Ministry for Primary Industries
Manatū Ahu Matua

Review of Submissions

Draft Import Health Standard for Semen and Embryos from Equids

Draft Risk Management Proposal for Equids

[Document Date]

Growing and Protecting New Zealand

Agriculture & Investment Services

REVIEW OF SUBMISSIONS

Review of Submissions Semen and Embryos from Equids

[Document Date]

Approved for general release

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1 Introduction

The draft import health standard for the importation into New Zealand of equids was notified for consultation on 22 December 2018.

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

United States Department of Agriculture	15 April 2019
New Zealand Equine Health Association, Dr Patricia Pearce	26 April 2019

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	CTO	Chief Technical Officer
IRA	Import Risk Analysis	CEM	Contagious equine metritis
USDA	United States Department of Agriculture	OIE	World Organisation for Animal Health
APHIS	USDA Animal and Plant Health Inspection Service	EIA	Equine infectious anaemia
EVA	Equine viral arteritis	EHV-1	Equine herpesvirus-1

2 Summary of Amendments

As a result of comments made, the following is a summary of amendments to be made to the *Review of Submissions Semen and Embryos from Equids*.

Copies of all external stakeholder submissions in their entirety are presented in Appendix 1.

2.1 Clause 1.6.3 – Teaser mares

Requirement in draft IHS for consultation

(1) If teaser mares are used in the collection of semen, the teaser:

a) Must be of equivalent health status to the donor; and

b) Must be examined by an approved veterinarian, including the external reproductive organs, to ensure the teaser animal is free from clinical evidence of infectious disease transmissible in semen on the day of semen collection.

Requirement in final draft IHS (amended after consultation)

(2) If teaser mares are used in the collection of semen, the teaser:

a) Must be of equivalent health status to the donor; and
b) Must not be used as a teaser from the time of sample collection until negative disease test results are returned; and
c) Must be examined by an approved veterinarian, including the external reproductive organs, to ensure the teaser animal is free from clinical evidence of infectious disease transmissible in semen on the day of semen collection

2.2 Clause 2.1 – Equine arteritis virus (EVA) testing for teaser mares

Requirement in draft IHS for consultation

No specific requirements. Covered by teaser mare requirement to be of equivalent health status to donors.

Requirement in final draft IHS (amended after consultation)

(1) Teaser mares:

a) Must be kept for the 28 days prior to use as a teaser on premises where no equid has shown any clinical signs of EVA during that period and show no clinical signs of EVA on the day of semen collection; and
b) Must be subjected to a test for EVA carried out on a single blood sample with negative results:

i) Collected not less than 21 days after entry into the semen collection centre if not a resident at the semen collection centre; or
ii) Collected at the beginning of each breeding season prior to being used for teasing if resident at the semen collection centre.

2.3 Clause 2.2 – Equine herpesvirus-1

Requirement in draft IHS for consultation

Title was Equine herpesvirus-1 (EHV-1) (abortigenic and paralytic forms).

Requirement in final draft IHS (amended after consultation)

Title is now just Equine herpesvirus-1 (EHV-1).

2.4 Clause 2.3 – Equine infectious anaemia virus (EIA) testing for embryos

Requirement in draft IHS for consultation

(1) Donors must:

a) Be kept on premises where no case of EIA has been reported during the 90 days prior to each collection; and
b) Show no clinical sign of EIA on the day of each collection; and
c) Be subjected to a test for EIA carried out in the 21 days prior to collection, with a negative result.

Requirement in final draft IHS (amended after consultation)

(2) Embryo donors must:

a) Be kept on premises where no case of EIA has been reported during the 90 days prior to and the 60 days after each collection; and
b) Show no clinical signs of EIA on the day of each collection; and
c) Be subjected to a test for EIA carried out in the 30-60 days after collection, with a negative result.

2.5 Clause 2.3 – Equine infectious anaemia virus (EIA) testing for teasers

Requirement in draft IHS for consultation

No specific requirements. Covered by teaser mare requirement to be of equivalent health status to donors.

Requirement in final draft IHS (amended after consultation)

(1) Teaser mares must:

a) Be kept on premises where no case of EIA has been reported during the 90 days prior to each collection; and
b) Show no clinical signs of EIA on the day of each collection; and
c) Must be subjected to a test for EIA carried out on a single blood sample with negative results:

i) Collected not less than 21 days after entry into the semen collection centre if not a resident at the semen collection centre; or
ii) Collected at the beginning of each breeding season prior to being used for teasing if resident at the semen collection centre.

2.6 Clause 2.4 – Contagious equine metritis (CEM) testing intervals

Requirement in draft IHS for consultation

(1) Donors and teaser mares must be kept, since birth or for at least 60 days prior to collection, on premises where no case of CEM has been reported during that time; and

a) Must have no direct or indirect contact with CEM during the 60 days prior to collection; and
b) Must show no clinical signs of CEM on the day of each collection; and
c) Must be subjected to a test for CEM not less than 7 days after entry into the collection centre for semen, or in the 30 days prior to collection for embryos, with negative results;

i) Stallions must be sampled two times at intervals of 4-7 days. Swab sampling sites are the urethra; urethral fossa and its sinus; and the penile sheath.
ii) Mares must be sampled two times at intervals of 4-7 days. Swab sampling sites are the clitoral fossa and sinuses; and

d) Must not receive antibiotics in the 7 days (systemic treatment) or 21 days (local treatment) before the first sample collection or during the CEM sampling period; and
e) Must be protected against any possibility of infection with CEM since the beginning of the tests

Requirement in final draft IHS (amended after consultation)

(2) Donors and teaser mares must be kept, since birth or for at least 60 days prior to collection, on premises where no case of CEM has been reported during that time; and

a) Must have no direct or indirect contact with CEM during the 60 days prior to collection; and
b) Must show no clinical signs of CEM on the day of each collection; and
c) Must be subjected to a test for CEM not less than 7 days after entry into the collection centre for semen, or in the 30 days prior to collection for embryos, with negative results;

i) Stallions must be sampled two times at intervals of 4-14 days. Swab sampling sites are the urethra; urethral fossa and its sinus; and the penile sheath.
ii) Mares must be sampled two times at intervals of 4-14 days. Swab sampling sites are the clitoral fossa and sinuses; and

d) Must not receive antibiotics in the 7 days (systemic treatment) or 21 days (local treatment) before the first sample collection or during the CEM sampling period; and
e) Must be protected against any possibility of infection with CEM since the beginning of the tests

2.7 Clause 2.5 – Dourine testing teaser mares

Requirement in draft IHS for consultation

No specific requirements. Covered by teaser mare requirement to be of equivalent health status to donors.

Requirement in final draft IHS (amended after consultation)

(1) Teaser mares must:

a) Be kept since birth, or for the 180 days prior to use as a teaser in a country which has been free from dourine for not less than the past 180 days; or
b) Be kept for the 180 days prior to use as a teaser on premises where no case of dourine was reported during that period and subjected to a diagnostic test for dourine with negative results, collected at the beginning of each breeding season prior to being used for teasing.

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. No internal submissions was received after the internal review deadline.

4 Review of Submissions

4.1 United States Department of Agriculture (USDA)

4.1.1 START DATE OF SEMEN COLLECTION

1.6.2(1)(b) and 1.7.2(1)(b): The United States requests clarification regarding whether semen and embryos can be collected for export to New Zealand from the first day the donor enters the center, or whether all testing must be completed prior to collection.?

MPI Response

Equine semen can be collected for export from the first day the donor enters the centre and stored until the completion of testing or other measures required for export. This information is contained in the guidance document. For equine embryos, testing must be completed prior to collection.

4.1.2 TRANSFER TO ANOTHER CONTAINER

1.8(3): The IHS states that where semen or embryos are transferred from one transport container to another, the following information must be recorded on the veterinary certificate: the date of transfer, approved collection center or storage facility, reason for transfer, and the name of veterinarian involved in the transfer. The United States is concerned specifically about points (28) and (25) of the model veterinary certificates for equine semen and embryos, which indicate that the veterinarian's signature is required on the veterinary certificate. However, the veterinarian who performed the transfer may not be available when the export health certificate is issued. Therefore, the United States requests that the veterinarian's signature not be required on this certificate, and the designated U.S. official's signature be considered adequate. If New Zealand chooses to maintain this requirement, then the United States requests clarification regarding the justification for this more stringent regulation.

MPI Response

MPI is able to consider alternative certification requests that provide equivalent risk mitigation when negotiating a new veterinary certificate accompanying consignments of equine germplasm from the USA to New Zealand. It is recommended this request is made when a request to negotiate certification requirements under this IHS are submitted to MPI.

4.1.3 LABORATORY RESULTS

1.10.2(1): The IHS states that the following information must accompany the semen and embryo shipments: original laboratory reports, copies of laboratory reports endorsed by the Official Veterinarian, or a tabulated summary of laboratory results endorsed by the Official Veterinarian. The United States is concerned specifically about point (10) in the model veterinary certificates for equine semen and embryos, which require the tabulated summary to be accompanied by copies of the reports endorsed by the Official Veterinarian. However, the United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS) reviews and verifies the test reports and the summary table to ensure that each donor listed on the certificate was tested for each disease, using the appropriate test, within the correct timeframe. Therefore, the United States requests that New Zealand accept the summary table endorsed by APHIS without requiring copies of the reports endorsed by APHIS. If there is any doubt about a particular consignment, then a copy of the test reports can be requested. If New Zealand affirms that the reports in their entirety are necessary, then the United States asks for clarification on the reasoning for more stringent regulation.

MPI Response

This is an error in the model certificate wording. It should be the same as what is written in the IHS: original laboratory reports, copies of laboratory reports endorsed by the Official Veterinarian, or a tabulated summary of laboratory results endorsed by the Official Veterinarian. This will be amended in the model certificate.

4.1.4 CEM FREEDOM

2.4(2): The United States requests clarification regarding whether the Chief Technical Officer (CTO) recognizes the United States as free from contagious equine metritis (CEM). The last occurrence of CEM in the United States was in 2014. If the CTO does not recognize the United States as free, then we request clarification regarding the criteria that needs to be met to be considered free.

MPI Response

MPI has not been approached by the USDA to assess the freedom from CEM claim. MPI assesses self-declarations for disease freedom following the OIE *Code* Chapter 1.6 Procedures for Self Declaration and for Official Recognition by the OIE.

4.1.5 EVA TESTING OPTIONS

Point (29): The certificate indicates that option (29)(g) applies only to frozen semen. Frozen semen may use options (29)(a)-(g) and fresh chilled semen may use options (29)(a)-(f).

However, there does not appear to be an option (29)(g) listed on the certificate. Can New Zealand confirm when option (29)(g) is applicable??

MPI Response

This is an error. It should read “Frozen semen may use options (29)(a)-(f) and fresh chilled semen may use options (29)(a)-(e). This will be amended in the model certificate.

4.1.6 TEASER MARES

Point (33)(c)(2): The United States requests that “mares” be changed to “teaser mares” for clarification, as in (34)(b)(ii). We request confirmation that these points can be lined-out if teaser mares are not used. If teaser mares are used, then we request clarification regarding whether the laboratory results for teaser mares must be included in the tabulated summary or laboratory reports that accompany the health certificate?

MPI Response

MPI agrees that this should be clarified by changing “mares” to “teaser mares”. A note will be added to indicate that if teaser mares were not used that this clause may be deleted. Test results will be required for teaser mares and the testing has now been specified for clarification.

4.1.7 TERMINOLOGY FOR EMBRYO COLLECTION

Point (11): This point covers the embryo collection team. This is not terminology that is commonly used in the United States. Therefore, the United States requests that “name and address of embryo collection herd/center” is changed to “name and address of the embryo collection team” or that New Zealand clarify that our alternative language would be sufficient.

MPI Response

This is an error. It should refer to the embryo collection team. This will be amended in the model certificate.

4.2 NZEHA, Dr Patricia Pearce

4.2.1 RISK ASSESSMENT DATA

The MPI surveillance Annual report only stated that 34 import permits were issued for semen in 2019. NZ Stats via infoshare only records the dollar value of semen and embryo imports and country of origin. In 2018 New Zealand imported NZ$2 million worth of equine semen and NZ$800,000 worth of equine embryos based on a search using the HS codes in the Guidance document. Does MPI Have other data to inform this risk assessment process?

MPI Response

The HS code for embryos is 0511990045 – Animal products; n.e.c. in chapter 5, embryos. This HS code is not specific to equine embryos and in fact is the HS code used for embryos of all species. The information from infoshare will be showing the total value of all embryos from all species imported into New Zealand, most of which is likely sheep and cattle.

For equine semen and embryos, permits are only required where an equivalence is granted or if the commodity is required to be directed to a transitional facility. Where the imported semen and embryos meet the requirements as written, no permit would be required.

MPI does have access to other data from our Intelligence and Targeting Team which can data mine our imports data to specify further the types of imports.

4.2.2 APPROPRIATE LEVEL OF PROTECTION (ALOP)

Where has MPI pitched its ALOP with regards equine semen and embryos in the consulted documents?

MPI Response

The ALOP is reflected in the choice of the final requirements that go into the IHS based on the risk analysis process carried out as per the OIE *Code* Section 2.

4.2.3 CLEARANCE CRITERIA

What verification between what is certified and what product actually enters occurs for semen and embryos that are entering New Zealand?

MPI Response

Semen and embryos entering New Zealand have all required documentation reviewed by MPI to determine that it is complete and correct. Where there are issues with documentation MPI holds the shipment until all documentation has been provided and is correct. The seals on the tanks are also checked to see that they are intact. Only after this will the shipment be cleared.

MPI is developing a germplasm verification programme to verify tank contents of germplasm against the germplasm listed on the veterinary certificate. In addition to this, the model certificate wording will be more specific with wording similar to the following: “The semen for export, all of equivalent health status, was identified and placed under the supervision of the Official Government Veterinarian in fresh liquid nitrogen in a container(s) which was either new, or, prior to loading, the shipper was emptied and inspected and any loose straws removed. The shipper, including all surfaces contacting the straws, was disinfected”.

4.2.4 SELF-REPORTING AS A RISK MANAGEMENT MEASURE

Does MPI have any information on the efficacy of self reporting as a risk management measure?

MPI Response

MPI does not have any information on the efficacy of self-reporting as a risk management measure, however this is the same wording used for many OIE listed diseases (as per the disease chapter recommendations) and what is also used in the import of live equids. New Zealand also uses self-reporting as a risk management measure when exporting the same commodities to other countries.

4.2.5 COUNTRY FREEDOM

Do the countries to which these standards apply, undertake active ongoing surveillance programmes for those diseases where country freedom is offered as the only risk management measure…e.g. CEM?

MPI Response

There is no disease in this IHS where country freedom is the only risk management measure. CEM has two options, the first is country freedom and the second is the testing. When country freedom is assessed, MPI requires supporting evidence which would include information such as surveillance.

As per the IHS, any new country that requests access must have their country exporting systems and certification assessed by MPI prior to the negotiation of a veterinary certificate. The evidence must include details about all of the following:

1. The ability of the exporting country's Competent Authority to verify the animal health status of equids in the exporting country, zone, or compartment, with respect to the risk organisms identified in the IHS.
2. The adequacy of the national systems and/or programmes and standards in the exporting country for regulatory oversight of the equine industry.
3. The capability of the exporting country's Competent Authority to support the issue of veterinary certificates as required by the IHS.
4. Where applicable, the pre-export isolation (PEI) facility and operating protocols.

The evidence will be obtained during evaluation of the Veterinary Services of the Competent Authority of the exporting country in accordance with Chapter 3 of the OIE *Code*.

The CTO must be satisfied with the exporting country systems prior to preparation of equids for export to New Zealand. MPI reserves the right to audit facilities from countries approved to export equids to New Zealand either during the approval process or anytime thereafter.

The official approval letter that is sent by MPI to the exporting countries notes that MPI expects any changes to the disease situation in the country or changes to certification be notified to MPI.

4.2.6 EQUINE INFECTIOUS ANAEMIA

We would propose that the more stringent of the risk management options offered in the 2009 IRA be considered for this IHS:

Semen could be imported provided that:

1. donors show no clinical sign of EIA on the day of semen collection and for the 60 days after semen collection; and
2. no case of EIA has been associated with any premises where the animals were kept during the 3 months prior to semen collection; and the 60 days after semen collection, and
3. donors are subjected to an ELISA or AGID test EIAV antibody 30 - 60 days after germplasm collection with negative results.

NB. In most cases antibody can be detected by the AGID within 45 days of infection however, although rare, this can be as long as 60 days

Embryos could be imported provided that:

1. both male and female donors show no clinical sign of EIA on the day of germplasm collections and for the 60 days after germplasm collection; and
2. no case of EIA has been associated with any premises where the animals were kept during the 3 months prior to and the 60 days after germplasm collection; and
3. donors are subjected to an AGID test or ELISA for EIAV antibody 30-60 days after germplasm collection with negative results.

The semen and embryos must remain under quarantine at the collection centre until the end of the observation period for clinical disease and the post collection EIA tests have been completed on the donors. The donors may not necessarily complete their post collection observation period and tests at the collection centre, but could have follow up inspections and tests at their home establishments. Of course if through subsequent movement and contact with an infected horse they succumb to disease post collection it will render the germplasm under quarantine ineligible for export to New Zealand.

MPI Response
MPI does not agree that equine semen requirements need to be changed. Donor stallions are managed in essentially the same way as live horses for import into New Zealand. All stallions must be resident at the semen collection centre (only with other equids of equivalent health status) for 21 days before the testing occurs. For horses imported into New Zealand, we require 21 days of PEI and an EIA test is carried out on samples taken in the 21 days prior to export.

MPI agrees to a partial change of the embryo requirements. The semen donors will be required to meet the current requirements which we believe manages the EIA risk in these animals. For female donors the following changes will be made:

Embryos could be imported provided that donors:

1. Are kept on premises where no case of EIA has been reported during the 90 days prior to and the 60 days after each collection; and
2. Show no clinical signs of EIA on the day of and the 60 days after each collection; and
3. Are subjected to a test for EIA carried out in the 30-60 days after collection, with a negative result.

4.2.7 EQUINE HERPES VIRUS

The IRA (2009) states that EHV-1 can display a wide range of diseases from inapparent respiratory infection to abortion and potentially fatal neurological disease. The same organism is involved in this wide variation of expression of the disease. By including a qualifier, "(abortigenic and paralytic forms)" in brackets in the IHS Part 2, 2.2 (1) a) it could be interpreted by the reader they could collect and export from the semen or embryos if respiratory disease was observed but no abortion or paralysis. It is understood that clinical signs can be interchangeable. The NZEHA recommends removal of the existing bracketed terms after EHV-1.

MPI Response
MPI agrees to remove the bracketed terms.

4.2.8 EQUINE VIRAL ARTERITIS

Page 10 of the guidance document discusses option 29(g) but no paragraph (g) is included.

MPI Response

See response 4.1.5.

4.2.9 GERMPLASM TRANSPORT

Section 26 of the transport requirements for semen and Section 23 in the model certificate for embryos could be further strengthened:

Proposed wording should include verification that the new or cleaned and disinfected transport containers were verified by the Official Veterinarian as being empty of all germplasm. From that point onwards while not under the direct supervision of the Official Veterinarian the container shall always be sealed using tamper evident seals.

MPI Response

See second paragraph of response 4.2.3.

4.2.10 MODEL CERTIFICATE

Model embryo certificate section (26) (EVA) – how is it determined if a country would choose between complying with 26(a) or 26(b)? Should 26(b) be deleted?

MPI Response

The certifying official veterinarian will cross out the clauses that are not used. There are three options all together:

1. Meet (a)(i), or
2. Meet (a)(ii), or
3. Meet (b).

This is as per the OIE *Code* recommendations.

5 Appendix 1: Copies of Submissions

5.1 United States Government

BEGIN U.S. COMMENTS

The United States appreciates the opportunity to comment on New Zealand's draft technical regulation for "Import Health Standard for Semen and Embryos from Equids," notified to the World Trade Organization as G/SPS/N/NZL/588 on February 15, 2019. The United States offers the following comments for your consideration.

Comments on Import Health Standards (IHS):
1.6.2(1)(b) and 1.7.2(1)(b): The United States requests clarification regarding whether semen and embryos can be collected for export to New Zealand from the first day the donor enters the center, or whether all testing must be completed prior to collection.

1.8(3): The IHS states that where semen or embryos are transferred from one transport container to another, the following information must be recorded on the veterinary certificate: the date of transfer, approved collection center or storage facility, reason for transfer, and the name of veterinarian involved in the transfer. The United States is concerned specifically about points (28) and (25) of the model veterinary certificates for equine semen and embryos, which indicate that the veterinarian's signature is required on the veterinary certificate. However, the veterinarian who performed the transfer may not be available when the export health certificate is issued. Therefore, the United States requests that the veterinarian's signature not be required on this certificate, and the designated U.S. official's signature be considered adequate. If New Zealand chooses to maintain this requirement, then the United States requests clarification regarding the justification for this more stringent regulation.

1.10.2(1): The IHS states that the following information must accompany the semen and embryo shipments: original laboratory reports, copies of laboratory reports endorsed by the Official Veterinarian, or a tabulated summary of laboratory results endorsed by the Official Veterinarian. The United States is concerned specifically about point (10) in the model veterinary certificates for equine semen and embryos, which require the tabulated summary to be accompanied by copies of the reports endorsed by the Official Veterinarian. However, the United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS) reviews and verifies the test reports and the summary table to ensure that each donor listed on the certificate was tested for each disease, using the appropriate test, within the correct timeframe. Therefore, the United States requests that New Zealand accept the summary table endorsed by APHIS without requiring copies of the reports endorsed by APHIS. If there is any doubt about a particular consignment, then a copy of the test reports can be requested. If New Zealand affirms that the reports in their entirety are necessary, then the United States asks for clarification on the reasoning for more stringent regulation.

2.4(2): The United States requests clarification regarding whether the Chief Technical Officer (CTO) recognizes the United States as free from contagious equine metritis (CEM). The last occurrence of CEM in the United States was in 2014. If the CTO does not recognize the United States as free, then we request clarification regarding the criteria that needs to be met to be considered free.

Point (29): The certificate indicates that option (29)(g) applies only to frozen semen. Frozen semen may use options (29)(a)-(g) and fresh chilled semen may use options (29)(a)-(f). However, there does not appear to be an option (29)(g) listed on the certificate. Can New Zealand confirm when option (29)(g) is applicable?

Point (33)(c)(2): The United States requests that "mares" be changed to "teaser mares" for clarification, as in (34)(b)(ii). We request confirmation that these points can be lined-out if teaser mares are not used. If teaser mares are used, then we request clarification regarding whether the laboratory results for teaser mares must be included in the tabulated summary or laboratory reports that accompany the health certificate.

Additional Comments on Model Veterinary Certificate for Equine Embryos:
Point (11): This point covers the embryo collection team. This is not terminology that is commonly used in the United States. Therefore, the United States requests that "name and address of embryo collection herd/center" is changed to "name and address of the embryo collection team" or that New Zealand clarify that our alternative language would be sufficient.

New Zealand continues to be an important market for U.S. agricultural products. The United States appreciates your consideration of these comments and looks forward to your response.

END U.S. COMMENTS

5.2 NZEHA, Dr Patricia Pearce

Consultation on a revised New Zealand Import Health Standard (IHS) for Semen and Embryos from Equids

Feedback from the New Zealand Equine Health Association

24 April 2019

1 Documents consulted

The draft documents consist of the following:
- Risk Management Proposal: Semen and Embryos from Equids (EQUIGERM.SPE)(MPI, no date);
- Import Health Standard: Semen and Embryos from Equids (EQUIGERM.SPE)(MPI, no date);
- Guidance Document: Semen and Embryos from Equids (EQUIGERM.SPE)(MPI, no date).

Other relevant documents utilised include:
- Approved Diagnostic Tests, Vaccines, Treatments, and Post-Arrival Testing Laboratories for Animal Import Health Standards (MPI-STD-TVTL)(Date: 8 May 2018) (MPI, 2018a);
- Import risk analysis: Equine germplasm from Australia, Canada, the european Union and USA (2009,IRA);
- Absence of Specified Animal Diseases from New Zealand (Biosecurity New Zealand)(Date: 1 January 2019) (MPI, 2019);
- OIE Terrestrial Animal Health Code (2018) chapters on CEM (OIE, 2018a) EIA (OIE, 2018b) ;
- OIE Terrestrial Manual (2018) chapters on CEM (OIE, 2018c), EIA (OIE, 2018d),

2. General Questions

The risk assessment process is in very many ways a numbers game and unfortunately there is little data available on the actual number of equine semen doses be it fresh or frozen, and embryos imported into New Zealand.

The MPI surveillance Annual report only stated that 34 import permits were issued for semen in 2019. NZ Stats via infoshare only records the dollar value of semen and embryo imports and country of origin. In 2018 New Zealand imported NZ$2 million worth of equine semen and NZ$800,000 worth of equine embryos based on a search using the HS codes in the Guidance document. Does MPI Have other data to inform this risk assessment process?

In December 2009, the Ministry for Primary Industries (MPI) completed an Import Risk Assessment (IRA) for equine germplasm from Australia, Canada, the European Union and USA (2009 IRA) and a range of IHS followed based on that assessment. Throughout that assessment risk management options were offered for each

organism that ranged in stringency. Almost without exception the least, or second least stringent options were selected in the resulting IHS. Importation of semen and embryos obviously represent a risk pathway to introduce disease as can be observed by the ongoing Mycoplasma bovis incursion in cattle in 2017 which is continuing to have a huge socio-economic impact. With this learning in mind, where has MPI pitched its ALOP with regards equine semen and embryos in these documents?

NZEHA seeks more understanding on the criteria MPI use to clear germplasm imports into New Zealand. This is especially important for semen where many of the establishments do not have full time veterinary supervision and although tanks may be sealed by Official Veterinarians" prior to that sealing is there opportunity for product to be added outside of the official process? What verification between what is certified and what product actually enters occurs for semen and embryos that are entering New Zealand?

Also concern to us is the level of reliance placced on collection from donors that attest they have been in a country free of a disease and must have been on premises free of disease for a period of time. These are of course important inclusions into a standard but they rely on clinical expression of disease and a culture of reporting disease and movement which is difficult to foster when the impacts of doing so usually result in negative impacts on the reporter. Does MPI have any information on the efficacy of self reporting as a risk management measure?

Do the countries to which these standards apply, undertake active ongoing surveillance programmes for those diseases where country freedom is offered as the only risk management meaure…eg CEM?

3. Risk organism-specific observations

3.1 Equine Infectious Anaemia (EIA)

Proposed changes to the IHS

The Terrestrial Code chapter on EIA was last amended in 2013 and does not make any recommendations for germplasm, it does however reference the value of PCR in some circumstances, for example to confirm infection. Is PCR testing of semen a possible verification mechanism to confirm absence of this organism?

The IRA 2009 listed three options in ascending order of stringency that could be considered for effective management of the risk of EIAV in the commodities. The July 2017 version chose the middle option of the three offered, suggesting a degree of comfort with only a moderate level of risk protection and this IHS under consultation proposes no changes from the July 2017 version.

Since then an incursion of Mycoplasma bovis into the New Zealand cattle sector has arisen from its introduction likely via imported germplasm. This resulted in a protracted time before the diagnosis of the first case and an extremely high social and economic cost. In light of this example the equine industry urges that MPI to review its comfort with the stringency of its measures against an EIAV. It is an organism which like M bovis is endemic in many of the countries we import from and commonly presents with subclinical infection.

Recommendations

We would propose that the more stringent of the risk management options offered in the 2009 IRA be considered for this IHS:

Semen could be imported provided that:

i. donors show no clinical sign of EIA on the day of semen collection and for the 60 days after semen collection; and

ii. no case of EIA has been associated with any premises where the animals were kept during the 3 months prior to semen collection; and the 60 days after semen collection, and

iii. donors are subjected to an ELIZA or AGID test EIAV antibody 30 - 60 days after germplasm collection with negative results.

NB. In most cases antibody can be detected by the AGID within 45 days of infection however, although rare, this can be as long as 60 days

Embryos could be imported provided that:

i. both male and female donors show no clinical sign of EIA on the day of germplasm collections and for the 60 days after germplasm collection; and

ii. no case of EIA has been associated with any premises where the animals were kept during the 3 months prior to and the 60 days after germplasm collection; and

iii. donors are subjected to an AGID test or ELISA for EIAV antibody 30-60 days after germplasm collection with negative results.

The semen and embryos must remain under quarantine at the collection centre until the end of the observation period for clinical disease and the post collection EIA tests have been completed on the donors. The donors may not necessarily complete their post collection observation period and tests at the collection centre, but could have follow up inspections and tests at their home establishments. Of course if through subsequent movement and contact with an infected horse they succumb to disease post collection it will render the germplasm under quarantine ineligible for export to New Zealand.

3.2 Equine Herpes Virus

The proposed IHS is unchanged from the 2017 version. The IRA (2009) states that EHV-1 can display a wide range of diseases from inapparent respiratory infection to abortion and potentially fatal neurological disease. The same organism is involved in this wide variation of expression of the disease. By including a qualifier, *"(abortigenic and paralytic forms)"* in brackets in the IHS Part 2, 2.2 (1) a) it could be interpreted by the reader they could collect and export from the semen or embryos if respiratory disease was observed but no abortion or paralysis. It is understood that clinical signs can be interchangeable. The NZEHA recommends removal of the existing bracketed terms after EHV-1

3.3 Equine Viral Arteritis

Page 10 of the guidance document discusses option 29(g) but no paragraph (g) is included.

Wording of the Model veterinary certificate

Section 26 of the transport requirements for semen and Section 23 in the model certificate for embryos could be further strengthened:

Proposed wording should include verification that the new or cleaned and disinfected transport containers were verified by the Official Veterinarian as being empty of all germplasm. From that point onwards while not under the direct supervision of the Official Veterinarian the continer shall always be sealed using tamper evident seals.

Model embryo certificate section (26) – how is it determined if a country would choose between complying with 26(a) or 26(b)? Should 26(b) be deleted?