Ministry for Primary Industries
Manatū Ahu Matua

Review of Submissions

Draft Import Health Standard: Semen and Embryos from Horses (*Equidae*) from Specified Countries

Draft Import Risk Analysis: Equine Germplasm from Australia, Canada, the European Union and the USA

Draft Risk Management Proposal: Semen and Embryos from Horses (*Equidae*) from Specified Countries

3 December 2015

Growing and Protecting New Zealand

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Regulation & Assurance Branch

REVIEW OF SUBMISSIONS

Semen and Embryos from Horses (*Equidae*) from Specified Countries

November 2015

Approved for general release

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Contents

1 Introduction

The draft Import Health Standard: Semen and Embryos from Horses (*Equidae*) was notified for consultation on 23 June 2015.

The Ministry for Primary Industries (MPI) received submissions from the following:

Alabar (NZ) Ltd	6 August 2015
EquiBreed NZ Ltd	17 August 2015
Department of Agriculture, Australia	21 August 2015

This document summarises the issues raised in the submissions, and presents the MPI response to each.

1.1 Acronyms Used in the Document

MPI	Ministry for Primary Industries	IETS	International Embryo Transfer Society
OIE	World Organisation for Animal Health	SCC	Semen collection centre
IRA	Import Risk Analysis	CEM	Contagious equine metritis
IHS	Import health standard	EHV-1	Equine herpesvirus-1
RMP	Risk management proposal	EIA	Equine infectious anaemia
GD	Guidance document	EVA	Equine viral arteritis

2 Summary of Amendments

As a result of submissions, the following amendments that have been made to the Import Health Standard: Semen and Embryos from Horses (HORSSEMB.SPE) and the associated Guidance Document.

2.1 Import Health Standard Amendments

Draft IHS	Provisional IHS
Part 1: Requirements	Part 1: Requirements
1.1 Application	1.1 Application
(1) This import health standard (IHS) applies to: a) semen from domestic horses (*Equidae*) that is ~~not genetically modified; and~~ i. fresh~~/~~chilled ~~ii. in screw top containers; or~~ ~~iii. frozen, in straws, ampoules or pellets; and~~ (b) embryos from domestic horses (*Equidae*) that are frozen, not genetically modified, in vivo derived and non-cloned.	(1) This import health standard (IHS) applies to: a) semen from domestic horses (*Equidae*) that is frozen/fresh-chilled and not genetically modified; and b) embryos from domestic horses (*Equidae*) that are frozen, not genetically modified, in vivo derived and non-cloned.
1.5 Diagnostic testing, vaccination and treatment	1.5 Diagnostic testing, vaccination and treatment
(1) Any laboratory conducting the 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.	(1) Any laboratory conducting the pre-export or surveillance testing where required by this IHS must be approved by the Competent Authority of a country approved to export semen and embryos from horses to New Zealand.
1.6 Embryo requirements	1.6 Embryo requirements
1.6.2 Embryo donor requirements	1.6.2 Embryo donor requirements
(1) The Competent Authority must have knowledge of and authority over the embryo donor(s) until completion of collection and testing required by this IHS.	(1) The embryo collection team must have knowledge of and authority over the embryo donor(s) until completion of collection and testing required by this IHS.
1.6.3 Fertilisation requirements	1.6.3 Fertilisation requirements
(1) Embryos produced for the consignment must be ~~fertilised from semen which was~~ either:	(1) The semen used to produce the embryo(s) for the consignment must be either:
1.7 Semen requirements	1.7 Semen requirements
1.7.2 Semen donor requirements	1.7.2 Semen donor requirements
(1) 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 ~~centre~~.	(1) Semen donors must be resident for at least 28 consecutive days at the semen collection centre prior to collection of the semen for export.
1.9 Storage	1.9 Storage
(3) Semen and embryos must 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.	(3) Semen and embryos must be in straws, ampoules, pellets, or new or disinfected containers which are sealed and tamper-evident, and clearly and permanently marked to identify the donor and the date(s) of collection. For embryos the marking must, in accordance with the Code, conform to the international standards of the IETS.
(5) Semen and embryos may be stored in a third country (other than the country of origin) if the third country is a specified country listed in this IHS. The consignment of semen and embryos must be accompanied by:	Deleted - duplication

1.10 Transport	1.10 Transport
(1) Transport containers must be ~~sanitised~~ and free of contamination.	(1) Transport containers must be new or disinfected and free of contamination.
1.12 The documentation that must accompany goods	1.12 The documentation that must accompany goods
(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.	(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. For fresh semen only, the documentation must be emailed to MPI within 24 hours prior to arrival.

2.2 Guidance Document Amendments

Draft GD	Provisional GD
5.6 Semen collection and processing	**5.6 Semen collection and processing**
(2) Semen can be contained in various types of receptacles, such as a vial, goblet, ampoule, or straw, as long as they are tamper-evident and separate semen from individual donors.	(2) Semen can be contained in various types of receptacles, such as a vial, goblet, ampoule, screw-top container or straw, as long as they are tamper-evident and separate semen from individual donors.
5.8 Antibiotics effective against Leptospirosis	**5.8 Antibiotics effective against Leptospirosis**
(1) Antibiotics that can be added to the semen or embryos of horses (*Equidae*) for export to New Zealand include, but are not limited to: b) 500 IU per ml penicillin; or	(1) Antibiotics that can be added to the semen or embryos of horses (*Equidae*) for export to New Zealand include, but are not limited to: b) 500 IU per ml penicillin in conjunction with an aminoglycoside; or
5.9 Model veterinary certificate for horse semen	**5.9 Model veterinary certificate for horse semen**
3) The semen is contained in (*delete as appropriate*) a) Straws; or b) Ampoules; or c) Pellets.	(3) The semen is contained in (*delete as appropriate*) a) Straws; or b) Ampoules; or c) Pellets; or d) Screw-top containers (applicable to fresh semen only).
(16) Semen is in new or sanitised containers, which are sealed and tamper evident, and clearly and permanently marked to identify the donor and the date(s) of collection.	(16) Semen is in new or disinfected containers, which are sealed and tamper evident, and clearly and permanently marked to identify the donor and the date(s) of collection.
(19) Semen was placed in a container which is sanitised and free of contamination.	(19) Semen was placed in a container which is disinfected and free of contamination.
(24) Equine infectious anaemia (EIA) a) Donors showed no clinical sign of EIA on the day of each collection; and i) Donors were kept on premises where no case of EIA has been reported during the 90 days prior to each collection; and ii) Donors were subjected to a test listed in the MPI document: MPI Approved Diagnostic Tests, Vaccines, Treatments and Post-arrival Testing Laboratories for Animal Import Health Standards (MPI-STD-TVTL), either * i Not less than 30 days after entry into the collection centre; or ii 30-60 days after collection; or iii Annually at the start of the breeding season, with negative results. *(*Delete as applicable)*	(24) Equine infectious anaemia (EIA) a) Donors showed no clinical sign of EIA on the day of each collection; and i) Donors were kept on premises where no case of EIA has been reported during the 90 days prior to each collection; and ii) Donors were subjected to a test listed in the MPI document: *MPI Approved Diagnostic Tests, Vaccines, Treatments and Post-arrival Testing Laboratories for Animal Import Health Standards (MPI-STD-TVTL)*, within 30 days prior to collection, with negative results.
(27) *Taylorella* spp. (Contagious equine metritis, CEM) (delete as applicable) a) Donors were from a country or zone where no case of CEM has been reported by the Competent Authority of the exporting country; or b) Donors were from a country with an official control programme for CEM; and i) Showed no clinical sign of CEM on the day of each collection; and ii) Have been subjected to a test* listed in MPI-STD-TVTL with negative results either	(27) *Taylorella* spp. (Contagious equine metritis, CEM) *(delete as applicable)* a) Donors were from a country imposing control measures for CEM as described in the *Manual* or otherwise approved by MPI; and i) Have had no direct or indirect contact with CEM during the two months prior to collection; and i Showed no clinical sign of CEM on the day of each collection; and ii Have been subjected to a test* listed in MPI-STD-TVTL with negative results

i Twice with a 4-7 day interval during the 30 days prior to the collection period; or ii Annually at the start of the breeding season; and iii) Have been protected against any possibility of contagion since the beginning of the tests; and iv) Donors have not been treated with antibiotics for at least 7 days before commencing the testing and throughout the sample collection period; or	twice with a 4-7 day interval during the 30 days prior to the collection period; and iii Have been protected against any possibility of contagion since the beginning of the tests; and iv Have not been treated with antibiotics for at least 7 days before commencing the testing and throughout the sample collection period; or ii) have previously shown signs of CEM or have been in direct or indirect contact with CEM during the two months prior to collection; and i Were treated for CEM; and ii After treatment, were subjected to an effective method of testing* listed in MPI-STD-TVTL, with three swabs taken at 7-day intervals with negative results followed by testing of the first three mares mated or inseminated by the stallion with negative results; and iii Have been protected against any possibility of contagion since the beginning of the tests. (*Swabbing sites are the prepuce, the urethral sinus and the fossa glandis (including its diverticulum))
5.10 Model veterinary certificate for horse embryos	5.10 Model veterinary certificate for horse embryos
Embryo collection team and herd approval requirements	Embryo collection team and herd approval requirements
(7) At the time of collection of embryos for export to New Zealand, the embryo collection team was approved by and registered with the Competent Authority of the exporting country.	(7) At the time of collection of embryos for export to New Zealand, the embryo collection team was approved by and registered with the [*Competent Authority of the exporting country*].
(8) The Competent Authority has knowledge of and authority over the embryo collection herd until completion of collection and testing of the embryo(s) exported to New Zealand specified in this IHS.	(8) The embryo collection team veterinarian has knowledge of and authority over the embryo collection herd until completion of collection and testing of the embryo(s) exported to New Zealand specified in this IHS.
(17) Embryos are sealed in receptacles, which are clearly and permanently marked to identify the donor and the date(s) of collection. A code is used for this information and its decipher accompanies the consignment (delete as appropriate and initial). The marking is in accordance with the OIE Code.	(17) Embryos are sealed in receptacles, which are clearly and permanently marked to identify the donor and the date(s) of collection. A code is used for this information and its decipher accompanies the consignment (delete as appropriate and initial). The marking is in accordance with the IETS Standards.
(19) Embryos were placed in a container which is ~~sanitised~~ and free of contamination. Disinfectant (active chemical) and date (delete and initial if container was new): _____	(19) Embryos were placed in a container which is disinfected and free of contamination. Disinfectant (active chemical) and date (delete and initial if container was new): _____
(24) Equine infectious anaemia (EIA)	**(24) Equine infectious anaemia (EIA)**
a) Donors showed no clinical sign of EIA on the day of each collection; and	a) Donors showed no clinical sign of EIA on the day of each collection; and

i) Donors were kept on premises where no case of EIA has been reported during the 90 days prior to each collection; and ii) Donors were subjected to a test listed in the MPI document: MPI Approved Diagnostic Tests, Vaccines, Treatments and Post arrival Testing Laboratories for Animal Import Health Standards (MPI-STD-TVTL), ~~either * i Not less than 30 days after entry into the collection centre; or ii 30-60 days after collection; or iii Annually at the start of the breeding season, with negative results. (*Delete as applicable)~~	i) Donors were kept on premises where no case of EIA has been reported during the 90 days prior to each collection; and ii) Donors were subjected to a test listed in the MPI document: MPI Approved Diagnostic Tests, Vaccines, Treatments and Post-arrival Testing Laboratories for Animal Import Health Standards (MPI-STD-TVTL), 30 days prior to collection, with negative results.
(27) *Taylorella* spp. (Contagious equine metritis, CEM) (delete as applicable) a) Donors were from a country or zone where no case of CEM has been reported by the Competent Authority of the exporting country; or b) Donors were from a country with an official control programme for CEM; and i) Showed no clinical sign of CEM on the day of each collection; and ii) Have been subjected to a test* listed in MPI-STD-TVTL with negative results either i Twice with a 4-7 day interval during the 30 days prior to the collection period; or ii Annually at the start of the breeding season; and iii) Have been protected against any possibility of contagion since the beginning of the tests; and iv) Donors have not been treated with antibiotics for at least 7 days before commencing the testing and throughout the sample collection period; or	(2) ***Taylorella* spp. (Contagious equine metritis, CEM)** *(delete as applicable)* a) Donors were from a country imposing control measures for CEM as described in the *Manual* or otherwise approved by MPI; and i) Have had no direct or indirect contact with CEM during the two months prior to collection; and i Showed no clinical sign of CEM on the day of each collection; and ii Have been subjected to a test[1] listed in MPI-STD-TVTL with negative results twice with a 4-7 day interval during the 30 days prior to the collection period; and iii Have been protected against any possibility of contagion since the beginning of the tests; and iv Have not been treated with antibiotics for at least 7 days before commencing the testing and throughout the sample collection period; or ii) have previously shown signs of CEM or have been in direct or indirect contact with CEM during the two months prior to collection; and i Were treated for CEM; and ii After treatment, were subjected to an effective method of testing[2] listed in MPI-STD-TVTL, with three clitoral swabs taken at 7-day intervals with negative results followed by testing of three endometrial swabs during the next three oestrus periods with negative results; and iii Have been protected against any possibility of contagion since the beginning of the tests.

3 Internal Submissions

According to MPI process an internal review period is available to staff of MPI to comment and recommend changes prior to public consultation on an import health standard. One internal submission was received after the internal review deadline. The recommendations as a result of these submissions are included in this document.

3.1 Auckland International Airport and target evaluators

3.1.1 Section 1.12

MPI staff pointed out that currently, one certificate per importer covering multiple donors from the same semen collection centre is allowed, rather than supplying a separate certificate for each donor. The requirement for a separate certificate for each donor was therefore removed.

Draft IHS	**Provisional IHS**
Part 1: Requirements	**Part 1: Requirements**
1.12 The documentation that must accompany goods	**1.12 The documentation that must accompany goods**
(1) The semen and embryos must arrive in New Zealand with: a) 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 centre name and date of donor entry; v) Name and address of importer (consignee) and exporter (consignor); vi) For each donor; certification and endorsements that the requirements outlined in Part 1 and Part 2 of this IHS have been met;	(1) The semen and embryos must arrive in New Zealand with: a) 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 centre name and 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;

It was also pointed out that whereas the IHS required originals or endorsed copies, or an endorsed tabulated summary of lab results, the GD model certificate only stipulated endorsed copies or endorsed tabulated results. “Original” was added to the model certificates for both semen and embryos.

Draft GD	**Provisional GD**
5.9 Model veterinary certificate for horse semen	**5.9 Model veterinary certificate for horse semen**
(6) Copies of laboratory reports, or an endorsed, tabulated summary, including test date, type, and results for each donor, are attached to this veterinary certificate.	(6) Original or copies of laboratory reports, or an endorsed, tabulated summary, including test date, type, and results for each donor, are attached to this veterinary certificate.
5.10 Model veterinary certificate for horse embryos	**5.10 Model veterinary certificate for horse embryos**
(5) Copies of laboratory reports, or an endorsed, tabulated summary, including test date, type, and results for each donor, are attached to this veterinary certificate.	(5) Original or copies of laboratory reports, or an endorsed, tabulated summary, including test date, type, and results for each donor, are attached to this veterinary certificate.

3.2 Other amendments made by Animal Imports

The requirement for embryo donors to have been resident at the place of embryo collection for 28 days was removed. Risks are mitigated by the disease-specific requirements. The fertilisation requirements for embryos have been deleted, since for embryos, the risk analyses assessed the risks associated with embryos, not oocytes plus semen. The assessment of risks identified the risks (and measures) necessary for embryos regardless of the health status of the semen used to make them.

Since the OIE *Terrestrial Animal Health Code* does not specify recommended measures for managing EIA in equine semen and embryos, and the IRA recommends adopting the *Code* recommendations for live horses, the requirements were specified in the IHS (Part 2: Specified Requirements for Identified Risk Organisms).

Because the OIE included recommended measures for managing glanders when importing equine semen and embryos in the 2015 amendment of the *Code*, generic glanders measures were added to the IHS and model certificate for semen.

Draft IHS	**Provisional IHS**
Part 1: Requirements	**Part 1: Requirements**
1.6.3. Fertilisation requirements	**1.6.3. Fertilisation requirements**
(1) The semen used to produce the embryo(s) for the consignment must be either: a) Imported directly from New Zealand or is eligible for import into New Zealand; or b) Collected, processed, and stored at a semen collection facility that complies with the semen centre protocols of the exporting country (where MPI deems this to be equivalent); or From donors that were inspected, found free from clinical evidence of infectious diseases transmissible in semen, and satisfied the testing and isolation requirements of this IHS.	Deleted.
(2) The semen centre veterinarian must ensure that the donor is free from clinical evidence of infectious diseases transmissible in semen on the day of collection.	(2) The semen centre veterinarian must ensure by clinical examination including that of the external reproductive organs that the donor is free from clinical evidence of infectious diseases transmissible in semen on the day of collection.
Part 2: Specified Requirements for Identified Risk Organisms	**Part 2: Specified Requirements for Identified Risk Organisms**
2.2 Equine infectious anaemia virus (EIA)	**2.2 Equine infectious anaemia virus (EIA)**
(1) Donors ~~must meet~~ the ~~Code recommendations~~ for ~~managing EIA in horses~~.	(1) Donors showed no clinical sign of EIA on the day of each collection; and a) Donors were kept on premises where no case of EIA has been reported during the 90 days prior to each collection; and b) Donors were subjected to a test listed in the MPI document: MPI *Approved Diagnostic Tests, Vaccines, Treatments and Post-arrival Testing Laboratories for Animal Import Health Standards (MPI-STD-TVTL)*, within 30 days prior to collection with negative results.

For the cases where a tabulated summary for each consignment is not used, a table for recording donor and embryo information has been inserted at the top of the model certificate.

<table>
<tr><th>Draft GD</th><th>Provisional GD</th></tr>
<tr><td>5.10 Model veterinary certificate for horse semen/ embryos</td><td>5.10 Model veterinary certificate for horse semen/embryos</td></tr>
<tr><td>Part II: Specific Requirements</td><td>Part II: Specific Requirements</td></tr>
<tr><td></td><td>
<table>
<tr><td>Donor identification</td><td></td></tr>
<tr><td>Breed</td><td></td></tr>
<tr><td>Date of birth</td><td></td></tr>
<tr><td>Country of birth</td><td></td></tr>
<tr><td>Date(s) of collection</td><td></td></tr>
<tr><td>Straw identification</td><td></td></tr>
<tr><td>Number of straws</td><td></td></tr>
</table>
*only to be filled out in case the tabulated summary of tests and results is not used
</td></tr>
</table>

4 Review of Submissions

4.1 Alabar (NZ) Ltd

4.1.1 Testing requirements for EIA

Currently the donor stallions must be tested for EIA no less than 21 days after entering the semen collection centre. The new IHS proposes testing for EIA no less than 30 days after the donor stallion enters the collection centre. This would mean an inconvenience to New Zealand breeders and a major competitive disadvantage for [Alabar]. [Alabar] requests there be no changes to the current EIA testing requirements.

MPI Response

The proposed measures are in line with the OIE *Code* for live horses and based on the IRA. Australia's Department of Agriculture has the option of proposing an equivalent measure when negotiating the veterinary certificate for semen and embryos from horses to New Zealand. This could include a different testing window for shuttle stallions that have been in quarantine for several weeks and tested several times prior to entering the SCC. The requirements in the IHS will remain in line with the *Code* for live horses, but will be prescribed in the IHS.

4.2 EquiBreed NZ Ltd

4.2.1 GD clause 5.8

Antibiotics effective against leptospirosis

[EquiBreed NZ's] understanding is that penicillin alone is not fully effective against Leptospirosis and therefore must be used in conjunction with an effective antibiotic.

MPI Response

The wording "in conjunction with an aminoglycoside" was added to "500 IU per ml penicillin" in the Guidance Document (clause 5.8.1) after consultation with Richard Clough, IDC Wallaceville. The MPI document, *Approved Diagnostic Tests, Vaccines, Treatments and Post-Arrival Testing Laboratories for Animal Import Health Standards* (MPI-STD-TVTL) was also updated accordingly.

4.3 Department of Agriculture; G/SPS/N/NZL/520 29 June 2015

4.3.1 Application

1.1.(a) semen from domestic horses (Equidae) that is fresh/chilled or frozen, in straws, ampoules or pellets and not genetically modified;

Chilled semen is not typically transported in straws, ampoules or pellets as those are used for frozen semen. Fresh semen is usually transported in plastic screw top containers.

The guidance document states that semen can be contained in various types of receptacles, such as a vial, goblet, ampoule, or straw, as long as they are tamper-evident and separate semen from individual donors. Therefore is it possible to amend 1.1 a) to include these additional containers. Additionally these need to be amended in the sample health certificate to allow for transport of chilled semen.

MPI Response

Clause 1.1.(a) was amended as follows:

a) semen from domestic horses (*Equidae*) that is not genetically modified and
   a. fresh/chilled in screw top containers or
   b. frozen in straws, ampoules or pellets.

Additionally, the model certificate in the GD was amended as follows:

(5) The semen is contained in *(delete as appropriate)*

a) Straws; or
b) Ampoules; or
c) Pellets; or
d) Screw-top containers (applicable to fresh semen only).

Clause 5.6(2) of the GD has been amended as follows:

Semen can be contained in various types of receptacles, such as a vial, goblet, ampoule, screw-top container or straw, as long as they are tamper-evident and separate semen from individual donors.

Clause 3 of the model certificate for semen has been amended as follows:

The semen is contained in *(delete as appropriate)*

i) Straws; or
ii) Ampoules; or
iii) Pellets; or
iv) Screw-top containers (applicable to fresh semen only).

4.3.2 Diagnostic testing, vaccination and treatment

1.5.(1) Any laboratory conducting the 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.

The Department of Agriculture does not approve testing laboratories; certification of export testing is based on tests being performed at a laboratory that is accredited by Australia's National Association of Testing Authorities (NATA). Therefore we suggest the following change:

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

MPI Response
This could be incorporated as an equivalent measure when negotiating the veterinary certificate accompanying consignments of equine germplasm from Australia to New Zealand.

4.3.3 Embryo donor requirements

1.6.2(1) The Competent Authority must have knowledge of and authority over the embryo donor(s) until completion of collection and testing required by this IHS.

The Competent Authority will approve an embryo collection team. It seems most appropriate that the approved embryo collection team veterinarian has this knowledge and authority. Therefore we suggest the following change:

1.6.2(1) The ~~Competent Authority~~ approved embryo collection team veterinarian must have knowledge of and authority over the embryo donor(s) until completion of collection and testing required by this IHS.

MPI Response
The clause was amended as suggested in both the IHS and the GD.

1.6.2(2) Embryo donors must not be situated on a premise/with other horses that is/are 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.

A 'premise' is not singular for premises. Therefore we suggest the following change:

1.6.2(2) Embryo donors must not be situated on ~~a premise~~ premises/with other horses that …

MPI Response
The clause was amended as suggested.

4.3.4 Fertilisation requirements

1.6.3(1) Embryos produced for the consignment must be fertilised from semen which was either:

Embryos are created when oocytes are fertilised by semen. Therefore we suggest the following change:

1.6.3(1) ~~Embryos produced~~ The semen used to produce the embryos for the consignment must be ~~fertilised from semen which was e~~ither:

MPI Response
Clause 1.6.3(1) in the IHS was amended as follows:

The semen used to produce the embryo(s) for the consignment must be either:

The GD model certificate already had the suggested wording.

4.3.5 Semen donor requirements

1.7.2(1) 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 centre. During this time semen donors must not be used for natural mating and must be isolated from animals not of equivalent health status.

Could the time required to be isolated in the actual semen collection centre be clarified as this is not clear in the IHS or guidance document. Are the donors required to do this initial 28 days in isolation before admission into the semen centre and then an additional 30 days before they are eligible to donate semen?

MPI Response
The interpretation of this requirement was indeed be that semen donors have to be isolated 28 days prior to entry into the SCC.
MPI acknowledges that no other trading partners have this requirement of 28 days isolation of equine semen donors prior to entering the SCC and has amended clause 1.7.2.1 as follows:

i) Semen donors must be resident for at least 28 consecutive days at the semen collection centre prior to collection of the semen for export. During this time semen donors must not be used for natural mating and must be isolated from animals not of equivalent health status.

4.3.6 Storage

1.9.3 Semen and embryos must 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.

See guidance document for more information about semen containers.

For fresh semen that is transported in screw top containers, will a label across the cap be considered appropriate for 'tamper-evident'? If not could tamper-evident please be clarified. What does the sanitised container refer to, could this please be clarified? If the marking must conform to IETS standards, how does this apply to semen?

There appears to be a typographical error, the following change may be appropriate:

Semen and embryos must be in straws, ampoules, pellets or sanitised containers ……

MPI Response
Tamper-evident would mean that the container cannot be opened without the seal being broken or otherwise visibly tampered with. This implies that a label across the top does not suffice, since it could potentially be peeled off in order to open the container and stuck back on. A circular adhesive band such as used as festival wristbands would be an example of tamper-evident seals for such screw top containers for fresh semen.
The term "sanitised" was inserted to allow various methods of disinfection and sterilisation to be applied to containers as required by the *Code* in the chapter on *in vivo* derived embryos from livestock and equids. MPI acknowledges that the term "sanitation" is not generally used in biosecurity and is inappropriate.
The IETS standard for marking only applies to embryos.

The clause has been amended as follows, including correction of the typographical error:

1.9.3. Semen and embryos must be in straws, ampoules, pellets or new or disinfected 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. For embryos the marking must, in accordance with the *Code*, conform to the international standards of the IETS.

See guidance document for more information about semen containers.

4.3.7 The documentation that must accompany goods

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

For fresh semen this is not practical – the product is collected and arrives in NZ within 20 hours. Could this clause be amended to manage fresh semen documents on a shorter timeframe?

MPI Response
The clause has been amended as follows:

1.12.4. Documentation copies must be sent to the Biosecurity Inspector at the airport/port of arrival at least one working day in advance of importation. For fresh semen only, the documentation must be emailed to MPI within 24 hours prior to arrival.

From the guidance document (GD-HORSSEMB.SPE):

4.3.8 Equine infectious anaemia (EIA)

24.a. Donors showed no clinical sign of EIA on the day of each collection; and
*i) Donors were kept on premises where no case of EIA has been reported during the 90 days prior to each collection; **and***

Are donors able to reside at multiple premises as long as they meet the 90 day premises freedom requirement?

MPI Response
Yes.

*24.a.(ii) Donors were subjected to a test listed in the MPI document: MPI Approved Diagnostic Tests, Vaccines, Treatments and Post-arrival Testing Laboratories for Animal Import Health Standards (MPI-STD-TVTL), either ******
*i Not less than 30 days after entry into the collection centre; **or***

What about the timing of semen collection in relation to this requirement or is it irrelevant?

MPI Response
Collection can commence 28 days after the stallion has entered the SCC. Testing has to be done at least 30 days after the stallion has entered the SCC.

24.a. ii(ii) 30-60 days after collection; ***or***

Is the stallion required to still be in the semen collection centre?

MPI Response
No, the test is meant to ascertain that the donor stallion wasn't infected with EIA at time of collection.

24.a.ii(iii) Annually at the start of the breeding season, with negative results.

Is this when the stallion is in the collection centre and is it related to the timing of semen collection?

MPI Response
This option was added to accommodate the Australian situation whereby fresh semen donor stallions get approved for an entire breeding season, and consignments of their semen can be allowed clearance into New Zealand with one certificate rather than an increasing amount of documentation without the need for a permit (which would have the equivalence decision added). However, upon re-reading the correspondence between then DAFF and MPI, it appeared that no equivalent measures for testing were agreed, only equivalent certification. The donors must still comply with all IHS requirements, meaning regular testing. The option for annual testing at the start of the breeding season has been removed and the same condition will be considered upon when negotiating the veterinary certificate.

4.3.9 Equine viral arteritis (EVA)

25.a. Donors were kept in an establishment where no equid has shown any clinical sign of EVA for the 28 days immediately prior to semen collection and showed no clinical sign of EVA on the day of semen collection; and

Is this a single establishment or can this include the time in pre-centre isolation?

MPI Response
This can include multiple establishments. The requirement for 28 days pre-SCC isolation has been removed. The clause has been amended as follows:

25.a. Donors were kept in an establishment(s) where no animals have shown any signs of EVA for the 28 days prior to shipment.

iii) Were subjected to a test for EVA as prescribed in MPI-STD-TVTL on a blood sample with negative results within 14 days prior to semen collection, and had been separated from other equids not of equivalent health status for 14 days prior to blood sampling until the end of semen collection; or

Could you please clarify if the test can be performed before the donor enters the collection centre during the 28 day pre-centre isolation period or should the testing be performed once in the centre?

MPI Response
Testing can be done during the 28-day stand-down period prior to collection. The requirement for 28 days isolation prior to the stallion entering the SCC has been removed.

5 Appendix 1: Copies of Submissions

5.1 Alabar (NZ) Ltd

ALABAR (NZ) LIMITED

480 Seagrove Road RD4 Pukekohe 2679 New Zealand P +64 9 232 1800 F +64 9 232 1799 E alabar@alabar.co.nz

6 August 2015

Anne Kramer
Animal Imports Team
Ministry For Primary Industry

Anne.Kramer@mpi.govt.nz

As discussed, following is our submission re the proposed new equine semen import health standard.

Background: For the last fifteen years we have imported fresh equine semen from Australia (we also export fresh semen to Australia). Many of our stallions are shuttle stallions from North America arriving out of quarantine in August each year. As the semen is fresh, we import on a seasonal basis from late September through to the end of January each year. We have consignments arriving every second day throughout this period. These imports are a significant part of our overall business – and also of real significance to the New Zealand Standardbred breeding industry. In the time we have been operating we have bred in excess of 7000 mares in New Zealand with semen imported from Australia. In the 2014/15 breeding season, approximately 15% of all Standardbred mares bred in New Zealand were bred with fresh semen Alabar imported from Australia.

Submission: – We are concerned about the wording around EIA testing in the draft IHS. All shuttle stallions are tested for EIA in quarantine. The shuttle stallions we bring to New Zealand can supply semen for mares in both New Zealand and Australia immediately without any further EIA testing. The ones we stand in Australia require a further EIA test before their semen can be imported into New Zealand (this test has to be done 21 days after they arrive at our Australian export facility although approval may be given to do the testing immediately if all other horses in the export facility have been in the facility for at least 21 days). This can present a very tight time frame (with the date they arrive out of quarantine and the time it takes to get a result from the testing) to be able to meet the start date for the breeding season.

The possibility of there being a residency requirement of 30 days prior to EIA retesting would be virtually untenable for us. It would mean the semen from the stallions wouldn't be cleared for import into New Zealand until October. This would be a major inconvenience to New Zealand breeders and a major competitive disadvantage for our company.

We request there be no change to the current EIA testing requirements.

Many thanks for your consideration.

Regards

Graeme Henley
GENERAL MANAGER

alabar.co.nz

5.2 EquiBreed NZ Ltd

Dear Anne,

As discussed at our meeting on 25 June 2015, may I recommend that the list of approved antibiotics in semen extender be known to be effective against Leptospirosis. A microbiology laboratory (NCDI?) will have the latest information and be able to provide confirmation, but my understanding is that penicillin alone is not fully effective against Leptospirosis and therefore must be used in conjunction with an effective antibiotic.

Kind regards
Lee

5.3 Department of Agriculture, Australia

Department of Agriculture comments

Draft Import Health Standard: Semen and Embryos from Horses (*Equidae*) from Specified Countries HORSSEMB.SPE

G/SPS/N/NZL/520 29 June 2015

1.1 Application

a) semen from domestic horses (Equidae) that is fresh/chilled or frozen, in straws, ampoules or pellets and not genetically modified;

Chilled semen is not typically transported in straws, ampoules or pellets as those are used for frozen semen. Fresh semen is usually transported in plastic screw top containers.

The guidance document states that semen can be contained in various types of receptacles, such as a vial, goblet, ampoule, or straw, as long as they are tamper-evident and separate semen from individual donors. Therefore is it possible to amend 1.1 a) to include these additional containers. Additionally these need to be amended in the sample health certificate to allow for transport of chilled semen.

1.5 Diagnostic testing, vaccination and treatment

(*1) Any laboratory conducting the 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.*

The Department of Agriculture does not approve testing laboratories; certification of export testing is based on tests being performed at a laboratory that is accredited by Australia's National Association of Testing Authorities (NATA). Therefore we suggest the following change:

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

1.6.2 Embryo donor requirements

(1) The Competent Authority must have knowledge of and authority over the embryo donor(s) until completion of collection and testing required by this IHS.

The Competent Authority will approve an embryo collection team. It seems most appropriate that the approved embryo collection team veterinarian has this knowledge and authority. Therefore we suggest the following change:

(1) The ~~Competent Authority~~ approved embryo collection team veterinarian must have knowledge of and authority over the embryo donor(s) until completion of collection and testing required by this IHS.

(2) Embryo donors must not be situated on a premise/with other horses that is/are 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.

A 'premise' is not singular for premises. Therefore we suggest the following change:

(2) Embryo donors must not be situated on ~~a premise~~ premises/with other horses that ……..

1.6.3 Fertilisation requirements

(1) Embryos produced for the consignment must be fertilised from semen which was either:

Embryos are created when oocytes are fertilised by semen. Therefore we suggest the following change:

(1) ~~Embryos produced~~ The semen used to produce the embryos for the consignment must be ~~fertilised from semen which was e~~ither:

1.7 Semen requirements:

1.7.2 Semen donor requirements

(1) 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 centre. During this time semen donors must not be used for natural mating and must be isolated from animals not of equivalent health status.

Could the time required to be isolated in the actual semen collection centre be clarified as this is not clear in the IHS or guidance document. Are the donors required to do this initial 28 days in isolation before admission into the semen centre and then an additional 30 days before they are eligible to donate semen?

From the guidance document (GD-HORSSEMB.SPE):

*(**24) Equine infectious anaemia (EIA**)*

a) Donors showed no clinical sign of EIA on the day of each collection; and

*i) Donors were kept on premises where no case of EIA has been reported during the 90 days prior to each collection; **and***

Are donors able to reside at multiple premises as long as they meet the 90 day premises freedom requirement?

*ii) Donors were subjected to a test listed in the MPI document: MPI Approved Diagnostic Tests, Vaccines, Treatments and Post-arrival Testing Laboratories for Animal Import Health Standards (MPI-STD-TVTL), either **

*i Not less than 30 days after entry into the collection centre; **or***

What about the timing of semen collection in relation to this requirement or is it irrelevant?

*ii 30-60 days after collection; **or***

Is the stallion required to still be in the semen collection centre?

iii Annually at the start of the breeding season, with negative results.

Is this when the stallion is in the collection centre and is it related to the timing of semen collection?

*(*Delete as applicable)*

(25) Equine viral arteritis (EVA) *(delete as applicable)*

a) Donors were kept in an establishment where no equid has shown any clinical sign of EVA for the 28 days immediately prior to semen collection and showed no clinical sign of EVA on the day of semen collection; and

Is this a single establishment or can this include the time in pre-centre isolation?

iii) Were subjected to a test for EVA as prescribed in MPI-STD-TVTL on a blood sample with negative results within 14 days prior to semen collection, and had been separated from other equids not of equivalent health status for 14 days prior to blood sampling until the end of semen collection; or

Could you please clarify if the test can be performed before the donor enters the collection centre during the 28 day pre-centre isolation period or should the testing be performed once in the centre?

1.9 Storage

(3) Semen and embryos must 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.

See guidance document for more information about semen containers.

For fresh semen that is transported in screw top containers, will a label across the cap be considered appropriate for 'tamper-evident'? If not could tamper-evident please be clarified. What does the sanitised container refer to, could this please be clarified? If the marking must conform to IETS standards, how does this apply to semen?

There appears to be a typographical error, the following change may be appropriate:

(3) Semen and embryos must <u>be in</u> straws<u>, ampoules, pellets</u> or sanitised containers ……

1.12 The documentation that must accompany goods

(*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.*

For fresh semen this is not practical – the product is collected and arrives in NZ within 20 hours. Could this clause be amended to manage fresh semen documents on a shorter timeframe?