Ministry for Primary Industries
Manatū Ahu Matua

Review of Submissions

Draft Import Health Standard for
Semen and Embryos from Sheep *(Ovis aries)*
And Goats *(Capra hircus)*

June 2015

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Regulation & Assurance Branch

REVIEW OF SUBMISSIONS

Draft Import Health Standard for
Semen and Embryos from Sheep *(Ovis aries)*
and Goats *(Capra hircus)*

June 2015

Approved for general release

Howard Pharo
Manager Import and Export Animals
Ministry for Primary Industries

Contents

1 Introduction

1) The draft import health standard for the importation into New Zealand of *Semen and Embryos from Sheep (Ovis aries) and Goats (Capra hircus)* was notified for consultation on 14 March 2014.

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

a)	Federated Farmers	16 May 2014
b)	Ian McDougall	17 May 2014
c)	University of Auckland	29 April 2014
d)	European Union	14 May 2014
e)	Australian Government	15 May 2014
f)	Triple N Goat Stud	15 May 2014
g)	Beef & Lamb New Zealand	16 May 2014
h)	Jock Allison	16 May 2014

2) 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	CCPP	contagious caprine pleuropneumonia
IRA	Import Risk Analysis	EAE	enzootic abortion of ewes
IHS	Import Health Standard	CCHF	Crimean Congo haemorrhagic fever virus
FMD	foot and mouth disease	PPR	peste des petits ruminants
BTV	bluetongue virus	GD	Guidance Document
RMP	Risk Management Proposal	MPI-STD-TVTL	Approved diagnostic tests, vaccines, treatments, and post-arrival testing laboratories for animal import health standards

2 Summary of Amendments

1) As a result of comments made, the following is a summary of amendments to be made to the *Import Health Standard for Semen and Embryos from Sheep (Ovis aries) and Goats (Capra hircus)* and the associated *Guidance Document (GD)*.
2) The parts and sections described below refer to those in the draft IHS for external consultation. The part and section numbers do not correspond to the final draft as a result of reformatting.

2.1 Import health standard amendments

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

1) Part 2, section 6 (4c) has been changed to: Transfer must not be through a bluetongue infected zone. See the other change to this sentence listed below in Other amendments.
2) Part 2, section 7 (1) has been changed to: Embryo donors must not be situated in a herd/flock 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 the testing of the donors as required by this IHS.
3) Part 2, section 7 (6) indicating requirements for the semen used to produce embryos has been deleted.
4) Part 2, section 8 (3) has been deleted because there is no scientific justification for adding trypsin to the washing procedure. Embryos are to be collected, processed and stored as per the OIE *Code* requirements.
5) Part 2, section 9 (3) has been changed to: Semen and embryos must be in straws or sanitised containers which are sealed and tamper-evident, and clearly and permanently marked to identify the donor and the date(s) of collection.
6) Part 3, section 1 (1d) has been changed to: be subjected to a BTV test in accordance with the *Code* and *MPI-STD-TVTL*, with negative results.
7) Part 3, section 2 (1a) has been changed to: where CCHF has not been recognised by the Competent Authority for the 21 days before collection. A new option has been added: (3) Donors must be tested for CCHFV in accordance with *MPI-STD-TVTL*.
8) Part 3, section 4 (1) has been changed to: Semen donors must be resident since birth in countries where ovine pulmonary adenomatosis has not been recognised by the Competent Authority. (2) and (3) have also been changed to reflect that jaagsiekte sheep retrovirus is no longer considered a risk in embryo trade. Premise freedom (2b) has been changed from 10 years to 5 years. The option for testing (3) for jaagsiekte has been changed to: Semen donors must be subjected to an ovine pulmonary adenomatosis examination or test in accordance with *MPI-STD-TVTL*, with negative results.
9) Part 3, section 5 (1) has been changed to: Donors must be resident since birth in countries where MV has not been recognised by the Competent Authority; or.
10) Part 3, section 9 has been removed. The *Code* no longer provides recommendations for VS. The RMP now explains why risk mitigation is not necessary for VS.
11) Part 3, section 10 (2) has been changed to: Donors must be resident in an establishment where Wesselsbron disease has not been recognised for at least the 21 days prior to collection. Another option has also been added: Donors must be tested for Wesselsbron disease in accordance with *MPI-STD-TVTL*.
12) Part 3, section 12 (1b) has been changed to: Aliquots of semen or embryos/oocytes or collection/washing fluids from each collection must be subjected to a CCPP test in accordance with the *Code* and listed in *MPI-STD-TVTL*, with negative results.
13) Part 3, section 13 (2b) has been changed to: Tested for *Mycoplasma agalactiae* using a test in accordance with the OIE *Code* and listed in *MPI-STD-TVTL*, with negative results.
14) Part 3, section 15 (3b) has been changed to: Embryos/oocytes or collection/washing fluids from each embryo collection must be subjected to an EAE test in accordance with the *Code* and listed in *MPI-STD-TVTL*, with negative results.

2.2 Guidance document amendments

1) A new section has been added (5.6) to describe approved types of semen containers.
2) A new section has been added (6.1) to indicate that approved antibiotics effective against leptospirosis are listed in *MPI-STD-TVTL*.
3) The model veterinary certificates have been amended to reflect the amendments to the IHS which are listed above.
4) The model veterinary certificate for semen, Part 2, where it stated "pellet" it now states "pellet container".

2.3 Other Amendments

The following changes to the IHS are the result of MPI's further consideration of the documents:

1) A Permit to import section has been added (Part 1, section 13).
2) Additional information about the country specific veterinary certificate has been added (Part 1, section 14.2).
3) Part 1, the last sentence of section 4 has been deleted because permits are required for all importations.
4) Part 1, section 3 (2), *Leptospira* serovars has been added and Vesicular stomatitis virus has been deleted.
5) Part 2, section 1 has been moved. Eligibility criteria is now part of Application (1.1).
6) Part 2, section 2 has been moved. What countries this standard applies to is now part of Application (1.1).
7) A section has been created for *Leptospira* serovars (2.12). This section states that antibiotics must be added to semen and embryos as per the *Code*. This requirement was previously included through a reference to the *Code* in the section on collection and processing (1.11), however it did not indicate that the requirement manages the risk associated with *Leptospira* serovars.
8) Part 2, section 6 (4c), the wording has been changed to prevent donors from being transferred through a Rift Valley fever zone, or to be protected during the transit.
9) Part 2, section 8 (6) has been changed to: Antibiotics recommended in the *Code* or *IETS Manual* and listed in *MPI-STD-TVTL* must be added to embryo collection, processing, washing and storage media and to the semen diluents in accordance with the *Code.*
10) Part 2, section 9 (4), the wording has been changed to allow germplasm to be stored with any other germplasm which has been collected and processed in accordance with the *Code*.
11) Part 2, section 11 (2i) has been changed to: All diagnostic tests, including test type, date of sampling, and results must be clearly linked to each donor and in the form of either a tabulated summary or copies of laboratory reports.
12) Part 2, section 12 has been moved to the Introduction of the IHS.
13) Part 3, section 1 (1c), vector-protected has been changed to vector-proof, which is defined in Schedule 1.
14) Part 3, section 3 (1) has been removed. The section titled Exporting country systems and certification describes the approval process which will be undertaken for any country before MPI engages in certificate negotiation. Approval can only granted after a complete assessment of countries' disease freedom claims.
15) Part 3, section 5 (2bi) has been deleted. That measures is relevant only to semen donors, which must undergo pre-entry isolation and be collected only while in an approved collection facility. 2bii will manage the risk for embryos. The anticipated wording in the agreed veterinary certificates can be found in the model veterinary certificate in the GD. *MPI-STD-TVTL* will list the tests types and methodology once they become approved.
16) Part 3, section 6 (3b) has been changed to: Unvaccinated donors must be tested for PPR accordance with *MPI-STD-TVTL*.
17) Part 3, section 7 (2) has been changed to: Donors from RVF infected countries or zones must comply with the *Code* recommendations for semen and *in vivo* derived ruminant embryos; or. The *Code* now has measures for sheep and goat semen from RVF infected countries.
18) Part 3, section 9 has been deleted. The *Code* no longer recommends measures for vesicular stomatitis. The measures had been in place to align with the *Code,* but they are considered unwarranted because New Zealand does not have a known vector and because the virus is not considered to be in semen and embryos due to lack of viremia.
19) Part 3, section 12 (1bii) has been changed to indicate that donor testing must be in accordance with the *Code* and *Manual*.
20) Part 3, section 13 (2b) has been changed to indicate that donor testing must be in accordance with the *Code* or *MPI-STD-TVTL*.
21) Part 3, section 15 (3) has been deleted. 15 (2) has been changed to: Donors must comply with the *Code* Chapters on EAE for the importation of sheep and goat semen and embryos. The *Code* now has measures for goats and embryos.
22) The *IETS Manual* and its definition have been added to Schedule 2 of the final draft.
23) A semen collection facility has been defined in Schedule 2 of the final draft.

The model veterinary certificates have been amended to reflect the changes to the IHS described above.

3 Review of Submissions

3.1 Federated Farmers

3.1.1 Draft IHS, Part 2, Section 2.6: Semen collection by facility requirements (Page 7)

Point 4(c) in this section states "Transfer must be through a bluetongue infected zone, or donors must be protected from insect attack during transit" The Federation assumes that this is a typographical error and should read "Transfer must not (emphasis added) be through a bluetongue infected zone …"

MPI Response
The IHS wording has been amended to read "Transfer must not be through...".

3.1.2 Draft IHS, Part 3, Section 3.3: Foot and Mouth Disease virus (Page 11)

The Federation notes that, whereas the RMP document [Section 6.6.3] recommends that MPI should be satisfied that the countries are free from FMD and that the requirments to import align with the Code, the IHS [Section 3.3] require that (1) donors must be resident in a country or zone that is free from FMD or (2) imports must comply with FMD recommendations for ruminant semen in the *Code*.

The Federation requests that this apparent discrepancy be investigated.

MPI Response
The discrepancy was noted. MPI is no longer referencing its own list of FMD free countries for ovine/caprine semen and embryos. Any country exporting to New Zealand must first be approved for this commodity and must also satisfy the FMD recommendations in the *Code,* applying them to embryos where they are only specified for semen.

3.1.3 Draft IHS, Part 3, Section 3.17: Scrapie (Page 15)

The Federation notes that the Ministry allows [3.17(2) (c)] the importation of semen from sheep donors that have a scrapie resistant genotype, but that this option is not extended to goat semen donors.

In this regard, the Federation understands that a scrapie genotype in goats may have been identified and asks that, if and when (a) scrapie resistant genotype(s) is/are confirmed in goat semen, then goat semen importers be given the same opportunity to use this avenue to obtain semen.

MPI Response
MPI's import risk analysis for scrapie in sheep and goat germplasm briefly discusses the role of genotype in goat resistance to scrapie. The situation in goats is more complex than in sheep.
While variation at codon 142 is associated with incubation time and codon 222 may be associated with susceptibility, not enough is known, however, to determine whether breeding for scrapie resistance is possible in goats in the same way that it is in sheep.
If new evidence comes to light, MPI will conduct a review of the IHS risk measures for scrapie for goat semen to ensure eligibility of import is appropriate.

3.1.4 For consideration with regard to the future of importing genetic material from sheep and goats

The Federation notes that the accuracy, specificity and sensitivity of testing for TSE's in tissues continues to evolve and requests that, as/when the testing methodology permits, the Ministry consider their use as part of the risk management measures that are implemented in order to best protect New Zealand from these diseases.

The Federation believes that, overall, the risks associated with importing of genetic material in the form of germplasm are less than the risks associated with importing live animals. The Federation requests that this matter is kept in mind when the policy around importing genetic material is next reviewed.

MPI Response

MPI agrees that as the accuracy of testing for Identified Risk Organisms (including TSE's) improves and becomes available that it should have the ability to rapidly accommodate new tests and technologies where a risk analysis deems it appropriate. The *MPI-STD-TVTL* is an incorporation of material by reference document which was implemented as part of our process to facilitate this. The *MPI-STD-TVTL* contains current MPI approved tests and OIE recommendations which are able to updated and referenced as technologies change and increased scientific evidence or data becomes available. MPI is in constant review of the literature to ensure we are managing the biosecurity risk appropriately.

3.2 Ian McDougall

3.2.1 Jaagsiekte disease clause 28, 29 of guidance document

As there currently are no MPI Approved Diagnostic Tests for jaagsiekte I am proposing in addition to the above that either;

a) semen donors be > 5 years of age at the time of testing for the presence of jaagsiekte;
b) That bronchial washes of semen donors conducted at the completion of semen collection be subjected to PCR testing for the presence of jaagsiekte with negative results.

OR

a) semen donors be > 5 years of age at the time of testing for the presence of jaagsiekte;
b) semen donors be slaughtered at the completion of semen collection and their lungs and mediastinal lymph nodes subjected to histopathology, immunohistochemistry and PCR for jaagsiekte with negative results.

Or a combination of the above.

MPI Response
The test types required for semen will depend upon MPI's assessment of test type, validation, and method suggested by the exporting country at the time of veterinary certificate negotiation. While the IHS now says that the test and/or examination will be listed in *MPI-STD-TVTL*, the model veterinary certificate provides an example of what will be accepted during negotiation.

3.2.2 Jaagsiekte disease clause 31, 32 of guidance document

As there currently are no MPI Approved Diagnostic Tests for jaagsiekte I am proposing in addition to the above that either;

a) Embryos/oocytes or collection/washing fluids from each collection be subjected to PCR test for jaagsiekte with negative results;
b) That bronchial washes of embryo donors conducted at the completion of embryo collection be subjected to PCR testing for the presence of jaagsiekte with negative results.

OR

a) semen and embryos donors be > 5 years of age at the time of testing for the presence of jaagsiekte;
b) semen and embryos donors be slaughtered at the completion of embryo collection and their lungs and mediastinal lymph nodes subjected to histopathology, immunohistochemistry and PCR for jaagsiekte with negative results.

Or a combination of the above.

MPI Response
MPI has decided to eliminate jaagsiekte requirements for sheep and goat embryos because research indicates that there is strong evidence that embryo transfer is an effective barrier against the transmission of the jaagsiekte virus.

3.2.3 Health status of the semen used to fertilise the embryos, Part 2 section 2.7 (6)

Unless we can get some movement on the non-slaughter of rams and ewes that combine to produce embryos for export to NZ, then it is quite possible that the EU will be a no go (ie they may not sanction the slaughter of donors on animal welfare grounds).

There is evidence that embryo transfer and correct washing of embryos prevents the transmission of Jaagsiekte.

MPI Response

The risk analyses assessed the risks associated with embryos, not oocytes plus semen. They identified the risks (and measures) for embryos regardless of the health status of the semen used to make them. MPI has reassessed the requirements for semen used to fertilise embryos and decided to eliminate them.

3.3 Andrew Brown, University of Auckland

3.3.1 Quarantine/containment

Having read this draft standard I am curious to know why there are no requirements to place the recipients of this germplasm into quarantine/containment facility until the resulting progeny are of an age to screen for the pathogens listed in part 3 of the draft IHS, it would be at this point that a BACC release would be issued.

This would surely be prudent in order to protect New Zealand's Biosecurity.

MPI Response

Stakeholders within the sheep and goat industry have indicated to MPI that it is of great importance that they are able to source new genetics from the international community in a timely manner to ensure progression of the industry. MPI believes that our current legislative and IHS measures and implementation process are robust enough to ensure an acceptable level of biosecurity protection (ALOP) whilst still facilitating international trade opportunities for the primary sector. The requirements for specific risk organisms in the import health standard are concluded only after an in depth risk analysis assessment and internal, industry and international professional consultation has occurred. The current requirements for specific risk organisms pertinent to sheep and goat germplasm are deemed to be the least trade restrictive whilst still providing an ALOP.

3.4 European Union

3.4.1 Ovine Pulmonary Adenomatosis (OPA)

The EU understands that the new import requirements provide the following options:
Jaagsiekte sheep retrovirus (OPA):

(28) Donors were resident since birth in countries recognised by the Competent Authority as free from jaagsiekte; or

(29) Donors were resident:
a) in a country where jaagsiekte is notifiable;
b) only in premises that have remained free from jaagsiekte for at least 10 years prior to collection and no sheep/goat from a flock/herd of inferior health status was introduced during that period; and
c) in premises that include animals over 5 years of age; or

(30) Donors were subject to a jaagsiekte test listed in *MPI-STD-TVTL*, with negative results.

The EU would like to ask New Zealand to share with the EU any evidence that semen/embryos present a risk when used for artificial insemination (AI) or embryo transfer.

The EU would also like to highlight to New Zealand that Points 28 and 29 (above) will create some difficulty for EU Member States. While a (blood) PCR appears to be available (OIE manual suggests this, but there is no OIE reference laboratory for it), no tests appear to be listed in *MPI-STD-TVTL* for this disease.

The EU considers that the 'test' in question could be done as a post-mortem examination of the donor animal (the OIE manual also suggests this). EU Member States will be able to slaughter/make post-mortem examination of the donor animal after the semen/embryos have been collected and once the donor is at least 5 years old. Where necessary additional investigations could be carried out, in analogy to point 1.2.(a) of Chapter II of Annex B to Directive 90/429/EEC (porcine semen), in ovine or caprine animals older than 5 years leaving the collection centre. Therefore, to allow exports from the EU, the EU would like to propose this as an additional option if a (blood) PCR is not available.

MPI Response
MPI's assessment of the risks in sheep and goat germplasm was published in 2005 and subject to public consultation. Our assessment of the risk of introducing Jaagsiekte can be found at the following link: https://www.mpi.govt.nz/document-vault/2835
We have given the 2005 assessment additional consideration and have decided that there is enough evidence (according to Parker et al 1998) to support removing measures for sheep and goat embryos. The OIE indicates that blood PCR has "a low diagnostic sensitivity when applied to individual animals, due to low concentrations of target DNA in the blood of clinically healthy animals..."
At this time, blood PCR will not be accepted.

Tests types and methodology will be discussed during veterinary certificate negotiation and approved tests will be listed in *MPI-STD-TVTL*.

The test option in the IHS has been reworded to be able to permit various test types during negotiation of the veterinary certificate.

3.4.2 Scrapie

The EU is glad to see that for ovine embryos, there are no scrapie-related requirements.

MPI Response
Your response has been noted.

3.4.3 Testing

The EU would like to ask New Zealand to clarify when samples have to be taken for the various tests (for some diseases in the case of semen and for all diseases in the case of embryos). Where the Import Health Standard simply requires a test in accordance with MPISTD-TVTL, does it mean on the day the semen/embryos is/are collected? In case of some diseases it would be difficult to certify country freedom as there is no monitoring of these diseases in place: Crimean Congo haemorrhagic fever virus, Jaagsiekte sheep retrovirus (ovine pulmonary adenomatosis), Wesselsbron virus. The last two are not listed by the OIE. EU legislation requires the owner's declaration that donor animals were not obtained from holdings and have not been in contact with animals from holdings in which these diseases have been clinically detected.

The draft Import Health Standard document, point 2.7(1) requires for donors of embryos to be resident in the embryo collection flock/herd for at least 28 days prior collection of embryos for export to New Zealand. It is the EU's view that there should rather only be required conditions based on the donor's health status in relation to specific diseases and health inspection of a donor on a day of collection of the embryos for export by the approved team veterinarian.

Information like name or address of the owner of the donor should rather not be required in the health certificates for imports into New Zealand of semen and embryos of animals of ovine and caprine species as it does.

MPI Response

The *MPI-STD-TVTL* reference document will contain the MPI approved test and methodology reference once they become approved as countries negotiate veterinary certificates. The IHS wording has been amended to elucidate this.

With regard to embryo donors Section 2.7 (1) the IHS wording has been amended to align with the OIE *Code*.

MPI accepts the EU's comment with regard to privacy legislation surrounding the name and address of the owner of the donor animal. This topic can be discussed during veterinary certificate negotiation.

Regarding CCHFV, Jaagsiekte, and Wesselsbron virus, the options have been reworded to facilitate certification. A test option has been added for CCHFV and Wesselsbron virus.

3.5 Australian Government

3.5.1 General comments

Australia notes that the new import health standard (IHS) is likely to result in a change in the origin of sheep and goat reproductive material being imported into New Zealand, and used in the national herd/flock. Australia will re-assess its current requirements for sheep and goat semen and embryos from New Zealand considering this divergence of risk management for scrapie for imported small ruminant genetic material. However, Australia recognises the importance of continuing trade in small ruminant genetic material from New Zealand to Australia, and will remain cognisant of this in amending its import conditions.

We have observed that an electronic link to the MPI list of approved tests and vaccines (MPI-STD-TVTL) was not available in either the IHS or Guidance document.

Australia also queries whether there is an error in Clause 2.6 Semen collection facility requirements Point 4(c), in that the clause appears to allow an option to transfer through a bluetongue infected zone without protection from insect attack. We suggest the clause should read 'Transfer must *not* be through a bluetongue infected zone....'

MPI Response
Scrapie comment noted.

The IHS wording has been amended to read "Transfer must **not** be through...".

The link has been added to the GD and IHS (http://www.mpi.govt.nz/document-vault/2040).

3.5.2 Scrapie

Australia confirms that its existing import policy for scrapie remains appropriate and current for imported small ruminant genetic material.

Australia is concerned with New Zealand's proposed scrapie import measures which are based on the findings and conclusions of the NZ Scrapie Import Risk Analysis (IRA). Our concerns have been noted in our response to the IRA and subsequent discussions with New Zealand veterinary authorities.

We maintain that the scrapie IRA underestimates the likelihood of scrapie being introduced by sheep or goat germplasm imported from countries not verified free from scrapie, however, we do not propose to revisit the technical detail on risks of scrapie transmission via small ruminant germplasm in this SPS notification response. Such discussions are occurring in other forums, such as the International Embryo Transfer Society, Quads and bilateral meetings.

MPI Response
Your response has been noted.

3.6 Duncan Fleming, Triple N Goat Stud, Auckland

3.6.1 General comments

As a goat stud operator is my prerogative to provide an excellent range of animals to prospective farms that will improve on their current stock. However in the recent years this has become extremely hard to do as our national herd has become inbred due to the culls in the 80's leaving only a small population of good quality animals and now finding animals of excellent pedigree that are not related by more than a generation has become almost impossible.

We had animals brought in from Australia in 2001 but the cost of this was prohibitive and it would not seem as if anyone is seeking to repeat this as the Australians do not keep semen in storage so the costs are high if straws are to be sent. The Americans however are very professional in all my dealings I have had with them and keep a good supply on hand meaning that the importation costs will be low and therefore viable for anyone wishing to increase herd production.

Reviewing figures from 3 of America's top farms there are large production gains to be made for our country with the right breeding which will benefit our national herds production figures especially now as goat milk is selling at a premium.

I believe the risk of disease is negligible as the Americans health standards are even stricter than our own.

This submission has the support of the Anglo Nubian Breed Society and Dairy Goat Co-op as well as numerous breeders nationwide of whom I have spoken to.

MPI Response
Your response has been noted.

3.7 Chris Houston, Beef and Lamb New Zealand

3.7.1 General comments

B+LNZ received email notification that these proposals were open for consultation on the 29th of April 2014, approximately six weeks after the stated release date of 14th March 2014. This has meant that a mere two weeks has been available to consider the proposals ahead of the 17th May deadline for comments. It is unusual for such consultation periods to end on a weekend.

In the time and with the resources available, B+LNZ has reviewed the proposal and has concluded that the measures proposed, if adequately implemented, are likely to satisfactorily manage risk organisms identified in the *Risk Management Proposal.*

MPI Response
Thank you for your response. An offer to extend the submission period was made.

3.8 Jock Allison

3.8.1 Suggested wording

Under 1.2 (1) on page 4 of the draft "What and whom this standard applies to" (to whom would be better grammar) it is stated "this IHS applies to importers of eligible consignments of semen and embryos from sheep". Wouldn't it be more accurate to say...

"this IHS specifies the risk management measures required for diseases of concern present in the source country (for sheep semen and embryos)" – "only after countries can be specified as "free" of some of the important OIE List A and B diseases to the satisfaction of MPI, and only after the risk management procedures for specified diseases of concern are implemented can any consignment of semen and or embryos be deemed eligible for entry into New Zealand".

MPI Response

Your comment has been noted and your suggestion regarding the heading "what and whom" has been forwarded to our standards integration team for review**.**
This IHS applies to importers of eligible consignments of semen and embryos from sheep and goats.
The information in the paragraph you have offered is covered under section 2.3 Exporting country systems and certification.

3.8.2 Clarification of wording

Further I note that under 1.8 (1) on page 5 of the draft IHS the statement "this is not an exhaustive list of compliance requirements and it is the importers responsibility to be familiar with and compliant with New Zealand laws". What does this mean? It could be code for "we can introduce any other requirements that we see fit at any time"? This is fair enough, but close cooperation and communication is of paramount importance. This simply reinforces the need for the prospective importer to have a much closer cooperative relationship with MPI, and an expectation that enquiries are responded to in a timely fashion.

Failure to have such an association can be very expensive to an importer as I can attest to in a previous importation. When the importer is now paying for MAF time, this is even more critical.

MPI Response

Section 1.8 Other Information clause 1 states that the IHS is not an exhaustive list of compliance requirements and that it is the importer's responsibility to be familiar with and comply with all New Zealand laws.

This simply means that New Zealand has legislation pertaining to imported commodities outside of the jurisdiction of the Biosecurity Act 1993 (the Act). The Import health standard outlines the measures required by the Act so it is the importers responsibility to be familiar with and comply with other relevant New Zealand legislation. This is generic information only, and may or may not apply specifically to this IHS.

3.8.3 Embryo treatment

It is noted that embryos must be treated with trypsin during the washing procedure as described in the IETS manual. In the Terrestrial Animal Health Code, Chapter 4.7 under Article 4.7.5, 2 it is stated "sometimes, for example when inactivation or removal of certain viruses, such as bovine herpesvirus-1 and Aujeszky's disease virus, is required. The standard washing procedure should be modified to include additional washes with the enzyme trypsin, as described in the IETS *Manual*"

Further under 4.7.7 (2) it is stated "Enzyme treatment is necessary only when pathogens for which the IETS recommends this additional treatment (such as trypsin) may be present. **It should be noted that such treatment is not always beneficial and it should not be regarded as a general disinfectant. It may also have adverse effects on embryo viability, for instance in the case of equine embryos where the embryonic capsule could be damaged by the enzyme"**

Any embryologist who has observed the rapid shrinking of embryos during trypsin washing would have concerns about effects on subsequent viability, and the use of such treatment when the IETS think it is not required we suggest should be avoided.

MPI Response
Although it has been determined that trypsin treatment is detrimental to the integrity of the zona pelucida of equine embryos, there is no evidence to suggest the same is true of sheep and goat embryos.

However, your comment regarding its use has been taken into consideration and the IHS wording Section 2.8, (3) has been deleted because there is no scientific justification for adding trypsin to the washing procedure. Embryos are to be collected, processed and stored as per the OIE C*ode* requirements.

3.8.4 Guidance document specific requirements

In the Guidance document under Part III Specific Requirements (17) on page 9/20, it is stated "semen in new or sanitised containers which are sealed and tamper evident, and clearly and permanently marked to identify the donor and date(s) of collection. A code is used for this information and its decipher accompanies the consignment..... Etc".

Then under (21) on the same page "the transport container in which the semen is transported to NZ was sealed ..... using tamper evident seals".

I note that the semen will most likely be in straws, these will have the donor, dam and date of freezing on the straws, the straws will be placed in goblets, and the goblets will be in buckets, which will be in the liquid N container. A manifest will be with the container, which will be sealed with the tamper proof seal. The containers within the main container will have no marking (usually colours for the plastic goblets). Suggest some clarification is required in the writing.

MPI Response
The IHS and model veterinary certificates have been reworded to clarify that containers in which semen pellets are stored must be tamper-evident and that straws are an example of a tamper-evident container.

3.8.5 Main concerns

i) That the standards for importation for both semen and embryos be set as soon as possible. We note that the "Import Risk Analysis: Scrapie in sheep and goat germplasm was completed 39 months ago, and it is this analysis and apparent acceptance that embryos have a negligible risk of transmission of disease, that makes a new approach possible and likely to be commercially attractive to would be importers. The new approach we assume eliminates the requirement for the quarantine of progeny from either artificial insemination or embryo transfer.

   When the submissions from the consultation have been considered by MPI, then notice must be quickly given to industry of what the new IHS conditions are to be.

ii) Further, the costs of the MPI veterinary discussions with interested parties must be defined, and the relationships re cost sharing if relevant with different groups who may have aspirations to make importations from the same geographical areas / countries/

   If required by interested parties, they must have the acceptance from MPI that they are themselves allowed to consult with veterinary administrations in other countries to facilitate and expedite progress in the development of commercial business opportunities. Of course MPI can expect to be kept informed of such discussions, but for business interests to be able to develop opportunities in different countries they must have greater freedom to operate. This would be at an early stage of project development, as the MPI / individual Country Veterinary Administration direct contact is required in all of the certification.

iii) The "short time frame" stipulation is not meant as a criticism of the MPI, but rather as a commercial reality requirement. If MPI do not have the staff and time to move things forward within an acceptable time frame, then some cooperation with the private sector seems to be a way forward. .....

(1) The definition of draft IHSs for specific counties, which should allow intending importers to scope sources of livestock in those countries.
(2) Following visits to those countries / areas, then an intending importer can produce proposals for consideration by the livestock owners, and the Veterinary Administrations of both countries.

Proposals to import are becoming so exacting (as they should be) that personnel commitment outside of MPI will need to be provided to make importation programmes a reality within a reasonable time.

iv) One of the principals of Charollais New Zealand (Mr Murray Rohloff) is travelling to the UK and Europe for 7 weeks in late June. Some indication of the likelihood of MPI approving the importation of ovine semen from Europe prior to the time he leaves would be useful.

It is probable that the summation of the responses from the consultation will not be completed by late June, and communicated to industry, thus we are hopeful that communication by email with the appropriate MPI personnel can provide an outline of probable conditions for importation so that at least some preliminary discussions can be held with sheep breeders, veterinary contractors (embryo recovery), or artificial insemination centres. If this is possible then it is logical that Mr Rohloff would like to check off what information local veterinary practitioners know about possible source flocks

MPI Response

In response to 1.8.5, (iii)

(1) The IHS Section 2.2 what countries this standard applies to: Semen and embryos from sheep and goats may be imported into New Zealand from all countries that meet the requirements of this IHS.

(2) The importer is able to undertake initial investigations and communications with relevant industry bodies to facilitate progression of potential commercial business opportunities. However, MPI is unable to consult on any country specific condition requirements until we have engaged with the Competent Authorities of such countries and negotiation of veterinary certification has been completed. The onus of risk for any preliminary discussions prior to completion of the veterinary certificate process is on the importer. MPI endeavours to complete the Review of Submissions and issue of the IHS for sheep and goat germplasm in an expeditious manner.

4 Appendix 1: Copies of Submissions

4.1 Federated Farmers

SUBMISSION

TELEPHONE 0800 327 646 WEBSITE WWW.FEDFARM.ORG.NZ

FEDERATED FARMERS OF NEW ZEALAND

To Animal Imports: Semen and Embryos from Sheep and Goats
Animal & Animal Products Directorate
Standards Branch
Ministry for Primary Industries
Wellington
New Zealand

On the: Draft IHS on Semen and Embryos from Sheep (*Ovis aries*) and Goats (*Capra hircus*)

Date: 16 May 2014

Contact: **DAVID BURT**
INDUSTRY ADVISOR, PRIMARY SECTOR

Federated Farmers of New Zealand
Box 715, Wellington 6140, New Zealand

P 04 494 9182
F 04 473 1081
dburt@fedfarm.org.nz

SUBMISSION TO THE MINISTRY FOR PRIMARY INDUSTRIES ON THE DRAFT IMPORT HEALTH STANDARD ON SEMEN AND EMBRYOS FROM SHEEP AND GOATS

1. EXECUTIVE SUMMARY

1.1 Federated Farmers of New Zealand welcomes the opportunity to comment on the Draft IHS on Semen and Embryos from Sheep and Goats

1.2 While, in general, the Federation is supportive of the document, we do have two concerns – around the FMD virus and scrapie – and we also make two suggestions relating to the future importing of genetic material. These matters are discussed further below.

1.3 We would be pleased to discuss the matter with you in more detail should you believe this is necessary. Please contact David Burt, Industry Advisor, Primary Sector [E-Mail dburt@fedfarm.org.nz] in the first instance.

2. BACKGROUND

2.1 Our submission is in accordance with the call for submissions, in March 2014, by the Ministry for Primary Industries, on the "Draft Import Health Standard on Semen and Embryos from Sheep (*Ovis aries*) and Goats (*Capra hircus*)" [OVCAGERM.GEN] document and two supporting publications:

- "Draft Guidance Document Semen and Embryos from Sheep and Goats" [OVCAGERM.GEN]" and
- "Risk Management Proposal Semen and Embryos from Sheep (*Ovis aries*) and Goats (*Capra hircus*)" March 2014

3. SPECIFIC COMMENTS

3.1 Draft IHS, Part 2, Section 2.6: Semen collection by facility requirements (Page 7)

3.1.1 Point 4(c) in this section states "Transfer must be through a bluetongue infected zone, or donors must be protected from insect attack during transit" The Federation assumes that this is a typographical error and should read "Transfer must not (emphasis added) be through a bluetongue infected zone …"

3.2 Draft IHS, Part 3, Section 3.3: Foot and Mouth Disease virus (Page 11)

3.2.1 The Federation notes that, whereas the RMP document [Section 6.6.3] recommends that MPI should be satisfied that the countries are free from FMD and that the requirments to import align with the Code, the IHS [Section 3.3] require that (1) donors must be resident in a country or zone that is free from FMD or (2) imports must comply with FMD recommendations for ruminant semen in the Code.

3.2.2 The Federation requests that this apparent discrepancy be investigated.

3.3 Draft IHS, Part 3, Section 3.17: Scrapie (Page 15)

3.3.1 The Federation notes that the Ministry allows [3.17(2)(c)] the importation of semen from sheep donors that have a scrapie resistant genotype, but that this option is not extended to goat semen donors

3.3.2 In this regard, the Federation understands that a scrapie genotype in goats may have has been identified and asks that, if and when (a) scrapie resistant genotype(s) is/are confirmed in goat semen, then goat semen importers be given the same opportunity to use this avenue to obtain semen.

4. GENERAL COMMENTS

4.1 For consideration with regard to the future of importing genetic material from sheep and goats

4.1.1 The Federation notes that the accuracy, specificity and sensitivity of testing for TSE's in tissues continues to evolve and requests that, as/when the testing methodology permits, the Ministry consider their use as part of the risk management measures that are implemented in order to best protect New Zealand from these diseases.

4.1.2 The Federation believes that, overall, the risks associated with importing of genetic material in the form of germplasm are less than the risks associated with importing live animals. The Federation requests that this matter is kept in mind when the policy around importing genetic material is next reviewed.

5. ABOUT FEDERATED FARMERS OF NEW ZEALAND

4.1 Federated Farmers of New Zealand is a member-based organisation representing farming and other rural businesses. Federated Farmers has a long and proud history of representing the needs and interests of New Zealand farmers.

4.2 The Federation aims to add value to its members' farming business. Our key strategic outcomes include the need for New Zealand to provide an economic and social environment within which:

- Our members may operate their business in a fair and flexible commercial environment;
- Our members' families and their staff have access to services essential to the needs of the rural community; and
- Our members adopt responsible management and environmental practices.

4.2 Ian McDougall

Submission re: Semen and Embryos from Sheep and Goats reference the document OVCAGERM.GEN

Submission by:
Ian McDougall MRCVS BVM&S
Elite Charollais Ltd,
404 Tancreds Road,
Lincoln,
Christchurch,
New Zealand.
Email: meatsheep@gmail.com
Mobile +61427127498

Introduction

My comments are restricted to the disease jaagsiekte. I note that Australia, a country free from jaagsiekte successfully imported ovine semen and embryos from countries not free from jaagsiekte in 2004 and 2005 with no subsequent evidence of the transmission of the disease with either the semen or the embryos.
AQIS required that prior to the export of the ovine semen and embryos to Australia, the semen and embryos donors were subjected to the following measures:

Measures for Embryo Donors
EITHER
have only lived in flocks which include animals older than 5 years, and in which, as far as can be determined, after due enquiry and examination of official records, all animals remained free from jaagsiekte, based on the absence of clinical signs, for at least 5 years immediately prior to collection of embryos during which no animals were introduced from flocks with a lesser jaagsiekte status;

OR
gave a negative result to a pathological examination or immune or nucleic acid test for jaagsiekte virus/viral components in lung and associated lymphoid tissues in accordance with procedures approved by the Veterinary Administration of the exporting country for the detection of jaagsiekte.

AND
the embryos were collected, washed, processed and stored in accordance with OIE Animal Health Code (Appendix 4.2.3.3.).

Measures for Ovine Semen Donors
EITHER
have only lived in flocks which include animals older than 5 years, and in which, as far as can be determined, after due enquiry and examination of official records, all animals remained free from jaagsiekte, based on the absence of clinical signs, for at least 5 years immediately prior to collection of semen during which no animals were introduced from flocks with a lesser jaagsiekte status
AND
gave a negative result to a pathological examination or immune or nucleic acid test for jaagsiekte virus/viral components in lung and associated lymphoid tissues in accordance with procedures approved by the Veterinary Administration of the exporting country for the detection of jaagsiekte.

Published research

Several significant trials conducted in the UK demonstrated that transmission of the virus by the transfer of washed embryos did not occur (Parker et al. 1998). In one study, 38 of 51 progeny from jaagsiekte positive donors survived for at least 5 years without evidence of jaagsiekte in recipients or progeny. A range of British breeds were represented in both the donor and recipient ewes. Recipients were obtained from separate flocks which had a long history of freedom from jaagsiekte. In a separate study, 4 of 5 progeny from uninfected donors mated to an infected ram survived for at least 5 years and did not

develop jaagsiekte. The recipients and their progeny were kept in a closed, isolated jaagsiekte-free flock.

Parker BNJ, Wrathall AE, Saunders, RW, Dawson M, Done SH, Francis PG, Dexter I, Bradley R (1998) Prevention of transmission of sheep pulmonary adenomatosis by embryo transfer. Vet Rec 142:687-689

Comments re OVCAGERM.GEN

1. **Re: Draft document OVCAGERM.GEN; Semen and Embryos from Sheep and Goats; Model Veterinary Certificate for International Trade in Semen from Sheep (Ovis aries) and Goats (Capra hircus)**

My comments are restricted to the section:

Jaagsiekte sheep retrovirus (ovine pulmonary adenomatosis), sections;
(28) Donors were resident since birth in countries recognised by the Competent Authority as free from jaagsiekte; or
(29) Donors were resident:
a) in a country where jaagsiekte is notifiable;
b) only in premises that have remained free from jaagsiekte for at least the 10 years prior to collection and no sheep/goat from a flock/herd of inferior health status was introduced during that period; and
c) in premises that include animals over 5 years of age.

As there currently are no MPI Approved Diagnostic Tests for jaagsiekte I am proposing in addition to the above that either;

c) semen donors be > 5 years of age at the time of testing for the presence of jaagsiekte;
d) That bronchial washes of semen donors conducted at the completion of semen collection be subjected to PCR testing for the presence of jaagsiekte with negative results.

OR

c) semen donors be > 5 years of age at the time of testing for the presence of jaagsiekte;
d) semen donors be slaughtered at the completion of semen collection and their lungs and mediastinal lymph nodes subjected to histopathology,
immunohistochemistry and PCR for jaagsiekte with negative results.

Or a combination of the above.

2. **Comments in draft document OVCAGERM.GEN; Semen and Embryos from Sheep and Goats; Model Veterinary Certificate for International Trade in Embryos from Sheep (Ovis aries) and Goats (Capra hircus)**

My comments ate restricted to the section:

Jaagsiekte sheep retrovirus (ovine pulmonary adenomatosis)
(31) Donors were resident since birth in countries recognised by the Competent Authority as free from jaagsiekte; or
(32) Donors were resident:
a) in a country where jaagsiekte is notifiable;
b) only in premises that have remained free from jaagsiekte for at least the 10 years prior to collection and no sheep/goat from a flock/herd of
inferior health status was introduced during that period; and
c) in premises that include animals over 5 years of age.

As there currently are no MPI Approved Diagnostic Tests for jaagsiekte I am proposing in addition to the above that either;

c) Embryos/oocytes or collection/washing fluids from each collection be subjected to PCR test for jaagsiekte with negative results;
d) That bronchial washes of embryo donors conducted at the completion of embryo collection be subjected to PCR testing for the presence of jaagsiekte with negative results.

OR

a) semen and embryos donors be > 5 years of age at the time of testing for the presence of jaagsiekte;
b) semen and embryos donors be slaughtered at the completion of embryo collection and their lungs and mediastinal lymph nodes subjected to histopathology, immunohistochemistry and PCR for jaagsiekte with negative results.

Or a combination of the above.

Summary
In my opinion by putting in place the measures outlined above or those outlined by AQIS published in "AN ANALYSIS OF THE DISEASE RISKS, OTHER THAN SCRAPIE, ASSOCIATED WITH THE IMPORTATION OF OVINE AND CAPRINE SEMEN AND EMBRYOS FROM CANADA, THE UNITED STATES OF AMERICA AND MEMBER STATES OF THE EUROPEAN UNION FINAL REPORT" August 2000; the presence of Jaagsiekte in an exporting country should not prevent the export of ovine or caprine embryos to New Zealand.

Yours sincerely

Ian McDougall MRCVS BVM&S

An additional email submission was received June 2015 regarding Part 2, section 7 (6):

"Unless we can get some movement on the non-slaughter of rams and ewes that combine to produce embryos for export to NZ, then it is quite possible that the EU will be a no go (ie they may not sanction the slaughter of donors on animal welfare grounds).

There is evidence that embryo transfer and correct washing of embryos prevents the transmission of Jaagsiekte. I gather that this is insufficient?"

4.3 Andrew Brown, University of Auckland

From: Andrew Brown [mailto:andrew.brown@auckland.ac.nz]
Sent: Tuesday, 29 April 2014 10:05 p.m.
To: Animal Imports
Subject: RE: Import Health Standard: Semen and Embryos from Sheep and Goats

Hi,
Thank you for the opportunity to comment on this Draft Import Health Standard "Semen and Embryos from sheep and goats".

Having read this draft standard I am curious to know why there are no requirements to place the recipients of this germplasm into quarantine/containment facility until the resulting progeny are of an age to screen for the pathogens listed in part 3 of the draft IHS, it would be at this point that a BACC release would be issued.

This would surely be prudent in order to protect New Zealand's Biosecurity.

Best regards

Andrew

Andrew Brown,

Team Leader- Specialist & Containment Facility,

Vernon Jansen Unit,

Faculty of Medical & Health Sciences,

The University of Auckland,

85 Park Road,

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4.4 European Union

Ref. Ares(2014)1515013 - 13/05/2014

EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Directorate G - Veterinary and International affairs
Unit G6 - Multilateral International relations

Brussels,
SANCO G6 VS/ise D(2014) 1610755

To:	**SPS National Enquiry Point of New Zealand** Mrs Sally Jennings, Coordinator, SPS New Zealand, PO Box 2526, Wellington, New Zealand	**Telephone:** **E-mail:**	+ 64 4 894 0431 sps@maf.govt.nz
From:	**Ella Strickland** EU SPS Notification Authority SANCO G6, F101 2/68	**Telephone:**	+ 32 2 299 3030
Copy to:	**EU Delegation in Wellington** P.O Box 5106 Level 6, Sybase House, 101 Lambton Quay, Wellington	**Telephone:** **E-mail:**	+ 64 4 472 9145 delegation-new-zealand@ec.europa.eu
	New Zealand Mission to the EU Square de Meeûs 1, 7 étage, 1000 Brussels	**Telephone:** **E-mail:**	+ 32 2 512 10 40 nzemb.brussels@skynet.be
	MAYA MATTHEWS EU DEL GVA EVELYNE BENOIST		
	ENT-EU-TBT ENTR/C3 BERNARD VAN GOETHEM SANCO/G ALBERTO LADDOMADA SANCO/G2 LORENZO TERZI SANCO/G7 SANCO-EU-SPS SANCO/G6 TRADE-EU-SPS TRADE /D3		

Subject: EU comments to the Import Health Standard notified in document G/SPS/N/NZL/501

Dear Madam,

Please find attached the comments of the European Union on the text notified to the WTO in notification G/SPS/N/NZL/501.

It would be very much appreciated if any reply to this letter were also copied to the EU Delegation in Wellington.

Ella Strickland
EU SPS Notification Authority

EU Notification Authority and Enquiry Point of the WTO Agreement on SPS measures.
Rue Froissart 101, B-1049 Bruxelles (Belgium) Tel:+32 (0)2 29 54263, Fax: +32 (0)2 29 98090. Email: sps@ec.europa.eu

COMMENTS OF THE EUROPEAN UNION TO THE NOTIFICATION SUBMITTED BY NEW ZEALAND UNDER THE WTO AGREEMENT ON THE APPLICATION OF SANITARY AND PHYTOSANITARY MEASURES IN NOTICE G/SPS/N/NZL/497

The European Union (EU) would like to thank New Zealand for submitting notification G/SPS/N/NZL/501 concerning the draft requirements for the importation of semen and embryos from sheep (Ovis aries) and goats (Capra hircus) and for the opportunity to comment on the proposed text.

The EU is pleased to provide the following general and specific comments therein. A reply to these comments would be much appreciated.

In the notification, New Zealand states that Import Health Standards for these commodities are generic measures and that bilateral veterinary certificates can be negotiated with a single country. Currently, Australia is the only country with an Approved Exporting System.

1. Ovine Pulmonary Adenomatosis (OPA)

The EU understands that the new import requirements provide the following options:

Jaagsiekte sheep retrovirus (OPA):

(28) Donors were resident since birth in countries recognised by the Competent Authority as free from jaagsiekte; or

(29) Donors were resident:

a) in a country where jaagsiekte is notifiable;
b) only in premises that have remained free from jaagsiekte for at least 10 years prior to collection and no sheep/goat from a flock/herd of inferior health status was introduced during that period; and
c) in premises that include animals over 5 years of age; or

(30) Donors were subject to a jaagsiekte test listed in MPI-STD-TVTL, with negative results.

The EU would like to ask New Zealand to share with the EU any evidence that semen/embryos present a risk when used for artificial insemination (AI) or embryo transfer.

The EU would also like to highlight to New Zealand that Points 28 and 29 (above) will create some difficulty for EU Member States. While a (blood) PCR appears to be available (OIE manual suggests this, but there is no OIE reference laboratory for it), no tests appear to be listed in MPI-STD-TVTL for this disease.

The EU considers that the 'test' in question could be done as a post-mortem examination of the donor animal (the OIE manual also suggests this). EU Member States will be able to slaughter/make post-mortem examination of the donor animal after the semen/embryos have been collected and once the donor is at least 5 years old. Where necessary additional investigations could be carried out, in analogy to point 1.2.(a) of Chapter II of Annex B to Directive 90/429/EEC (porcine semen), in ovine or caprine animals older than 5 years leaving the collection centre. Therefore, to allow exports from the EU, the EU would like to propose this as an additional option if a (blood) PCR is not available.

2. Scrapie

The EU is glad to see that for ovine embryos, there are no scrapie-related requirements.

3. Testing

The EU would like to ask New Zealand to clarify when samples have to be taken for the various tests (for some diseases in the case of semen and for all diseases in the case of embryos). Where the Import Health Standard simply requires a test in accordance with MPI-STD-TVTL, does it mean on the day the semen/embryos is/are collected?

4. In case of some diseases it would be difficult to certify country freedom as there is no monitoring of these diseases in place: Crimean Congo haemorrhagic fever virus, Jaagsiekte sheep retrovirus (ovine pulmonary adenomatosis), Wesselsbron virus. The last two are not listed by the OIE. EU legislation requires the owner's declaration that donor animals were not obtained from holdings and have not been in contact with animals from holdings in which these diseases have been clinically detected.

5. The draft Import Health Standard document, point 2.7(1) requires for donors of embryos to be resident in the embryo collection flock/herd for at least 28 days prior collection of embryos for export to New Zealand. It is the EU's view that there should rather only be required conditions based on the donor's health status in relation to specific diseases and health inspection of a donor on a day of collection of the embryos for export by the approved team veterinarian.

6. Information like name or address of the owner of the donor should rather not be required in the health certificates for imports into New Zealand of semen and embryos of animals of ovine and caprine species as it does not seem relevant in relation to the health status of a donor animal or to its place of origin.

The EU would like to thank New Zealand once again for the opportunity to comment on its draft text and asks for its comments to be taken into consideration. The EU would also appreciate its questions being addressed in writing, at the earliest possible date and preferably before the proposed measure enters into force. The EU looks forward to engaging further with the New Zealand authorities to discuss this and related matters.

4.5 Australian Government

Australian Government

Comments from the Australian Government on the Government of New Zealand's Proposed Draft *Import Health Standard for Semen and Embryos from Sheep (Ovis aries) and Goats (Capra hircus)* as notified in G/SPS/N/NZL/501 published on *14 March 2014*

The Australian Government welcomes the opportunity to provide comments on the proposed draft of the Import Health Standard for Semen and Embryos from Sheep (*Ovis aries*) and Goats (*Capra hircus*) as notified by the World Trade Organization notification (G/SPS/N/NZL/501) dated 14 March 2014.

General comments

Australia notes that the new import health standard (IHS) is likely to result in a change in the origin of sheep and goat reproductive material being imported into New Zealand, and used in the national herd/flock. Australia will re-assess its current requirements for sheep and goat semen and embryos from New Zealand considering this divergence of risk management for scrapie for imported small ruminant genetic material. However, Australia recognises the importance of continuing trade in small ruminant genetic material from New Zealand to Australia, and will remain cognisant of this in amending its import conditions.

Australia understands that renegotiation of current export certificates for sheep and goat semen and embryos to New Zealand will occur during 2014/15 and looks forward to this activity.

We have observed that an electronic link to the MPI list of approved tests and vaccines (MPI-STD-TVTL) was not available in either the IHS or Guidance document.

Australia also queries whether there is an error in Clause 2.6 Semen collection facility requirements Point 4(c), in that the clause appears to allow an option to transfer through a bluetongue infected zone without protection from insect attack. We suggest the clause should read 'Transfer must *not* be through a bluetongue infected zone....'

Specific comments regarding scrapie

Australia confirms that its existing import policy for scrapie remains appropriate and current for imported small ruminant genetic material.

Australia is concerned with New Zealand's proposed scrapie import measures which are based on the findings and conclusions of the NZ Scrapie Import Risk Analysis (IRA). Our concerns have been noted in our response to the IRA and subsequent discussions with New Zealand veterinary authorities.

We maintain that the scrapie IRA underestimates the likelihood of scrapie being introduced by sheep or goat germplasm imported from countries not verified free from scrapie, however, we do not propose to revisit the technical detail on risks of scrapie

transmission via small ruminant germplasm in this SPS notification response. Such discussions are occurring in other forums, such as the International Embryo Transfer Society, Quads and bilateral meetings.

Conclusion

Australia welcomes further international discussion and debate concerning risks posed by scrapie for trade in small ruminant germplasm, and will advise New Zealand regarding our updated conditions for import of small ruminant genetic material from New Zealand in the near future. The update, which at this time will be specific to scrapie, should not adversely impact ongoing trade.

4.6 Duncan Fleming, Triple N Goat Stud

15 May 2014
Triple N Goat Stud
13 Bella Villa Drive
Waiuku
Auckland

To whom it may concern

I am writing with regards to the new Import Health Standard: Semen and Embryos from Sheep and Goats.

I currently run a goat breeding stud in South Auckland and was the person who had the goats added to the initial research back in 2012.

The importation of new genetics for goats is of interest to myself and others in the Caprine community New Zealand wide. I have spoken to numerous breeders throughout the country and they all support the idea of new genetics into our country's bloodlines.
As a goat stud operator is my prerogative to provide an excellent range of animals to prospective farms that will improve on their current stock. However in the recent years this has become extremely hard to do as our national herd has become inbred due to the culls in the 80's leaving only a small population of good quality animals and now finding animals of excellent pedigree that are not related by more than a generation has become almost impossible.
We had animal's brought in from Australia in 2001 but the cost of this was prohibitive and it would not seem as if anyone is seeking to repeat this as the Australians do not keep semen in storage so the costs are high if straws are to be sent. The Americans however are very professional in all my dealings I have had with them and keep a good supply on hand meaning that the importation costs will be low and therefore viable for anyone wishing to increase herd production.

Reviewing figures from 3 of Americas top farms there are large production gains to be made for our country with the right breeding which will benefit our national herds production figures especially now as goat milk is selling at a premium.

I believe the risk of disease is negligible as the Americans health standards are even stricter than our own.

This submission has the support of the Anglo Nubian Breed Society and Dairy Goat Co-op as well as numerous breeders nation wide of whom I have spoken to.

Regards

Duncan Fleming
ANBSNZ

4.7 Chris Houston, Beef & Lamb New Zealand

To who it may concern,

The purpose of this email is to provide feedback from Beef + Lamb New Zealand (B+LNZ) on the Draft Import Health Standard: Semen and Embryos from Sheep and Goats, recently released for consultation by the Ministry for Primary Industries (MPI).

1. Beef + Lamb New Zealand Ltd is the farmer-owned industry organisation representing New Zealand's sheep and beef farmers. B+LNZ invests farmer levies to help develop a growing sheep and beef industry providing sustainable returns for future generations. B+LNZ has four programmes – Farm, Market, People and Information – to deliver innovative tools and services to support informed decision making, and continuous improvement in market access, product positioning and farming systems for New Zealand's sheep and beef sector.

2. B+LNZ received email notification that these proposals were open for consultation on the 29th of April 2014, approximately six weeks after the stated release date of 14th March 2014. This has meant that a mere two weeks has been available to consider the proposals ahead of the 17th May deadline for comments. It is unusual for such consultation periods to end on a weekend.

3. In the time and with the resources available, B+LNZ has reviewed the proposal and has concluded that the measures proposed, if adequately implemented, are likely to satisfactorily manage risk organisms identified in the *Risk Management Proposal.*

4. B+LNZ is appreciative of the opportunity to comment on these proposals.

Best wishes,
Chris

Chris Houston | Senior Advisor - Technical Policy
beef + lamb new zealand
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4.8 Jock Allison

Jock Allison
M.Agr.Sc. Ph.D ONZM
AGRICULTURAL AND
MANAGEMENT CONSULTANT

5 Arthur Street, Dunedin, **NEW ZEALAND**
Telephone: 64 3 477 2903
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Email: jock.allison@xtra.co.nz

16th May 2014

Animal Imports: Semen and Embryos from Sheep and Goats
Animal & Animal Products Directorate
Standards Branch
Ministry for Primary Industries
PO Box 2526
Wellington
New Zealand

Dear Sir / Madame,

Semen and Embryos from Sheep & Goats : Consultation Documents

This submission is on behalf of the Ile de France NZ Joint Venture and the Charollais Sheep Genetics New Zealand Breed Society

There is interest in new importations from Europe, (probably UK and France) of semen in the first instance, but depending on the difficulties of and timing of the development of specific importation protocols there may be some interest in the importation of limited numbers of embryos. It is assumed that the breeds in question will be derived within the EEC, as will the Lacaune sheep milking breed if outside interest is shown in the importation of that breed.

New Genetic Material is Required : the Charollais and Ile de France Breeds

Australia has been the only source of genetic material from these breeds with one only consignment of Charollais embryos being imported a decade ago , and two small consignments of Ile de France since 2002 Embryos and semen have been imported to NZ from all sire lines present.

Performance recording is minimal in Australia, and is also minimal in source flocks from South Africa. Much more productive animals in both breeds are available in Europe. The breeds offer significant advantages for the New Zealand sheep meat industry.

- The Ile de France offers the summer/autumn dry eastern regions significant benefits as part of a maternal composite ....

  a) an extended breeding season, 4-6 weeks at each end,
  b) an increased lactation peak,
  c) ease of lambing/lamb survival traits,
  d) very fast growth rate,
  e) high carcass meat yields,
  f) ability to thrive on dry pastures,
  g) increased resistance to internal parasites, and
  h) fine wool, fibre diameter is reduced by 8-9 microns in crosses with Romneys, or produce "Smart Wool" compliant fleeces when crossed with Merinos (both significantly adding to wool incomes).

  In Australia, the Ile de France is only used and assessed as a Terminal. In France Maternal traits are recorded in France with huge progress made since the last exports to South Africa 40 years ago.

- In NZ the Charollais has proven to be an excellent Terminal Sire breed, with easy lambing, very high growth rates and high carcass meat yields. Superior genetics for muscling are present in the UK. The size of the gene pool is very limited in NZ.
- semen importations for both breeds are of immediate interest but we would consider embryos if there was a workable IHS, without the requirement to quarantine offspring. These specifications also apply to the importation of other sheep breeds, such a the Lacaune from France, and or the Assaf from Israel.

The Import Health Standard (IHS) :

It is assumed that this draft IHS is meant to be a prescribed template for the drafting of an IHS for specific countries, the risk management procedures specified for some diseases not being required if country, area, farm or AI centre freedom can be credibly established. Further we conclude that this consultation is about an IHS which would allow semen and embryos to be brought into New Zealand without the need to quarantine offspring for scrapie, as has been the requirement in the past. We request confirmation from MPI that this is indeed the intention of the new draft IHS.

I note an email from Mamie Thomas ..... which does seem to give this confirmation we are after.

I understand your concern and hope I can allay your concern. From the scrapie section in the risk management proposal (RMP) Angela has written the following:

6.22.3 Recommendation

For goat embryos the measures in the IHS should require country or zone freedom or establishment freedom or the OIE recommended measures for countries or zones not free from scrapie.

In accordance with the recommendations of the Code, for in-vivo derived sheep embryos the IHS should require no measures beyond the Code recommendations (collection and

processing of in vivo derived embryos from livestock and equids), which will be stated in the general requirements section.

For goat semen, the IHS should require country or zone freedom or establishment freedom.

For sheep semen the IHS should require country or zone freedom or establishment freedom or scrapie-resistant genotypes.

This is a very pleasing development and should facilitate the importation of new sheep genotypes which can add significantly to our flocks here in NZ.

Some points of clarification .....

1. Under 1.2 (1) on page 4 of the draft **"What and whom this standard applies to"(to whom would be better grammar)** it is stated **"this IHS applies to importers of eligible consignments of semen and embryos from sheep".** Wouldn't it be more accurate to say ....

"this IHS specifies the risk management measures required for diseases of concern present in the source country (for sheep semen and embryos)" – "only after countries can be specified as "free" of some of the important OIE List A and B diseases to the satisfaction of MPI, and only after the risk management procedures for specified diseases of concern are implemented can any consignment of semen and or embryos be deemed eligible for entry into New Zealand".

2. Further I note that under 1.8 (1) on page 5 of the draft IHS the statement "this is not an exhaustive list of compliance requirements and it is the importers responsibility to be familiar with and compliant with New Zealand laws". What does this mean? It could be code for "we can introduce any other requirements that we see fit at any time"? This is fair enough, but close cooperation and communication is of paramount importance. This simply reinforces the need for the prospective importer to have a much closer cooperative relationship with MPI, and an expectation that enquiries are responded to in a timely fashion.

Failure to have such an association can be very expensive to an importer as I can attest to in a previous importation. When the importer is now paying for MAF time, this is even more critical.

3. It is noted that embryos must be treated with trypsin during the washing procedure as described in the IETS manual. In the Terrestrial Animal Health Code, Chapter 4.7 under Article 4.7.5, 2 it is stated "sometimes, for example when inactivation or removal of certain viruses, such as bovine herpesvirus-1 and Aujeszky's disease virus, is required. The standard washing procedure should be modified to include additional washes with th enzyme trypsin, as described in the IETS manual"

Further under 4.7.7 (2) it is stated "Enzyme treatment is necessary only when pathogens for which the IETS recommends this additional treatment(such as trypsin) may be present. **It should be noted that such treatment is not always beneficial and it should not be regarded as a general disinfectant. It may also have adverse effects on embryo viability, for instance in the case of equine embryos where the embryonic capsule could be damaged by the enzyme"**

Any embryologist who has observed the rapid shrinking of embryos during trypsin washing would have concerns about effects on subsequent viability, and the use of such treatment when the IETS think it is not required we suggest should be avoided.

4. In the Guidance document under Part III Specific Requirements (17) on page 9/20, it is stated "semen in new or sanitised containers which are sealed and tamper evident, and clearly and permanently marked to identify the donor and date(s) of collection. A code is used for this information and its decipher accompanies the consignment ..... etc"

Then under (21) on the same page "the transport container in which the semen is transported to NZ was sealed ..... using tamper evident seals"

I note that the semen will most likely be in straws, these will have the donor, dam and date of freezing on the straws, the straws will be placed in goblets, and the goblets will be in buckets, which will be in the liquid N container. A manifest will be with the container, which will be sealed with the tamper proof seal. The containers within the main container will have no marking (usually colours for the plastic goblets). Suggest some clarification is required in the writing

Imports of New Ovine Genetic Material are Opportunities for Industry :

Time is of the essence, and the main concerns from the submitters are .....

1. That the standards for importation for both semen and embryos be set as soon as possible. We note that the "Import Risk Analysis : Scrapie in sheep and goat germplasm was completed 39 months ago, and it is this analysis and apparent acceptance that embryos have a negligible risk of transmission of disease, that makes a new approach possible and likely to be commercially attractive to would be importers. The new approach we assume eliminates the requirement for the quarantine of progeny from either artificial insemination or embryo transfer.

   When the submissions from the consultation have been considered by MPI, then notice must be quickly given to industry of what the new IHS conditions are to be.

2. Further, the costs of the MPI veterinary discussions with interested parties must be defined, and the relationships re cost sharing if relevant with different groups who may have aspirations to make importations from the same geographical areas / countries/

   If required by interested parties, they must have the acceptance from MPI that they are themselves allowed to consult with veterinary administrations in other countries to facilitate and expedite progress in the development of commercial business opportunities. Of course MPI can expect to be kept informed of such discussions, but for business interests to be able to develop opportunities in different countries they must have greater freedom to operate. This would be at an early stage of project development, as the MPI / individual Country Veterinary Administration direct contact is required in all of the certification.

3. The "short time frame" stipulation is not meant as a criticism of the MPI, but rather as a commercial reality requirement. If MPI do not have the staff and time to move

things forward within an acceptable time frame, then some cooperation with the private sector seems to be a way forward. .....

a) The definition of draft IHSs for specific counties, which should allow intending importers to scope sources of livestock in those countries.
b) Following visits to those countries / areas, then an intending importer can produce proposals for consideration by the livestock owners, and the Veterinary Administrations of both countries.

Proposals to import are becoming so exacting (as they should be) that personnel commitment outside of MPI will need to be provided to make importation programmes a reality within a reasonable time.

4. One of the principals of Charollais New Zealand (Mr Murray Rohloff) is travelling to the UK and Europe for 7 weeks in late June. Some indication of the likelihood of MPI approving the importation of ovine semen from Europe prior to the time he leaves would be useful.

   It is probable that the summation of the responses from the consultation will not be completed by late June, and communicated to industry, thus we are hopeful that communication by email with the appropriate MPI personnel can provide an outline of probable conditions for importation so that at least some preliminary discussions can be held with sheep breeders, veterinary contractors (embryo recovery), or artificial insemination centres. If this is possible then it is logical that Mr Rohloff would like to check off what information local veterinary practitioners know about possible source flocks

We look forward to progress being made on the finalisation of the IHS, and to associated discussions prior to the end of June.

Thank you for the opportunity to comment.

Yours faithfully

Dr Jock Allison – for the Ile de France and Charollais sheep breeders of NZ