures in place for endemic disease
- Facilities able to be cleaned and disinfected
- Risk of diseases such as lepto additionally managed by use of vaccination/treatment programme, and antibiotics added to semen diluent/extender.

Equipment must be single use disposable, or disinfected prior to use.

**(d) Control of processing**

Collection area physically separated from processing area

Equipment must be single use disposable, or disinfected prior to use

Separate room for cleaning and disinfecting laboratory equipment

Eggs sourced from poultry premises that do not represent an animal health risk – must be from an egg producer with a Risk Management Programme, or a flock tested annually for Salmonella

NZ poultry are free from many pathogenic Salmonella types

Other products of animal origin (e.g. milk powder) from commercially prepared/pasteurised ingredients or disease free source so do not represent an animal health risk

Antibiotics added to semen diluent/extender under controlled time/temperature to ensure effective contact time

Equipment for packaging, including straws, must be single use disposable, or disinfected prior to use.

**(e) Control of storage**

Storage area physically separated from collection and processing areas

Storage and transport containers must be disinfected prior to use

Cryogenic agent must not have been used for other products of animal origin.

Semen held in a separate storage container until negative results confirmed on post collection testing.

# Appendix 3: Testing *Guidance Information*