

**Review of submissions:
Draft Import Health Standard for Bovine Germplasm
– Semen and Embryos**

Biosecurity New Zealand
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Biosecurity Standards
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Approved for general release

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Introduction

The draft Import Health Standard (IHS) for bovine germplasm - semen and embryos was notified for public consultation on 22 June 2010.

This document reviews each submission in turn. Copies of submissions are presented in Appendix 1.

Review of submissions

Submissions received from various internal stakeholders.

Submissions received from various external stakeholders:

1. CRV AmBreed N Z; Robert Courtney – Embryo - 26/07/2010
2. CRV AmBreed N Z; Robert Courtney - Semen - 26/07/2010
3. CRV BV, and other Dutch AI organisations (Alta, AI Samen and AI Kampen); Jan Venneman - Semen - 26/07/2010
4. CRV BV, and other Dutch AI organisations (Alta, AI Samen and AI Kampen); Jan Venneman - Embryo - 26/07/2010
5. Genex, Billings Montana (via LIC); Dr. Harry Michael - 03/08/2010
6. Embryoplus (South Africa); Dr Robert Treadwell – 02/08/2010
7. New Zealand Hereford Association; Natalie Campbell – 03/08/2010
8. World Wide Sires NZ (on behalf of Select Sires and Accelerated Genetics, USA); Judy Hope – 03/08/2010
9. Kaitoa polled Herefords; Philip Barnett – 03/08/2010
10. Livestock and Animal Germplasm Trade Association; Jim Edwards - 03/08/2010
11. Federated Farmers of New Zealand; David Burt – 02/08/2010
12. Beef + Lamb New Zealand Ltd & Meat Industry Association; Chris Houston - 02/08/2010
13. DairyNZ and DCANZ; Fiona Hutchinson - 06/08/2010
14. Canadian Food Inspection Agency (CFIA) – Embryo – 20/08/2010
15. Canadian Food Inspection Agency (CFIA) – Semen – 20/08/2010
16. US Government – Semen – 20/08/2010
17. US Government – Embryo – 20/08/2010
18. European Commission – Semen – 24/08/2010
19. European Commission – Embryo – 24/08/2010
20. Denmark – Ministry of Food, Agriculture and Fisheries – Semen – 24/08/2010
21. Denmark – Ministry of Food, Agriculture and Fisheries – Embryo – 24/08/2010
22. Australia – Biosecurity Australia – Semen – 02/09/2010
23. Australia – Biosecurity Australia – Embryo – 02/09/2010
24. Canadian Food Inspection Agency (CFIA); Dr. Alain Moreau – Embryo – 08/09/2010

Internal stakeholders

Various internal MAF stakeholders responded and their comments included:

- The presence of grammatical and spelling errors, and redundancies; an example is the Bluetongue measures in the semen standard that state “26. Semen donors were kept in a BT virus free zone...”. This should rather state “26. Donors were kept in a BT virus free zone...”.
- That the requirements were not always consistent between the semen and embryo standards. Examples are:
 - Disinfection of transport containers are defined in the embryo standard but not in the semen standard.

- The clause “Donors have never recorded a positive test for Q fever and *M. bovis*’ was missing from the semen standard.
- The clause stating “The embryos for export must be stored in the frozen state for at least 28 days before shipment to New Zealand and during this time the donors and all animals in contact with them must have remained healthy and free from any diseases transmissible in embryos” was omitted from the semen standard and will be added.
- The clause describing semen used to fertilise embryos required amending to:
 - where natural service or fresh semen was used, donor males were inspected, and found free from clinical evidence of infectious diseases transmissible in semen, and were of an equivalent isolation and tested health status to the donor females.”
- It should be required that certification be in English. The statement was added under the documentation specification that “Documentation must be in English, but may be bilingual (language of exporting country/English).”
- The clause describing the Rift Valley Fever (RVF) measures for the semen IHS required amending. This has been changed to: “Donors were resident, for at least the 30 days prior to, and during semen collection for export to New Zealand, in a country or zone that is free from RVF in accordance with the OIE Code;”
- A clause requiring that semen not be frozen immediately after addition of antibiotics was required. This has been added: “After addition of antibiotics, the semen was kept above 5°C for at least 45 minutes.”

External stakeholders

1. CRV AmBreed N Z; Robert Courtney – Embryo IHS

- 1.1. **“This IHS should include in-vitro embryo production even though there are some references within this draft IHS to ova.”**

MAF Response

Embryos developed from oocytes fertilised *in vitro* differ morphologically and physiologically from embryos derived *in vivo*. These differences impact upon how infectious agents interact with these embryos.

The bovine germplasm import risk analysis completed in February 2009 specifically excluded *in vitro* embryos; hence the current IHS only includes *in vivo* derived embryos.

- 1.2. **“It appears that this draft has been a cut and paste of the semen draft where isolation is a requirement. Donor isolation is not a recommendation of embryo production in EU directives, OIE recommendation or IETS guides. In my opinion semen and embryo production are totally different. Semen and embryo IHS should not follow the same template. For disease freedom assurance, other ways of insuring freedom must be applied other than part reliance on isolation. OIE Article 4.8.6, Risk Management should form the basis of developing embryo disease assurances.”**

MAF Response

MAF has decided to amend the IHS to tailor the requirements to embryo production. This involves removing the need for donor isolation and rather use similar risk management measures as in OIE Article 4.7.5.

- 1.3. **“Clause 12: Additional wording required to meet the needs of international embryo trade “and in accordance of Directive 89/556/EEC and subsequent**

amendments (if in the European Union) and following recommendations of the current Manual of the International Embryo Transfer Society (IETS). “”

MAF Response

The reference to overseas country legislation will be managed within the bilateral negotiation process as an equivalence.

MAF has decided to amend the requirement to state:

“At the time of embryo collection for export to New Zealand, the embryo collection team was approved by and registered with the veterinary authority of the exporting country to collect, process, and store bovine embryos for export in accordance with the current recommendations of the OIE Code or legislation of the exporting country (where MAF deems this to be equivalent) and the current manual of the International Embryo Transfer Society (IETS).”

1.4. “Clause 13& 14: These clauses are not consistent with the OIE code article 4.7.2, Directive 89/556/EEC nor recommendations of the IETS Manual and should be removed. In my opinion under Article 5.3 of the WTO Agreement on Sanitary and Phytosanitary Measures, both these clauses do not meet the accepted criteria of this agreement. Isolation is not a mandatory requirement of embryo production.”

MAF Response

See 1.2

MAF has decided to amend clause 13 to state:

“The veterinary authority has knowledge of and authority over the embryo collection herd until completion of testing specified in this standard.

Donors must be resident in that embryo collection herd for at least 30 days prior to embryo collection for export to New Zealand.”

MAF has decided to amend clause 14 to state:

“Where a specific requirement for a risk organism is met by pre-collection testing, donors must be isolated from other cattle not of an equivalent tested health status, from the time of the pre-collection test until completion of embryo collection for export to New Zealand.”

1.5. “Clause 16: This clause is too restrictive and should be replaced with wording similar to OIE article 4.7.1 At the time of collection, the donor animals should be clinically inspected by the team veterinarian, or by a veterinarian responsible to the team veterinarian and certified to be free of clinical signs of diseases that could be transmitted in embryos.”

MAF Response

MAF has decided to amend the requirement to state:

“On the day(s) of collection of the embryos, the approved embryo collection team veterinarian, or veterinarian responsible to the team veterinarian, is responsible for monitoring the health status of each donor and recording that the donor was free from clinical evidence of infectious diseases transmissible in embryos.”

1.6. “Clause 18: Should have provision for in-vitro embryo production. Replace embryo with ova/embryo and “processing of invivo/ in-vitro derived embryo””

MAF Response

See 1.1

1.7. “Clause 19 “were fertilised in vivo/ in-vitro”

MAF Response

See 1.1

- 1.8. **“Clause 20: remove identified as not possible, as can not identify an embryo, as doesn’t have identification per say. Containers can but not embryos.”**

MAF Response

The intent of the clause is to ensure that there should be confidence that a specific embryo be derived from a correctly recorded sire and dam.

MAF has decided to amend the requirement to state:

“Embryos were collected, washed, processed, traceability maintained, and stored under conditions that comply with the recommendations in the IETS Manual ...”

- 1.9. **“Clause 20: Additional statement that if in-vitro embryo produced, then each embryo must be washed with fresh media separately and treated with fresh trypsin separately , Theriogenology 2003 Nov60(8): Bovine herpesvirus-1 associated with single, trypsin treated embryos was not infective for uterine tubal cells. Additional assurance for IBR, if donor not maintained from official IBR herd may also be gained by adding. Donors have a sample of non viable embryos/oocytes, collection fluids and/or wash fluids from each collection (samples as per OIE and IETS recommendations) in the consignment tested for IBR using virus isolation or validated transcriptase polymerase chain reaction with negative results”**

MAF Response

See 1.1

- 1.10. **“Clause 22: this clause is not strong. Indelible should be added “clearly indelibly marked” ”**

MAF Response

The identification of embryo straws is vital in allowing ongoing traceability and the IETS manual provides three options – labelling of the straw, labelled plugs or gummed labels. The clause will be amended to specify that the straws be permanently identifiable and complying with the methods specified by the IETS.

The Guidance document will describe procedures to be followed when inadequately identified germplasm is received.

MAF has decided to amend the requirement to state:

“All straws must have been sealed, and clearly and permanently marked to identify the donor and the date(s) of freezing. If a code is used for this information, its decipher must accompany the consignment. The marking should, in accordance with the OIE Code, conform to the international standards of the International Committee for Animal Recording (ICAR; www.icar.org) and the IETS.”

- 1.11. **“Clause 28: additional wording required in vivo/in vitro”**

MAF Response

See 1.1

- 1.12. **“Clause 35: This is embryo production so the statement relating to artificial insemination centre must be deleted. The bullet points are not applicable to**

ova/embryo collection facilities and are a cut and paste from the semen draft. This should all be replaced by donor/s tested with BVD antigen /PCR for the detection of active infection at time of collection. Ova/embryo harvesting, unlike semen collection does not tend to be a continuous harvest. This has the consequence that it is possible to test for active BVD infection at the very time of collection. The effect of this is that an isolation phase is not required to establish the BVD status of the ova/embryo. Additional safeguards are provided by ensuring viral testing in clause 36 is done. ”

MAF Response

See 1.2

MAF has decided to delete clause 36 and to amend the risk management measures for BVDV in clause 35 to state:

“EITHER

At the time of embryo collection for export to New Zealand, the exporting country was free of BVDV2, i.e. there have been no cases of BVDV2 for at least 3 years;

OR

Donors have been tested for BVDV including:

- prior to, or at the time of embryo collection for export to New Zealand, all donors were tested serologically for BVDV antibodies and antigen; AND
- seronegative donors were again tested serologically, 21 to 40 days subsequent to embryo collection for export to New Zealand, for BVDV antibodies and antigens.

Cattle that are not eligible as embryo donors for export to New Zealand are either:

- donors that are antigen-positive in initial testing; OR
- donors that seroconvert or are antigen-positive in the post-collection test.

OR

A pooled sample of embryos/oocytes, collection fluids and/or washing fluids from each embryo collection for export to New Zealand has been tested for BVDV2, by virus isolation (VI) or a MAF approved reverse transcriptase polymerase chain reaction (RT-PCR) test, with negative results.”

1.13. “Clause 36: I can not see where the validity of the 3 years residency comes in as any exposed animal can become infected and shed, 3 years of residency doesn’t imply resistance.

This clause should read Donors have a sample of non viable embryos/oocytes, collection fluids and/or wash fluids from each collection (samples as per OIE and IETS recommendations) in the consignment tested for BVDV2 using virus isolation or validated transcriptase polymerase chain reaction with negative results.”

MAF Response

See 1.12

1.14. “Clause 52: remove this clause as already covered in clause 16. “24 hours” in this clause is not valid and makes no sense in the epidemiology of Tuberculosis. Is it

possible some “Flag”? may show at 24 hours pre collection that is an indicator of TB?, that would not be indicated by clause 16. This I am not aware of. ”

MAF Response

This requirement that donors and other susceptible animals show no clinical signs of bovine tuberculosis is an OIE defined requirement. It includes both embryo donors as well as other susceptible animals in the herd, whilst clause 16 only refers to donor animals.

See 1.15

1.15. “Clause 53: remove reference to isolation. Should read..... during the 30 days prior to collection of embryos for consignment to New Zealand (may be 60 days to allow for repeat collection as not valid test if repeated at 30 days as commercially oocyte/embryo collections can be repeated within 60 days) else a post collection tuberculin test within 365 days. ”

MAF Response

MAF has decided to amend the risk management measures for tuberculosis to state:
“Donors and other susceptible animals in the embryo collection herd showed no clinical signs of bovine tuberculosis during the 24 hours prior to embryo collection for export to New Zealand;

AND EITHER

Donors were:

- from a embryo collection herd that is free from bovine tuberculosis, in accordance with the OIE Code or the veterinary authority of the exporting country; AND
- from a country or zone that has been recognised by MAF as being free of bovine tuberculosis;

OR

Donors were:

- from an embryo collection herd that is free from bovine tuberculosis, in accordance with the OIE Code or the veterinary authority of the exporting country, AND
- subjected to an OIE prescribed test for bovine tuberculosis during the period between 30 days prior to 12 months after embryo collection for export to New Zealand, with negative results.”

1.16. “Additional disease statement required as not covered in part C and be consistent with OIE and EU directive.

Donors must come from herds that are:

- **officially brucellosis free,**
- **enzootic bovine leucosis free or no clinical case of enzootic bovine leucosis during the past 3 years and negative to enzootic bovine leucosis serological test at time of collection.**
- **During previous year they must not have been in a herd(or herds) which have shown any clinical sign of infectious bovine rhinotracheitis/infectious pustular vulvovaginitis”**

MAF Response

For these diseases the OIE code requires, for *in vivo* embryos, the collection, handling and storage of embryos as per OIE standards. This is stated in the IHS. Furthermore enzootic

bovine leucosis is endemic to New Zealand and in the Import Risk Analysis (dated 13 February 2009)¹ is not described as being a risk organism.

2. CRV AmBreed N Z; Robert Courtney – Semen IHS

- 2.1. **“The proposed standard will if approved in its present form, would essential curtail bovine semen imports into New Zealand. Clauses such as, centre veterinarian being required to inspect donor animals on the day of collection and semen storage requirement are not the norm in many countries that we currently trade with.”**

MAF Response

The intent of the IHS is not to curtail imports, but rather to ensure that the biosecurity status of New Zealand is maintained.

See 2.3 for details on donor inspection and 2.5 for semen storage.

- 2.2. **“Clause 13: Why 30 days OIE code section 4.5.2.2 states 28 days. Even though 88/407/ECC Laying down the animal health requirements applicable to intra-community trade in and import of semen of domestic animals of the bovine species states 30 days.
Suggested change 28 days”**

MAF Response

MAF has decided to amend the clause to state:

“Prior to collection of semen for this consignment, the donors must be isolated for at least 28 days at a place specifically approved for this purpose by the veterinary authority. During this time they were not used for natural mating and were isolated from animals not of equivalent health status.”

- 2.3. **“Clause 16: This clause is too restrictive as centre veterinarian may not be present and inspect donor on day of collection. NZ OAP clause 6.14.1.b states on day of collection, the animal being collected from must not show any evidence of infectious disease that will compromise the integrity of the semen 88/407/ECC annex C. semen must be obtained by animals which: show no clinical signs of disease on the day semen is collected.
Suggested change: On day of collection, the animal being collected from must not show any evidence of infectious disease that will compromise the integrity of the semen
In New Zealand it is accepted that this can be by the centre veterinarian or skilled person under the supervision of the centre veterinarian.”**

MAF Response

MAF has decided to amend clause 16 to state:

“The approved semen collection centre veterinarian is responsible for ensuring that, on the day(s) of collection of the semen, the health status of each donor is monitored and recorded, and the donor does not show any evidence of infectious disease that would compromise the integrity of the semen.”

¹ <http://www.biosecurity.govt.nz/files/regs/imports/risk/cattle-germplasm-ra.pdf>

2.4. **“Clause 19. “Clearly marked” Not strong enough as markings may be lost
Suggested change: indelibly marked”**

MAF Response

See 1.10

MAF has decided to amend the requirement to state:

“All straws must be sealed, and clearly and permanently marked with the identification of the donor and the date(s) of collection.”

2.5. **“Clause 20 “stored with semen and embryo that is eligible for export to New Zealand” This is too restrictive as in a large centre not practicable because of storage issues.**

No evidence that infection can spread in storage tanks.

Canadian paper 2005 Apr;50(2):206-10.

Non-transmission of bacterial and viral microbes to embryos and semen stored in the vapour phase of liquid nitrogen in dry shippers.

Cryobiology. 2003 Apr;46(2):146-52. Microbial contamination of embryos and semen during long term banking in liquid nitrogen. Bielanski A, Bergeron H, Lau PC, Devenish.

The only risk during storage is if contaminated nitrogen used. This risk is excluded as only fresh nitrogen used.

As New Zealand has additional testing than the standard tests required in the EU in particular, this storage should only include storage with the standard EU testing regime. Equivalent health status should only involve these tests. Not Q fever or M bovis and other non standard diseases as specified in Import Health Standards.

Suggested change: remove clause as under both OIE and 88/407/ECC directives only fresh nitrogen allowed or stored in storage that only fresh nitrogen has been used. Or stored with germplasm of equivalent health status.”

MAF Response

The OIE Code Article 4.6.7 (3) prescribes that semen for export is stored, with fresh liquid nitrogen, separately from genetic material that does not meet the requirements of that chapter of the Code.

MAF has decided to amend the clause to state:

“The semen must only be stored with germplasm that has been collected and processed in compliance with the OIE Code. Containers must be stored, until export, in a place approved by the veterinary authority of the exporting country.”

2.6. **“Bluetongue**

These clause need to be consistent with OIE section 8.3.10 etc

Clause 26 why 100 days OIE section 8.3.9.1 states 60 days

Clause 27 why 100 days OIE section 8.3.10.1 states 60 days

Clause 28 why 28 days OIE section 8.3.11.b states 21 days”

MAF Response

MAF has decided to amend the risk management measures for Bluetongue to state:

“EITHER

At the time of collection the exporting country was free from BTV in accordance with the requirements of the OIE Code;

OR

Donors were kept in a BTV free zone, as defined by the OIE Code or recognised by MAF, for at least the 60 days immediately prior to, and during, semen collection for export to New Zealand;

OR

Donors were kept during the seasonally free period in a BTV seasonally free zone, as defined by the OIE Code, or otherwise protected from Culicoides, for at least 60 days immediately prior to, and during, semen collection for export to New Zealand;

OR

Donors were subjected to OIE prescribed antibody detection tests for BTV, such as the competitive enzyme linked immunosorbent assay (cELISA), at least every 60 days during, and between 21 and 60 days after semen collection for export to New Zealand, with negative results;

OR

Donors were subjected to OIE prescribed agent detection tests for BTV, such as a virus isolation (VI) test or a polymerase chain reaction (PCR) test, on blood samples collected at commencement and conclusion of, and at least every 7 days (for VI test) or at least every 28 days (for PCR test) during, semen collection for export to New Zealand, with negative results.”

2.7. **“BVD**

Clause 35/36 difficult to understand why both 35 and 36 are required Should be a “or” not a “and” statement. Clause 36, not sound scientifically in my opinion. Very difficult to extrapolate to the requirement for 3 years if on centre as any animal could shed if infected if there is a breakdown on centre. No where in the paper can I see how by virtue of being on a centre greater than 3 years you can not become infected. All donors should have there first frozen collection viral tested but not all ejaculates in a consignment unless there is a change of BVD serological status in any donor on centre. In this case all ejaculates in consignment must be tested. An infected non antibody positive animal will consistently shed so repeated testing not warranted. By doing a semen test on the first collection of all donors this would detect negative serological BVD shedders. Vet Microbiol. 2009 Oct 20;139(1-2):42-51. Epub 2009 May 3.Epidemiology of prolonged testicular infections with bovine viral diarrhoea virus. Results of this research demonstrated that prolonged testicular infections could result in detection of viral RNA in semen for 2.75 years with infectious virus grown from testicular tissue 12.5 months after viral exposure.”

MAF Response

MAF has decided to remove any requirements specific to animals that have been on the semen collection centre for less than 3 years.

MAF has decided to amend the risk management measures for BVDV to state:

“EITHER

At the time of collection of semen for export to New Zealand, the exporting country was free of BVDV2, i.e. there have been no cases of BVDV2 for at least 3 years;

OR

The semen collection centre must have been maintained free from BVDV2 from commencement until conclusion of semen collection for export to New Zealand through compliance with the recommendations in the OIE Code in relation to BVDV, including:

- testing all cattle prior to pre-entry isolation for antibodies and antigen using prescribed tests; AND
- testing all cattle during pre-entry isolation for antibodies (after 21 days isolation) and antigen, using prescribed tests; AND
- if any animal seroconverts, keeping all animals in pre-entry isolation until there is no more seroconversion for 3 weeks; AND
- only approving entry for groups where pre-entry isolation results indicate the absence of antigen-positive cattle; AND
- thereafter, annually re-testing seronegative cattle; AND
- for seropositive donors, testing of semen for BVDV, with negative results, prior to use of that animal as a semen donor.

OR

An aliquot of semen from each semen collection for export to New Zealand was tested for BVDV2, by VI or a MAF approved reverse transcriptase polymerase chain reaction (RT-PCR), with negative results.”

2.8. “IBR

Clause 42 4th bullet point: The post collection antibody test interval for sampling following collection should be stated. This interval should be greater than 21 days per European Food Safety Authority- AHAW Panel

“Definition of a BoHV-1-free animal and a BoHV-1-free holding, and the procedures to verify and maintain this status.” EFSA-Q-2005-018 2005”

MAF Response

MAF has decided to amend the risk management measures for BHV to state:

“EITHER

At the time of collection of semen for export to New Zealand, the exporting country was free of BHV 1.1, BHV 1.2a and BHV5 in accordance with the requirements of the OIE Code;

OR

The semen collection centre has been maintained free from BHV from commencement until conclusion of semen collection for export to New Zealand, through compliance with the recommendations in the OIE Code in relation to BHV, including:

- testing all cattle prior to pre-entry isolation for antibodies using a prescribed test, with negative results; AND
- testing all cattle in pre-entry isolation for antibodies, with negative results, or where an animal in a group has tested positive re-testing the remaining animals, with negative results, not less than 21 days after removal of the positive animal; AND
- thereafter, annually re-testing all donors for antibodies, with negative results;

OR

Donors were subjected to a prescribed antibody test for BHV, at least 21 days after semen collection for export to New Zealand, with negative results;

OR

An aliquot of semen from each semen collection for export to New Zealand was tested for both BHV1 and BHV5, by VI or MAF approved PCR test, with negative results.”

3. CRV BV, and other Dutch AI organisations (Alta, AI Samen and AI Kampen); Jan Venneman – Semen IHS

- 3.1. **“In general the requirements are beyond the EU requirements for the import of semen from NZ to countries in the EU and also beyond the OIE requirements for the import /export of bovine semen.”**

MAF Response

Under Article 3.1 of the WTO Agreement on Sanitary and Phytosanitary Measures (the SPS Agreement) the measures adopted in import health standards are to be based on international standards, guidelines and recommendations, where these exist. It also states (under Article 3.3) that measures providing a higher level of protection than international standards can be applied, if there is scientific justification, or if there is a level of protection that the member country considers is more appropriate following a risk assessment. The requirements in the draft IHS are based on a risk assessment completed in February 2009. This can be found at: <http://www.biosecurity.govt.nz/files/regs/imports/risk/cattle-germplasm-ra.pdf>

- 3.2. **“Article 13: according the EU regulations and the OIE code the period of isolation should be at least 28 days (in stead of 30).”**

MAF Response

See 2.2

- 3.3. **“Article 16: this requirement is too rigid; in our opinion the centre veterinarian is responsible for the clinical inspection of the donor animals at the days of semen collection. This can be done by the center veterinarian or a skilled person supervised by the center veterinarian. See also 88/407 annex C 1. a “Semen must be obtained from animals which: a show no clinical signs of disease on the day the semen is collected “”**

MAF Response

See 2.3 for the change to who may be responsible for the health inspection of the donor.

- 3.4. **“Is there any documentation supporting the requirement for separate storage? The only risk which has been suggested is that of contaminated liquid nitrogen which is excluded since only fresh nitrogen is to be used (OIE Animal Health Code).”**

MAF Response

See 2.5

- 3.5. **“Article 24 (second and third dot): sending summaries of the lab tests and copies of lab reports goes far beyond the regulations of the EU and the OIE code; import/export by means of international health certificates is based on thrust between veterinary authorities of individual countries; requiring the sending of all mentioned documents will be considered as a disqualification of the veterinary authorities of exporting countries”**

MAF Response

MAF has decided to amend the documentation requirements to state:

“The documentation that accompanies the consignment to New Zealand must consist of:

- an original zoosanitary certificate, signed and stamped on every page by an official of the competent veterinary authority of the exporting country;

AND

- an import permit issued under section 22(2) of the Act;

AND EITHER

- a tabulated summary of laboratory tests for each donor completed in accordance with the specific requirements in the zoosanitary certificate (indicating donor identification consistent with the zoosanitary certificate, dates of germplasm collection, and for each relevant disease the date/s samples were drawn, the test undertaken and the reported result);

OR

- copies of laboratory reports for all tests.”

The option of sending either the actual laboratory results or a summary of laboratory results will be decided during the zoosanitary certificate bilateral negotiations and could be dependant on the exporting country and exporter. Nevertheless, where documentation non-compliances are detected in the border clearance of germplasm shipments, MAF reserves the right to request copies of the actual laboratory reports. Furthermore, in the case of documentation non-compliances, MAF will recoup any additional costs from the importer.

- 3.6. **“Article 26: in the EU regulations, as well in the OIE, code 60 days are mentioned (in stead of 100 days).
Article 27: in the EU regulations, as well in the OIE, code 60 days are mentioned (in stead of 100 days).
Article 28: in the EU regulations, as well in the OIE code 21 days are mentioned (in stead of 28 days).”**

MAF Response

See 2.6 for the changes to the risk management measures for BTV.

- 3.7. **“Article 34: in regard to sero-positive donors the NZ requirements are going far beyond the EU regulations and the OIE code (testing prior to (every) initial dispatch to NZ versus prior to (only) the first general dispatch; NZ is asked to follow the recommendations in the OIE code for sero-positive donors.”**

MAF Response

See 2.7 for the changes to the risk management measures for BVDV.

In the case of testing of donors seropositive to BVDV, the testing is required prior to initial dispatch of semen from that donor and not prior to every initial dispatch to New Zealand. To enhance clarity and to align with the OIE Code, the clause will be amended to state:

- “for seropositive donors, testing of semen for BVDV, with negative results, prior to use of that animal as a semen donor.”

3.8. **“Article 35: this article goes far beyond the EU regulations and the OIE code and is therefor not acceptable.”**

MAF Response

See 2.7 for the changes to the risk management measures for BVDV.

3.9. **“Article 41: the sentence in which NZ requires the use of a NZ approved semen collection personnel is going too far.”**

MAF Response

The clause gives the option of assessing the FMD status of each exporting country on a case-by-case basis.

Owing to the extreme seriousness of the disease and the catastrophic consequences that would result from its introduction to New Zealand, it was concluded that, when germplasm did not originate from countries or zones that are free of FMD virus, more stringent measures may be applied. This may include use of New Zealand approved germplasm collection personnel or other measure that MAF deems fit.

3.10. **“Articles 61, 62 and 63: these articles are neither mentioned in the EU regulations, nor in the OIE code; besides, the exported semen is treated with antibiotics for *Mycoplasma bovis*.”**

MAF Response

Potential risks to New Zealand from *Mycoplasma bovis*:

Mycoplasma bovis is regarded as a major pathogen that causes respiratory disease, mastitis, abortion and arthritis in cattle. Introduction of this pathogen could cause similar syndromes and have a similar effect on the New Zealand cattle herd.

It has been demonstrated that when frozen semen containing *M. bovis* was inseminated into heifers it induced reproductive problems (Hirth et al, 1966)², and similar effects might arise when infected embryos are transferred into the uterus. In a CAB Review requested by the Health and Safety Advisory Committee of the International Embryo Transfer Society (IETS) (Wrathall et al, 2007)³ it states that potentially the import of contaminated semen (or subclinically infected cattle) could have been responsible for the introduction of *M. bovis* into the UK in the 1970s.

² Hirth RS, Nielsen SW, Plastringe WN. Bovine salpingoophoritis produced with semen containing a Mycoplasma.

Pathologia Veterinaria 1966;3:616–32.

³ Wrathall AE, Ayling RD and Simmons HA Risks of transmitting mycoplasmas by semen and embryo transfer techniques in cattle, sheep, goats and pigs; CAB Reviews: Perspectives in Agriculture, Veterinary Science, Nutrition and Natural Resources 2007 2, No. 036

The CAB Review states that it has to be assumed that insemination of mycoplasma-infected semen or transplantation of mycoplasma-infected embryos is likely to result in infection of the recipients, and, depending on the mycoplasma species involved, the recipients would either develop clinical disease or become asymptotically infected. These could then infect other, in contact animals in the importing country or farm and lead to losses in productivity and restrictions on export from the affected farms.³

The economic impact of *M. bovis* was illustrated in the 1990s when infection was inadvertently introduced, probably from mainland Europe, into Northern Ireland and the Irish Republic, where it rapidly became a major cause of respiratory disease and a frequent cause of mastitis and arthritis.(Brice et al, 2000; Byrne et al 2001)^{4,5}

In the UK, it is estimated that up to 1.9 million cattle are affected annually by respiratory disease which costs the cattle industry £54 million. Furthermore approximately 157,000 calves die annually as a result of pneumonia and related illnesses which would have a potential market value of £99 million. Across Europe with approximately 90 million cattle this extrapolates to total losses of 576 million Euros. It is likely that *M. bovis* is responsible for at least a quarter to a third of these losses although this is likely to be an underestimate. In the USA, the cost of *M. bovis* infections as a result of loss of weight gain and carcass value has been estimated at \$32 million USD per year. The losses due to bovine mastitis caused by *M. bovis* may be higher than that for respiratory disease with estimates from the USA of up to \$108 million USD per year with infection rates of up to 70% of a herd (Nicolas & Ayling, 2003)⁶.

New Zealand freedom from *Mycoplasma bovis*:

New Zealand is considered free of *M. bovis*. This is based on the absence of clinical syndromes as reflected in normal veterinary monitoring and surveillance mechanisms in the New Zealand livestock industries as well as active suspected exotic disease investigations where mycoplasmosis had been a differential diagnosis, and this disease freedom has been confirmed by microbiological surveys.

A survey done in 1999 on 353 dairy cattle all tested negative for *M bovis* – this provided a 95% confidence that *M bovis* was not present at 3% prevalence and assuming a 30% sensitivity for the serological test (Reichel et al, 1999)⁷.

A more extensive and recent survey was done by MAF in 2007 to confirm New Zealand freedom of *M bovis*. This used bulk tank milk testing by PCR and culture. The sampling frame was designed to detect a between herd prevalence of 2% with 99% confidence. Samples were randomly selected from each region throughout New Zealand based on the number herds within each region. A total of 244 herds were tested out of an estimated 11,267 eligible herds. A nested PCR was used, along with standard *Mycoplasma* culture techniques. All milk samples tested were negative by both PCR and culture. This and the historic evidence suggest

⁴ **Brice N, Finlay D, Bryson DG, Henderson J, McConnell W, Ball HJ.** Isolation of *Mycoplasma bovis* from cattle in Northern Ireland. *Veterinary Record* 2000;146:643–4.

⁵ **Byrne WJ, McCormack R, Brice N, Markey B, Ball HJ.** Isolation of *Mycoplasma bovis* from bovine clinical samples in the Republic of Ireland. *Veterinary Record* 2001;148:331–3.

⁶ **Nicholas RAJ and Ayling RD** *Mycoplasma bovis*: disease, diagnosis, and control *Research in Veterinary Science* Volume 74, Issue 2, April 2003, Pages 105-112

⁷ **Reichel M, Nicholas RAJ, Ross GP, Penrose ME.** Survey results for exotic *Mycoplasma* infections in cattle, goats, and sheep. *Surveillance* 26 (3), 12–13 1999

the New Zealand dairy industry at least, is free of *Mycoplasma bovis* or if it is present, it is at a low prevalence (<2%). (McDonald WL et al, 2009)⁸

If an exporting country had surveyed to demonstrate country freedom, this information could be submitted. MAF would assess the submitted survey criteria and this information could be taken into consideration in negotiation of zoosanitary certification.

Treatments and effect on germplasm:

A number of studies have demonstrated that *Mycoplasma* species readily attach to zona pellucida and are not efficiently removed by washing (Bielanski et al, 2000; Riddell et al, 1989)⁹. Furthermore, the antibiotics usually used in semen extenders and in the preparation of embryos may not be effective against *Mycoplasma* or *Ureaplasma* spp. (Bielanski et al 2000; Bielanski et al 1989).^{10, 11}. This is again recommended in the 2010 edition of the IETS manual that states that *Mycoplasma* spp. are resistant to embryo washing, trypsin treatment, and routine addition of penicillin, streptomycin, and gentamicin.

The inherent resistance of *Mycoplasma* spp. to many antibiotics, the increasing emergence of resistant strains (Loria et al, 2003)¹² and the undesirability of replacing traditional antibiotic cocktails with ones that are specific for *Mycoplasma* spp., but may not be as effective against other organisms, negates the use of antibiotics in extender and wash solutions as a completely reliable method for sanitizing germplasm.

The CAB Review recommends that due to the fallibility or lack of official recommendations for preventing the transmission of mycoplasmal diseases by AI and embryo transfer, additional strategies are needed. Testing aliquots of semen, or, in the case of embryos, testing samples of uterine flushing or embryo culture fluids being good examples.³

It has also been recommended in the OIE Scientific and Technical Review that bulls should be tested for *Mycoplasma*; animals shedding *M bovis* should be culled and all stored semen since their last negative finding should be destroyed. It also states that semen should be tested prior to importation, and that only non-infected semen is imported (Pfützner H and Sachse K, 1996)¹³.

The IHS does not require that compulsory surveillance for *Mycoplasma bovis* be in place, but due to subclinical infections, intermittent shedding and sequestered infections, MAF has prescribed the measure that donors have never recorded a positive test for *Mycoplasma bovis*.

We recognise that New Zealand requirements for this organism are unique. The presentation of this range of options seeks to provide a wide range of mechanisms to deliver assurance that the donor animal/s is not infected, while limiting restrictions on New Zealand access to on-shelf germplasm.

⁸ McDonald WL (2009) et al, Survey of bulk tank milk in New Zealand for *Mycoplasma bovis*, using species-specific nested PCR and culture *New Zealand Veterinary Journal*, Volume 57, Issue 1, pp 44-49, Feb 2009.

⁹ Riddell KP, Stringfellow DA, Panangala VS (1989). Interaction of *Mycoplasma bovis* and *Mycoplasma bovis* genitalium with preimplantation bovine embryos. *Theriogenology*, 32(4), 633-41.

¹⁰ Bielanski A, Devenish J, Phipps Todd B (2000). Effect of *Mycoplasma bovis* and *Mycoplasma bovis* genitalium in semen on fertilization and association with in vitro produced morula and blastocyst stage embryos. *Theriogenology*, 53(6), 1213-23.

¹¹ Bielanski A, Eaglesome MD, Ruhnke HL, Hare WC (1989). Isolation of *Mycoplasma bovis* from intact and microinjected preimplantation bovine embryos washed or treated with trypsin or antibiotics. *Journal of In Vitro Fertilisation and Embryo Transfer*, 6(4), 236-41.

¹² Loria GR, Sammartino C, Nicholas RA, Ayling RD (2003). In vitro susceptibilities of field isolates of *Mycoplasma agalactiae* to oxytetracycline, tylosin, enrofloxacin, spiramycin and lincomycin-spectinomycin. *Research in Veterinary Science*, 75(1), 3-7.

¹³ Pfützner H and Sachse K (1996) *Mycoplasma bovis* as an agent of mastitis, pneumonia, arthritis and genital disorders in cattle. *Rev Sci Tech Off Int Epiz* 15(4), 1477-1494

To provide a further option the IHS for embryos has been amended to include another measure that allows for demonstration of herd freedom via bulk milk tank testing.

MAF has decided to amend the risk management measures for *Mycoplasma bovis* to state:
“Donors have never recorded a positive test for *Mycoplasma bovis*;

AND EITHER

Donors were subjected to a MAF approved serological test for *Mycoplasma bovis*, with negative result, on a sample collected between 21 and 120 days after each semen collection for export to New Zealand;

OR

An aliquot of semen from each semen collection for export to New Zealand was tested for *Mycoplasma bovis*, by a MAF approved PCR test, with negative results;

OR

Within the 6 month period before or after semen collection for export to New Zealand, the resident herd of cattle on the semen collection centre has been tested for *Mycoplasma bovis*, with negative results. This testing can be a MAF approved serological test done on either the whole herd or a random sample of at least 60 animals (whichever is the lesser number); AND The semen collection centre herd has been isolated for the period between semen collection and diagnostic sampling.”

4. CRV BV, and other Dutch AI organisations (Alta, AI Samen and AI Kampen); Jan Venneman – Embryo IHS

- 4.1. **“In general the requirements are beyond the EU requirements for the import of embryo’s from NZ to countries in the EU and also beyond the OIE requirements for the import of bovine embryo’s.”**

MAF Response

See 3.1

- 4.2. **“Article 13 and 14: in these articles an approved/registered embryo collection facility is mentioned; however, embryo collection in the whole world is based on collection by approved embryo collection teams; in general donors are not isolated from other animals; articles 13 and 14 should therefor be deleted.”**

MAF Response

See 1.4

- 4.3. **“Article 18: what is the reason that only in vivo derived embryo’s can be exported to NZ? It should be possible to export in vitro derived embryo’s as well.”**

MAF Response

See 1.1

- 4.4. **“Article 30: sending of a summaries of lab tests and copies of lab reports goes far beyond the regulations of the EU and the OIE code; import/export by means of**

international health certificates is based on thrust between veterinary authorities of individual countries; requiring the sending of all mentioned documents will be considered as a disqualification of the veterinary authorities of exporting countries.”

MAF Response

See 3.5

- 4.5. **“Article 35: this article is completely copied from the draft import requirements for bovine semen; it does not make sense for bovine embryo’s; it is more logical to maintain the requirements in the current health certificate.”**

MAF Response

See 1.12 for the changes to the risk management measures for BVDV.

- 4.6. **“Article 36: this article goes far beyond the EU regulations and the OIE code and is therefore not acceptable.”**

MAF Response

See 1.12 for the changes to the risk management measures for BVDV.

- 4.7. **“Article 41: the sentence in which NZ requires the use of a NZ approved embryo collection personnel is going too far.”**

MAF Response

See 3.9

- 4.8. **“Article 53: we can do the tuberculosis test but we do not isolate the donor animals; see the comments to article 13 and 14.”**

MAF Response

See 1.15

- 4.9. **“Article 58, 59, 60 and 61: these articles are neither mentioned in the EU regulations, nor in the OIE code.”**

MAF Response

See 3.10

MAF has decided to amend the risk management measures for *Mycoplasma bovis* to state:
“Donors have never recorded a positive test for *Mycoplasma bovis*;

AND EITHER

Donors were subjected to a MAF approved serological test for *Mycoplasma bovis*, with negative result, on a sample collected between 21 and 120 days after each embryo collection for export to New Zealand;

OR

A sample of embryos/oocytes, collection fluids and/or washing fluids from each embryo collection for export to New Zealand was tested for *Mycoplasma bovis*, by a validated and MAF approved PCR test, with negative results;

OR

Within the 6 month period before or after embryo collection for export to New Zealand, the embryo collection herd has been tested for *Mycoplasma bovis*, with negative results. This testing can be either:

- a MAF approved bulk tank milk test; OR
- a MAF approved serological test done on either the whole herd or a random sample of at least 60 animals (whichever is the lesser number); AND

The embryo collection herd has been isolated for the period between embryo collection and diagnostic sampling.”

5. Genex, Billings Montana; Dr. Harry Michael – Semen IHS

“Bovine Tuberculosis

There is a problem with the wording in No. 56 Re: Tuberculosis which would be the only one we could qualify under. The sub statement would be better suited to the USA if it said, as it does in the Brucellosis statement, as follows: "Prior to entry into pre-isolation the donor Bulls were either from a country or zone that is free from Tuberculosis in accordance with the OIE Code"

..... The addition of the wording or zone is important as it fits the way the USDA controls Tuberculosis. The USA controls Tuberculosis on a State basis.”

MAF Response

MAF has decided to amend the risk management measures for tuberculosis to state:

“EITHER

The semen collection centre was:

- free from bovine tuberculosis in accordance with the OIE Code or the veterinary authority of the exporting country; AND
- located in a country or zone that has been recognised by MAF as being free of bovine tuberculosis;

OR

The semen collection centre has been maintained free from bovine tuberculosis from commencement, until conclusion of semen collection for export to New Zealand, through compliance with the recommendations in the OIE Code in relation to bovine tuberculosis, including:

- prior to pre-entry isolation the donors were from a herd free from bovine tuberculosis, either in accordance with the OIE Code or the veterinary authority of the exporting country; AND
- during the 30 days prior to entry to the semen collection centre, donors were tested using an OIE prescribed test for bovine tuberculosis, with negative results; AND
- at least annually all cattle resident in the semen collection centre have been tested using an OIE prescribed test for bovine tuberculosis, with negative results.”

6. Embryoplus (South Africa); Dr. Robert Treadwell – Embryo IHS

- 6.1. **“Our comment was on point 46 of the Embryo Standard on RVF, where we thought that they could add as possible alternative “OR All donor animals have been vaccinated against RVF with a modified live virus vaccine at least 30 days prior to movement to a quarantine facility.” which is basically the same as the proposed amendment to the Brazilian protocol.”**

MAF Response

MAF has decided to add to the risk management measures for RVF to state:

“Donors showed no evidence of RVF in the period from 28 days prior, to 28 days following embryo collection for export to New Zealand, and were vaccinated with a MAF approved vaccine against RVF at least 21 days prior to embryo collection.”

7. New Zealand Hereford Association; Natalie Campbell – Semen and Embryo IHS

- 7.1. **“We would like to ask that you explore the case for allowing on farm collection of embryos in North America and Australia, providing the protocols you have outlined are met, and the service is carried out by approved providers. By limiting collection to approved centres, we feel it is creating a monopoly and another layer of cost. We believe on-farm testing will relieve this cost, while testing protocols and approved operators would negate any risk.”**

MAF Response

The intent of the IHS is to allow on-farm collection of embryos. See 1.4.

- 7.2. **“We were not able to obtain a ‘list of approved countries’ from which export, in the guidance document (section C as described), but wish to enquire on the status of Uruguay as an exporting country for bovine genetic material as it has been free of Foot and Mouth for some time and contains a world class, state of the art bovine collection centre that several NZ Hereford Association board members can attest to.”**

MAF Response

At present MAF has designated certain countries as being eligible to export bovine germplasm to New Zealand. These are countries that currently export bovine germplasm to New Zealand. Any further additions to this list of eligible countries will be assessed on a case-by-case basis, but this is not part of the IHS development process. The list of approved countries is included in the Guidance document – these countries are the USA, Canada, Australia, European Union member countries (semen and embryos) and Switzerland and Norway (semen only).

8. World Wide Sires NZ (on behalf of Select Sires and Accelerated Genetics, USA); Judy Hope – Semen IHS

- 8.1. **“BVD - They still are looking for on-farm BVD testing- why is this necessary? These bulls are tested for BVD through CSS on the farm (SN, Capture Elisa or IP), in isolation (SN & virus isolation) (all SN+ animals have to have a semen virus isolation test before release for sale) and every 6 months for semi-annual testing (virus isolation). Then they want post test for negative animals. They have added semen testing to bull that have not been in stud for more than 3 years, the current**

regs allow for in stud 6 months or less. Adding Type 2 to their BVD regulations causes another issue. Many labs typically only test for Type 1 unless Type 2 is requested. The BVD recommendations will affect all previously stored semen for most places, so is there a grandfather type scenario? If not, I bet every code will have to be tested for M. bovis and BVD type2.”

MAF Response

See 2.7.

The measures for BVDV2 have been included since BVDV2 is exotic to New Zealand and if introduced would be expected to spread amongst susceptible cattle, with the potential to cause severe disease.

The eligibility of semen produced under the previous IHS requirement will be resolved during bilateral negotiations.

8.2. “IBR - This follows EEC isolation testing, the extra addition here is the post test or you can test the semen. Why can't we have a statement like Australia-"kept in an "IBR/IPV free herd", as defined in OIE Terrestrial Animal Health Code, at the time of collection of the semen." No post test.

Also, it mentions BHV5- I checked with the labs, they don't run for BHV5, just BHV1. The labs mentioned they don't have reagents for BHV5. The IBR recommendations will make any non-EU bull unavailable for export and for us it will not allow for any non-EU herd resident to be exported (no beef bulls).

IBR neg antibody tests after time of collection - gives no time frame like have in the past for a post test, how far can we dare go after the collection? Unlimited usually isn't an option.”

MAF Response

Only BHV1.2b has been isolated in New Zealand, with BHV1.1 and BHV1.2a being regarded as exotic. In addition BHV5 encephalitis has not been described in New Zealand. For this reason the BHV requirements are specifically tailored to New Zealand's biosecurity status. The semen can be tested by either virus isolation or a validated PCR – the virus isolation will indicate the presence of either strain of BHV.

See 2.8 for the changes to the risk management measures for BHV.

8.3. “Vesicular stomatitis would now 100km radius instead of AI center which makes no sense. How can we validate this statement? We don't have knowledge or control of all the animals in a 100km radius. We cannot certify this. The other option of insect free premises is ridiculous but luckily Ohio is a long way from Arizona.”

MAF Response

MAF has decided to amend the risk management measures for VS to state:

“EITHER

Donors were resident in a country that is free from VS in accordance with the OIE Code;

OR

VS is officially notifiable in the exporting country and no reported cases have occurred within 100km of the semen collection centre during the period from 30 days prior to commencement, until 30 days after conclusion of semen collection for export to New Zealand;

OR

Donors were:

- resident for the 30 days prior to and during semen collection in a herd where no case of VS was reported in that period; AND
- subjected to a validated serological test for VS, between 21 to 42 days after semen collection for export to New Zealand, with negative results.”

8.4. **“Crimean Congo Haemorrhagic Fever. It doesn't appear to be in the North American continent. Mostly, Africa, Asia, China, South Africa, Uganda areas. The US labs do not have a test for this. Maybe need to suggest this as country freedom statement. APHIS will have to sign off on it too.”**

MAF Response

MAF has decided to amend the risk management measures for CCHF to state:
“EITHER

The exporting country has been recognised by MAF as being free of CCHF or CCHF is officially notifiable in the exporting country, and there has not been a reported case of CCHF in the exporting country for the 21 days before and during semen collection for export to New Zealand;

OR

Donors were serologically tested for CCHF using MAF approved methods such as an enzyme linked immunosorbent assay (ELISA) to detect IgG and IgM antibodies. Blood samples must be collected within 7 days prior to commencement of semen collection and every 21 to 60 days thereafter, until 21 to 60 days after conclusion of semen collection for export to New Zealand. The results must indicate:

- that any donor seronegative at the start of testing has maintained a seronegative status; AND
- that any donor seropositive at the start of testing did not have a rise in titre over consecutive tests.”

8.5. **“TB and Brucellosis - US is not free from TB, our bulls come from all different states with different TB status. All bulls are TB tested before coming into stud, but not all herds have had a whole herd TB test to come into stud based on their state status. OIE discusses the options for herd free status etc. I can't see making these herds do a whole herd TB test just to bring a bull into stud when the state doesn't require it. I don't know how many states this could effect. How each herd manages this testing is up to each state and their status and where they are selling animals to. I would like to see this statement stay as the donor bull was tested 30 days prior to departure to semen collection center. This may be the same for Brucellosis being from an officially free herd.”**

MAF Response

See 5.1 for the changes to the risk management measures for tuberculosis.

MAF has decided to amend the clauses for brucellosis to state:
“EITHER

Donors have been kept since birth in a country or zone that is free from bovine brucellosis, in accordance with the OIE Code;

OR

The semen collection centre has been maintained free from bovine brucellosis from commencement, until conclusion of semen collection for export to New Zealand, through compliance with the recommendations in the OIE Code in relation to bovine brucellosis, including:

- prior to pre-entry isolation the donors were either from a country or zone that is free from bovine brucellosis in accordance with the OIE Code or were from a herd officially free from bovine brucellosis; AND
- during the 30 days prior to pre-entry isolation donors were tested using an OIE prescribed serological test for bovine brucellosis, with negative results; AND
- all cattle in pre-entry isolation were tested using an OIE prescribed serological test for bovine brucellosis, with negative results; AND
- at least annually all cattle resident in the semen collection centre were tested using an OIE prescribed test for bovine brucellosis, with negative results.”

8.6. **“Mycoplasma bovis - Per our CSS protocol, antibiotics are added to provide effective microbiological control of mycoplasma, ureaplasma, etc. If we were to have to test as they are recommending, it would be very costly as sending raw semen, eliminates how much processed semen we can produce for sale on one ejaculate. We couldn't pre-qualify unless we submitted serology testing. This could limit how many bulls we could offer NZ.”**

MAF Response

See 3.10 for the changes to the risk management measures for *Mycoplasma bovis*. MAF agrees that it need not be raw semen submitted for PCR testing.

8.7. **“Testing for some of their added disease are not quality tests: M. bovis, borna, etc. Not to mention, the actual possibility of transmitting these diseases thru frozen semen doesn't seem to be taken into consideration at all.”**

MAF Response

The risk analysis indicates that Borna disease is an emerging disease and since the risk is deemed not to be negligible, risk management measures are justified.

The risk analysis extrapolated from studies done on rats that indicated that animals may remain persistent shedders of virus and the virus may be shed in various body secretions. In addition peripheral mononuclear cells of cattle have been found to contain viral RNA (Hagiwara et al 1996)¹⁴ and semen could potentially be infected with mononuclear cells.

The duration that animals have been resident in a herd that had no case of Borna disease has been amended to 12 months – this is owing to the fact that the incubation period can be up to several months (Ludwig and Kao 1990)¹⁵. It is also reported that whilst most infections of cattle are not apparent, clinical cases of disease do occur (Ludwig and Kao 1990).

¹⁴ Hagiwara K, Nakaya T, Nakamura Y, Asahi S, Takahashi H, Ishihara C, Ikuta K (1996). Borna disease virus RNA in peripheral blood mononuclear cells obtained from healthy dairy cattle. *Medical Microbiology and Immunology.*, 185(3), 145-51.

¹⁵ Ludwig H, Kao M (1990). Borna disease in sheep. In: Dinter Z, Morein B (eds). *Virus infections of ruminants*. Pp. 529-38, Amsterdam, Oxford, New York, Tokyo.

Whilst the tests for Borna disease may not be immediately useful, MAF will retain the option to allow for future developments. The testing requirements and process has not been defined and, if this option was selected, would require MAF approval.

MAF has decided to amend the risk management measures for Borna disease to state:
“EITHER

Donors have been resident since birth in a country or countries that have never had a reported case of Borna disease;

OR

Borna disease is officially notifiable in the exporting country, and the donors have been resident for the previous 3 months in herds, where there have been no reported cases in the 12 months prior to semen or embryo (as applicable) collection for export to New Zealand;

OR

Donors or aliquots of semen or embryos/oocytes, collection fluids, and/or washing fluids from each semen or embryo (as applicable), collection for export to New Zealand, have been tested for Borna disease, using a MAF-approved test and process, with negative results.”

For *Mycoplasma bovis* see 3.10.

8.8. **“Bluetongue
We would like to see a BTV PCR on semen as a possible option.”**

MAF Response

In order to align with international standards, risk management measures are aligned, as far as possible, with OIE Code measures. The OIE Code makes no reference to PCR testing on semen.

8.9. **“Lab test results
Point 24 - This asks for test results for the health paper, the next part, are they asking for test results for the isolation (qualification to enter) and semi-annual testing. It is enough to have to provide test results for the health paper test date but to add isolation & semi-annual testing too is much. They would be getting a book for each bull. The other sections that refer to pre-entry for the various test- I hope they don't want the copies of test to go with it either. It would take days to get the documents together for one health paper if this is what they are wanting! Finally, we should strive to get away from sending tests results with the health certificate and they appear to be asking for more! An accredited veterinarian signs the paper attesting the health testing as well as the federal veterinarian but they want to see the actual test results.”**

MAF Response

See 3.5

9. Kaitoa polled Herefords; Philip Barnett – Embryo IHS

9.1. **“I wish to submit there is a case for on farm collection of embryo's in North America/ Australia providing the protocols you have outlined are met, and the**

service is carried out by approved providers . By limiting collection to approved centers it is creating a monopoly and another layer of cost.”

MAF Response

The intent of the IHS is to allow on-farm collection of embryos. MAF has decided to remove the limitation from embryo collection from germplasm centres. See 1.4.

9.2. “Finally I failed to obtain` list of approved countries from which to export in the guidance document.”

MAF Response

See 7.2

10. Livestock and Animal Germplasm Trade Association; Jim Edwards – Embryo IHS

10.1. “Part B, paragraph 13:

“During the collection of embryos for consignment to New Zealand, and until the testing specified in this standard was completed, donors were held in a veterinary authority approved and registered embryo collection facility. During this time they were isolated from animals not of an equivalent health status.”

The requirement to hold donors in an approved embryo collection facility does not accord with either the OIE or the OAP.

The definition of embryo collection facility (centre) refers only to the place of collection and in fact there is no definition of a collection of facilities that incorporates a holding facility to perform the donor hormone programming regime (during which time supposed isolation would take place).

The new OAP made this very clear with a specific definition of collection facility 8.5.1.b so the requirement in section 13 of the IHS is inconsistent with the OAP definition as well as the definition in the OIE glossary.

The phrase “During the collection of embryos” quite clearly refers to the period when the veterinarian or technician is collecting the embryos from the donor in the approved facility for this purpose.

The only reference in the OIE to embryo collection is in fact 4.7.4.1.c which stipulates donors are to be inspected for signs of disease by a veterinarian at the time of collection.

The OIE Terrestrial Animal Health Code, Article 4.7.4, paragraph 1.b, states only that “the donor animals should not be situated in a herd/flock subject to veterinary restrictions for OIE listed disease or pathogens for relevant species (see Chapter 1.2. of the Terrestrial Code), other than those that are in IETS Category 1 for the species of embryos being collected (see Article 4.7.14. and footnote1).”

Article 4.7.2 requires that the embryo team be supervised by a “specifically approved” team veterinarian, and goes on to state that:

“The collection team should have adequate facilities and equipment for:

collecting embryos;

processing and treatment of embryos at a permanent site or mobile laboratory;
storing embryos.

These facilities need not necessarily be at the same location.”

Nowhere in the OIE Code Chapter 4.7. “Collection and Processing of in-vivo derived Embryos from Livestock and Horses” is there a requirement for the donors to be resident on a registered embryo collection facility, so this is clearly an anomaly that is open to misinterpretation by overseas competent authorities.

Similarly, MAF Biosecurity's "Revised Official Assurance Programme - Live Animals and Germplasm" does not require donors to be resident in a registered embryo collection facility.

Part 8 of the OAP, "Requirements for Embryo Teams" states that "this part sets out the requirements for New Zealand embryo teams to be approved for collecting, processing and storing embryos from ruminants, equidae and other species for export" and that "these requirements are based, in part, on the recommendations related to collection, processing and storage of embryos in the OIE Code and IETS Manual, and will be used when auditing embryo teams."

The Livestock and Germplasm Trade Association therefore considers that the imposition, by the draft IHS, of having to hold donors in a registered embryo collection facility cannot be justified and in fact that MAFBNZ have confused terminology and have proposed requirements inconsistent with both the OIE, IETS and their own OAP.

The Association submits that it would be sufficient to require that donors be isolated from any other animals of a non-equivalent health status from the time of pre-collection testing until the embryo collections have been completed.

Recent communication from Dr Stone indicated that this requirement was related to the risk analysis for BVD type 2. However the recommendation was related more to semen centres and the attempt to align embryo collection with semen collection, as far as donor isolation, should not necessarily follow."

MAF Response

See 1.4 and 9.1.

MAF has decided to remove the need for pre-collection donor isolation (unless an exporter opts for pre-collection testing), post-collection donor isolation and also removes the reference to an approved embryo collection facility. The requirement of an approved embryo collection team remains.

This aligning the IHS with the OIE Code, IETS as well as the New Zealand Official Assurance Programme (OAP) – this being the document defining the relevant standards required for a New Zealand export germplasm centre.

10.2. "Part B, paragraph 13:

"During the collection of embryos for consignment to New Zealand, and until the testing specified in this standard was completed, donors were held in a veterinary authority approved and registered embryo collection facility. During this time they were isolated from animals not of an equivalent health status."

The LAGTA submits that keeping donors in isolation after the collection of the embryos, and until the completion of any post-collection health testing, is not necessary from a biosecurity viewpoint.

Once the embryos have been collected and frozen, there is no risk to them from the donors being in contact with animals of a lesser health status.

The risk of the donors becoming sero-positive after contact with these animals, and thus failing a post-collection health test, is purely a commercial risk on the part of the owner of the donors.

Further, there is no requirement for such mandatory post collection isolation in either the OIE guidelines, the IETS manual or the NZ OAP."

MAF Response

See 10.1

10.3. **“Part B, Paragraph 14:**

“Prior to collection of embryos for this consignment the donors must be subject to a period of isolation of at least 30 days in accommodation specifically approved for this purpose by the veterinary authority of the exporting country. During this time they were isolated from animals not of an equivalent health status”.

There is no requirement for any mandatory donor isolation in either the OIE guidelines, the IETS manual or the NZ OAP.

There appears to be concern within MAFBNZ related to the risk of BVD2 infection related to embryos, and this has been promulgated as the reason for the imposition of this inconsistent request.

The LAGTA submits that there may be adequate biosecurity reasons for pre-collection isolation for importations from countries where this or other diseases may present a risk. However, this does not currently apply to the main regions (the EU, Canada and Australia) from which most embryos are being imported. The requirement for pre-collection isolation of donors should therefore not be mandatory, but should be decided on a country by country basis.

Article 4.7.5 of the OIE code related to risk management involving in vivo derived embryos states in section 3 that risk mitigation for diseases not included in IETS Category 1 should be based on:

- a) post collection surveillance of donors**
- b) testing of embryo fluids etc and or blood samples which appears to be related to the post collection period and relative incubation periods of disease agents”**

MAF Response

See 10.1

10.4. **“Paragraph 16:**

This paragraph is not consistent with OIE guidelines. It should reflect the wording in OIE section 4.7.4.1.c”

MAF Response

See 1.5 for the change to who may be responsible for the health inspection of the donor.

10.5. **“Paragraph 17:**

Given the LAGTA submission number 3, above, bullet point 3 may need to be changed to reflect changes to donor isolation requirements.”

MAF Response

Since there may be situations where the option of donor isolation may be utilised, the clause pertaining to potential isolation status of the semen donor will remain.

10.6. **“Paragraph 19:**

It is not possible to identify embryos other than by DNA testing. The wording of this paragraph should be changed so that it is the straw containing the embryos that are identified, not the embryos themselves.”

MAF Response

See 1.8

10.7. **“Paragraph 22:**

There should be reference to indelible labeling of the actual straw or ampoule. If

**an attached plug is used for a label, or if gummed labels are used, these must be permanently attached but the straw itself should also be indelibly labeled, at least with a cipher or code and an individual straw number.
The IETS also requires an individual straw identification for every straw.”**

MAF Response

See 1.10

10.8. “Paragraph 30: bullet point #3

The LAGTA submits that it should not be necessary for copies of laboratory reports to be included in the accompanying documentation if the Team Veterinarian has signed an ED or export certificate or health certificate which has been sighted and signed over by the exporting country competent veterinary authority prior to export. This appears to be overkill and certainly is not consistent with the NZ OAP and export procedures.

This paragraph also refers to donors “resident on a collection facility”, which is inconsistent with the LAGTA submission number 1 above.”

MAF Response

See 3.5

The paragraph has been amended to remove the reference to testing on a collection facility.

10.9. “Paragraph 53

This paragraph refers to a mandatory donor isolation period which is inconsistent with submission number 3 above.”

MAF Response

See 1.15

10.10. “Part C Specific Requirements for Identified Risk Organisms.

There is inconsistency between testing requirements for donor testing and isolation, particularly between BVD2 and M. bovis. The former is an IETS category 3 disease, yet has a more stringent pre-entry requirement than M. bovis, which is a category 4 disease.

This appears to be without logic and there is no link between IETS categories and the requirement for mandatory donor isolation as per semen IHS, in fact quite the contrary.

The LAGTA submits that isolation and testing requirements for BVD2 should be more in line with those for M. bovis and Q Fever, namely post collection serological testing and / or post collection PCR testing of collection or washing fluids.”

MAF Response

MAF has removed the isolation requirement and amended the testing requirements for BVDV2 so as to remove the need for pre-collection testing for BVDV.

See 1.12

10.11. “Inconsistency with trading partners

The sections in the Draft IHS related to disease testing and embryo donor mandatory isolation are not consistent with those in the Import Health Standards for embryos imported into Australia. For example, the requirements for BVD2 testing of donor cows and donor isolation.”

MAF Response

The IHS is based on a risk analysis that pertains specifically to the disease situation in New Zealand, and hence there may be variances with import standards developed by other countries.

11. Federated Farmers of New Zealand; David Burt – Semen and Embryo IHS

11.1. “Streamlining of the IHS process

Federated Farmers understands that IHS documents will become more generic in nature - rather than market focused as they are now - and that the mechanism(s) to be used to meet IHS requirements around the importation of animal material are to be detailed in separate, market specific, “guidance documents”.

The Federation is supportive of this change, with the proviso that a process exists to ensure the relevant guidance and other documents are updated appropriately when the underpinning IHS documents are amended.”

MAF Response

As stated, the IHS is a legal document defining the disease management measures required by New Zealand. Guidance material describing how disease management measures, as written in the IHS, are to be applied is included in the Guidance Document. In addition negotiated zoosanitary certificates are to be included in the Guidance Document.

MAF has processes to ensure that updates are made to standards and guidance material as and when required.

11.2. “Negotiation of Zoosanitary certificate content [PART A: Outcomes, Clause #9]

The standards state that “MAF and the veterinary authority of the exporting country will negotiate” and, later, “... Upon conclusion of the negotiations ...”

An alternative, stronger wording is suggested for the first sentence of this section: “MAF will, in conjunction with the competent veterinary authority of the exporting country, determine how the relevant identified risks are to be managed.””

MAF Response

MAF has decided to amend the clause to state:

“MAF will, in conjunction with the veterinary authority of the exporting country, determine how the relevant identified risks are to be managed, taking into account:

- the verifiable health status of the exporting country/zone/compartment; AND
- the national systems and standards in the exporting country for regulatory oversight of the germplasm industry; AND
- the capabilities and preferences of the exporting country’s Competent Authority.

Once this determination has been concluded, country-specific Zoosanitary Certificate templates will be included in the guidance document.”

11.3. “Alignment of the two IHS [“bovsemid.gen” (Bovine Semen, 21 June 2010) and “bovemid.gen” (Bovine Embryos, 21 June 2010)] documents

The structure and content of these documents is, as might be expected, very similar. Examining the two documents however, there are a number of differences in the wording not attributable to the different (semen/embryo) foci. For example, the wording of clause relating to the disinfection of transport containers (#’s 21 and 25 for semen and embryos respectively) is different, with requirements around the disinfection process specified for the latter but not the former.

It is recommended that the two documents – if it is not feasible to combine them – should be examined to ensure that, where appropriate, the wording used is consistent and current. [Page 3 of the draft Risk Management Proposal document notes that “... the import health standards for bovine semen and embryos are presented in a single standard ...”. Does this mean that they are to be published as one document?]

MAF Response

The various inconsistencies between the semen and embryo have been removed and the two standards aligned, where possible.

MAF has decided to amend the clause in the Risk Management Proposal to state:

“In accordance with new MAF processes, the import health standards for bovine semen and embryos are each presented in a single standard addressing all requirements to manage biosecurity risks.”

11.4. “Document phrasing

The preamble (eg Part A) of the documents – correctly - frequently uses “imperative” phrasing, such as “... the requirements that must be met ...” [Scope, #4, page 3], but a number of the [Part C] “Requirements” are written as “... must have been ...” [eg #'s 17 – 19 (Semen)] or “... were ” [eg #'s 19 – 20 (Embryos)]. It is recommended that the requirements to be met are written in “must be” form.”

MAF Response

Comment noted and changes to phrasing made as required.

11.5. “Part B: Donor and centre health status

Clause #16 includes the sentence that ends “... evidence of infectious diseases caused by micro-organisms transmissible in semen.” be rewritten as “evidence of diseases of concern.””

MAF Response

See 2.3 for changes to how donor health status is defined.

11.6. “Part B: Semen collection, processing storage and transport

Clause #20 of the Semen IHS requires that semen “must have been stored only with other embryos or semen that is eligible for export to New Zealand”. How is this requirement reconciled with the need to effectively quarantine/store semen while it is undergoing testing – the results of which may make it (in)eligible for export to New Zealand?”

MAF Response

See 2.5. The IHS will require that semen be stored with only other embryos or semen that meets the standards specified in the OIE Code – this incorporates the entire storage period.

11.7. “Part C: Specific requirements – Bovine viral diarrhoea type 2

The terminology used is inconsistent in that this disease is referred to both as “BVD2” and “BVDV2”.

MAF Response

Comment noted and inconsistencies corrected as required.

- 11.8. **“Part C: Specific requirements – Bovine viral diarrhoea type 2**
4.3.2 The draft “Risk management proposal” document refers, in respect of this disease, to the need for a “validated RT-PCR” (page 7), but the requirement for a validated test is omitted in the Semen IHS [Clause #35].”

MAF Response

Since the PCR test for BVDV2 is at present not validated, the Risk management proposal document will be amended to state a 'MAF approved' PCR test for BVDV.

- 11.9. **“Part C: Specific requirements – Bovine viral diarrhoea type 2**
In a similar vein, in discussing this disease, the draft “Risk management proposal” notes (paragraph 2, page 7) that “at present there is no validated VI or RT-PCR test that could be used for germplasm”. In this case, should both the VI and RP-CR tests have a requirement for a validated test in the IHS?”

MAF Response

The OIE prescribed test for BVDV is agent identification. The RMP has been updated to confirm that the virus isolation method for BVD has been validated (Voges et al., 1998)¹⁶.

- 11.10. **“Part C: Specific requirements - Crimean Congo haemorrhagic fever**
The wording of both the IHS is, in part, ambiguous, in that Clause #37 (Semen) or #38 (Embryos) refers to “Verification of tick freedom ... at least monthly where no ticks were found.” This statement could usefully be reworded as“... at least monthly with negative results”.

MAF Response

The clause requiring isolation and verification of tick freedom as a measure against CCHF has been removed.

See 8.4 for the changes to the risk management measures for CCHF.

- 11.11. **“Part C: Specific requirements - Crimean Congo haemorrhagic**
Clause #38 (Semen) refers to “... until 21 to 60 days after the conclusion of embryo collection ...”. Should this instead be “... semen collection ...”?”

MAF Response

Noted and amended to “semen collection”.

- 11.12. **“Part C: Specific requirements – Foot and mouth disease**
Clause #41 (Semen, Embryos) states “... MAF ... or require any other measures deemed necessary to ensure compliance with facility and operating standards upon which the approval is based.” This statement could usefully be made stronger by restating it as “... MAF ... take any other measures necessary to ensure the conditions on which the approval is based are met.””

MAF Response

Where importation is to be done from a country or zone that is not free of FMD, each importation will be assessed on a case-by-case basis. MAF interprets this to mean that any measures may be necessary as required.

¹⁶ Voges., H., Horner, G.W., Rowe, S & Wellenberg, G.J (1998) Persistent bovine pestivirus infection localised in the testes of an immuno-competent, non-viraemic bull. *Veterinary Microbiology*, Volume 61 (3), 165-175

See 3.9

11.13. “Part C: Specific requirements – Vesicular stomatitis

Clause #51 (Semen) states “... until 30 days after collection for export to New Zealand”. Should this instead state “... until 30 days after collection of semen for export ...”

MAF Response

Noted and corrected.

11.14. “Part C: Specific requirements – Bovine brucellosis

Clause #7 of the Semen IHS identifies several Brucellosis organisms of concern (B. abortus, B. melitensis, B. suis), but Clause #53, refers only to B abortus. Is this intentional?”

MAF Response

MAF has decided to amend the clause to state:

“All cattle in pre-entry isolation were subjected to an OIE prescribed serological test for bovine brucellosis, with negative results;”

11.15. “Part C: Specific requirements – Mycoplasma bovis

Clause #61 (Semen) states “... on a sample collected between 21 and 120 days after the last collection of germplasm ...”. Should this rewritten as “... after each collection” as is the case in Clause #59 of the Embryos IHS?”

MAF Response

See 3.10 for the changes to the risk management measures for *Mycoplasma bovis*.

11.16. “Risk Management Proposal document - Other Mollicutes

Under the “Other risk management considerations” heading (page 15), there is a highlighted word apparently requiring comment.”

MAF Response

Noted and corrected.

11.17. “Risk Management Proposal document – Leptospirosis

It is accepted that the identified risks around this disease (pp 16 – 17) are addressed by the inclusion of measures included in the general text [Part B] of the IHS. Nevertheless, if the audience for the publications under discussion is intended to encompass people who may not have a good technical level of understanding of the subject, it would be useful to include (eg as a footnote in the Risk Management Proposal document), a comment referring readers to where in the IHS documents this risk is dealt with.”

MAF Response

The RMP describes that the leptospirosis risk would be managed by ensuring germplasm was collected and prepared in accordance with the recommendations of the OIE Code chapter on collection and processing of bovine semen, and the OIE Code chapter on collection of embryos of livestock, including the use of suitable antibiotics in semen diluents and embryo washing media. These requirements are specifically included in the IHS.

12. Beef + Lamb New Zealand Ltd & Meat Industry Association; Chris Houston – Semen and Embryo IHS

- 12.1. **“The absence of clear information indicating how and why the current proposals differ, both materially and in respect to consequential risk, from the current status quo has made meaningful review of these drafts challenging. B+LNZ and MIA strongly recommend that such information be provided as part of future consultation rounds for these types of documents. The point above is exacerbated by the fact that specific arrangements will be negotiated bilaterally at some future point, hence limiting the understanding achievable by reviewers of the proposed future risk management regimes. This is further complicated by the omission of the approved countries list that is referenced to the guidance document for the standards themselves.”**

MAF Response

In consideration of the fact that the new Import Health Standards incorporate the new approach to Import Health Standards, and are not individualised for each country, it was anticipated that the Risk Management Proposal document would give an adequate understanding of how the disease management measures were derived from the Import Risk Analysis. The request for a ‘bridging document’ explaining the differences between the current IHS and new IHS is noted and will be considered for future import health standards.

- 12.2. **“Ease of review would be facilitated by providing the guidance document that is intended to accompany the standards.”**

MAF Response

Upon completion of bilateral negotiations and subsequent to the import health standards being issued, a guidance document outlining which risk management measures apply to specific countries and the bilaterally-agreed format for zoosanitary certification for the trade will be issued.

- 12.3. **“We note that post-border traceability of germplasm imports is governed by Regulations 6, 7 and 8 of the Biosecurity (Imported Animals, Embryos, and Semen Information) Regulations 1999. We trust that MAF will provide adequate regulatory oversight and audit compliance with these regulations, taking appropriate action where non-compliance is found.”**

MAF Response

MAF considers that the biosecurity risks for imported germplasm must be effectively managed through compliance with the zoosanitary requirements to be specified within the import health standards. The legal requirements under the Biosecurity (Imported Animals, Embryos, and Semen Information) Regulations 1999 remain in place as long as those regulations are in force. However, consideration of the need or otherwise for these regulations from a biosecurity risk management perspective, or the systems for monitoring compliance, is beyond the scope of the current work to review import health standards.

13. DairyNZ and DCANZ– Semen and Embryo IHS

- 13.1. **“DairyNZ and DCANZ support the establishment of a new process for managing the development of new Import Health Standards (IHSs), and their basis being technical risk analysis undertaken to identify the hazards, assess the risks, and determine suitable risk management options where justified.”**

MAF Response

Noted

- 13.2. **“We recognise the strong value proposition that importation of germplasm makes to the New Zealand dairy industry and also other sectors of the cattle industry. We accept that germplasm importation properly managed should present less risk than live animal importation in relation to the introduction of diseases exotic to New Zealand. When considering risk management for imported germplasm it must also be recognised that other options exist rather than current direct widespread dissemination of germplasm once imported. Examples of this would include the use of quarantine herds and then subsequent multiplication and dissemination of animals and/or germplasm when absence of pathogens has occurred. These may be of some value when considering how risks are managed for identified diseases where some degree of uncertainty exists regarding the adequacy of pre-border risk mitigation measures.”**

MAF Response

The intent of the Import Risk Analysis and consequent Import Health Standard is to define risk management measures that would deliver an acceptable level of risk protection to New Zealand. These risk management measures are based on international standards, guidelines and recommendations, and follow the fundamental biosecurity risk management principle of managing risks off-shore to the extent possible. In addition the application of a quarantine multiplier herd concept is expensive to set up and run, and hence that system would only be used in exceptional circumstances.

- 13.3. **“The Ministry of Agriculture and Forestry’s Import Risk Analysis (IRA): Cattle germplasm from all countries ISBN 978-0-478-3316-4, 13 February 2009, is an excellent document and sets out clearly the details regarding hazards, and risk mitigation steps including commentary on their adequacy, for diseases exotic to New Zealand and where diseases endemic to New Zealand are under official management , e.g. bovine tuberculosis. No reference is made in this or the consultation documents to the risk mitigation steps applied by the New Zealand bovine germplasm processing industry in relation to endemic diseases they currently manage. We would contend that current domestic measures are designed to ensure bovine germplasm does not transmit diseases of economic significance to the cattle industry and these or equivalent measures should be referenced in the IRA and included in the IHSs. If the issue is one of the risk management measures used domestically not being ‘Officially Mandated’ by MAF BNZ, then consideration needs to be given to rectifying this situation.”**

MAF Response

New Zealand has obligations under the World Trade Organisation Agreement on Application of Sanitary and Phytosanitary Measures (SPS Agreement). Article 2 of that agreement requires members to avoid discrimination in situations where similar conditions prevail. That means that, in the absence of requirements for endemic diseases that apply to germplasm produced and traded domestically in New Zealand, similar conditions on imported product cannot be justified.

MAF nevertheless recognises the economic significance of endemic diseases to the domestic cattle industry. Guidance notes about domestic measures currently in place for certain endemic diseases may be included in the guidance document.

13.4. **“Section 4 of the IRA under Commodity Definition states that the commodities being considered are frozen semen and *in vivo* derived frozen embryos from healthy cattle. Neither the Risk Management Proposal (RMP), 21 June 2010, nor the IHSs refer to this statement. The draft IHSs must be explicitly defined as only applying to these commodities and not covering fresh semen, *in vitro* derived embryos, and cloned embryos. An additional assumption in the IRA is that the commodities ‘be stored in a frozen state for at least 28 days before shipment to New Zealand and that during this time the donor animals and all animals in contact with them will have remained healthy and free from any diseases that are considered to be of non non-negligible risk in this risk analysis.’ This statement along with appropriate measures designed to demonstrate freedom from the specified diseases needs to be reflected in the IHSs. The current drafts do not appear to reflect this situation adequately.”**

MAF Response

MAF has decided to modify the relevant clauses describing the scope of the IHS to state: “This standard specifies the requirements that must be met to import frozen bovine semen into New Zealand, bovine semen being semen derived from any member of the sub-family *Bovinae*” and

“This standard specifies the requirements that must be met to import, non-cloned, *in vivo* derived bovine embryos into New Zealand, bovine embryos being embryos derived from any member of the sub-family *Bovinae*.”

The requirement that ‘germplasm be stored in a frozen state for at least 28 days before shipment to New Zealand and that during this time the donor animals and all animals in contact with them will have remained healthy and free from any diseases’ was added to the semen standard.

This duration will be increased to 30 days due to OIE clause 8.5.16 that specifies that when importing from FMD free countries or zones where vaccination is not practised or FMD free compartments, donors should show no clinical signs of FMD for the 30 days after semen collection.

13.5. **“Bluetongue: Agreement with the proposed IHS measures and their justification even though the IRA describes the risk as negligible.”**

MAF Response

Noted

13.6. **“Borna disease: We require more information about why a more general MAF approved test is specified in the IHS instead of the specific methods stated in the IRA.”**

MAF Response

The test method of intracerebral inoculation into rabbits is not a very practical option and the PCR test is, at present, more relevant for research purposes. The clause describing MAF approved tests for Borna disease retains the option to allow for future developments.

See 8.7 for the changes to the risk management measures for Borna disease.

13.7. **“BVD: Specific requirements solely relating to BVDV 2 are not accepted as adequate. It is our view that other strains of BVD including endemic strains are of economic importance and must not be present in imported (and domestically produced) germplasm. Risk management steps must be in place to ensure BVDV is**

not present. In our view it is reasonable to require the germplasm collection premise to be free of BVDV in accordance with the OIE Code.”

MAF Response

See 13.3

- 13.8. **“Crimean Congo Haemorrhagic Fever (CCHF): Additional detail is sought in regard to why both 37 and 38 should not be combined to effectively manage the risks in countries where the disease is present.”**

MAF Response

See 8.4 and 11.10 for the changes to the risk management measures for CCHF.

- 13.9. **“Foot and Mouth disease: Greater detail is required to provide assurances that the proposed management measures in the IHSs relating to countries where FMD is present will adequately mitigate the risk. Given the very significant impact FMD would have on sectors of New Zealand’s livestock industry our strongly preferred position is that imports only occur from countries recognised as FMD free. The IRA clearly states; ‘in the view of the extreme seriousness of the disease and the catastrophic consequences that could result from the introduction of FMDV, it could be considered that the OIE recommendations for bovine germplasm are not sufficient to provide the appropriate level of protection against this hazard and importation of germplasm from countries that are infected with foot-and-mouth disease could be prohibited.’”**

MAF Response

See 3.9 and 11.12.

- 13.10. **“IBR/IPV: The proposed measures are supported.”**

MAF Response

Noted

- 13.11. **“Lumpy Skin Disease: Information is requested in regard to the sensitivity of the current validated PCR tests.”**

MAF Response

It has been demonstrated that the PCR test is adequately sensitive to detect LSD infected animals, and indeed the PCR test is able to detect cases where infection could not be detected by virus isolation (Irons et al)¹⁷.

- 13.12. **“Rift Valley fever: We would question the achievability of the proposed management measure of holding donor animals in mosquito free premises. Evidence is sought that this has been achieved and that it has consistently managed the hazard.”**

MAF Response

See 6.1

¹⁷ **Irons PC, Tuppurainen ES, Venter EH (2005).** Excretion of lumpy skin disease virus in bull semen. *Theriogenology*, 63(5), 1290-7.

Considering the current OIE code, MAF has decided to remove the clause requiring mosquito free premises and the clause requiring a donor to be 6 months in a RVF infected country, during which climatic changes predisposing to outbreaks have not occurred.

MAF has decided to add the option:

“Donors were serologically tested for RVF, using an OIE prescribed test, on the day of semen/embryo (as applicable) collection for export to New Zealand, and at least 14 days later, and showed no significant rise in titre.”

13.13. “Vesicular stomatitis: As for Rift Valley Fever.”

MAF Response

See 8.3.

13.14. “Bovine brucellosis: The management proposals are supported”

MAF Response

Noted

13.15. “Bovine tuberculosis: Clarification is required in regard to the OIE Tb freedom requirements as stated in the IHSs. If it is a period prevalence of < 0.2% but the disease is still present in cattle in the exporting country then additional testing requirements for donors may need to be applied.”

MAF Response

The OIE specified limit for country or zone freedom requires:

- that over 3 consecutive years, regular and periodic testing of the national herd has demonstrated that 99.9% of cattle and 99.8% of herds are free of bovine tuberculosis;
- that TB be a notifiable disease;
- that there is a surveillance programme through ante- and post-mortem inspection.

See 1.15 and 5.1 for the changes to the risk management measures for tuberculosis.

The change requires that the exporting country or zone be recognised as free of tuberculosis by MAF. This would be determined during the bilateral negotiation process and would be dependent on the tuberculosis surveillance method of that country and the frequency of testing.

13.16. “Contagious bovine pleuropneumonia: It is recommended that consideration be given to adding a post collection test of the donor animal to those already proposed.”

MAF Response

The testing protocol in the IHS is based on the OIE code and there are no extenuating reasons for additional measures beyond what is specified there.

13.17. “Mycoplasma bovis and other Mollicutes: We accept the requirements proposed for Mycoplasma bovis but question the justification for not including the other exotic Mollicutes identified in the IRA as causing disease conditions of economic significance in cattle, and the fact that likelihood of transfer by semen or embryos is considered non negligible.”

MAF Response

Measures have only been included for *Mycoplasma bovis* since New Zealand has demonstrated freedom to this microorganism.

- 13.18. **“Exotic Salmonella: The justification for not including management requirements for exotic salmonella, specifically S. Dublin and S.typhimurium DT104 is not accepted. The cost of culture is not regarded as significant relative to the hazard being managed and potential impact of introduction of these species within the New Zealand cattle population.”**

MAF Response

There is no documented evidence of venereal transmission and *Salmonella* species generally require higher levels of contamination than would be likely to be present in germplasm, and an oral route of entry, to be infective.

Owing to this and the fact that culturing for *Salmonella* is required prior to addition of antibiotics, it is not always reliable and would increase costs, MAF decided to not implement any measures against *Salmonella* spp.

- 13.19. **“Q fever: The proposed management measures are supported.”**

MAF Response

Noted

- 13.20. **“Given the issues set out above we believe it is essential that a meeting occur between the *production* animal industry technical staff and BNZ technical staff to allow sharing of technical information and viewpoints. We acknowledge that previous consultation has occurred between BNZ and industry technical staff, however this occurred primarily with those associated with the processing and/or importation of germplasm. We believe that further joint discussions would allow all parties to establish what is technically feasible and reasonable and also complies with New Zealand’s international obligations under the WTO SPS agreement and international technical standards.”**

MAF Response

Noted

- 13.21. **“DairyNZ would like to thank MAF BNZ for the opportunity to comment on the Draft Import Health Standard for Bovine embryos and semen and the Risk Management Proposal for Bovine Semen and Embryos. We look forward with engaging with MAF BNZ on these standards as they move forward.”**

MAF Response

Noted

14. Canadian Food Inspection Agency (CFIA) – Embryo IHS

Note that codes used with regard to each disease:

TBN = conditions for this disease have to be negotiated

OK = this disease is not a concern for Canada.

14.1. **“Article 7: Mycoplasma bovis is not a notifiable disease in NZ.”**

MAF Response

MAF is in the process of declaring *Mycoplasma bovis* as a notifiable disease.

14.2. **“Article 11: The CFIA raises the point that after a period of 60 days, an imported animal becomes a Canadian animal. The reference to the 60 days residency period in the exporting country is actually included in certification of bovine embryos from Canada to NZ and there is no scientific reason to augment this period to 90 days. Animals are regularly imported from the USA and a period of 60 days is sufficient to evaluate the health status of an imported animal. Furthermore, a change in the period could compromise eligibility of embryos that are presently or were collected for NZ. The period of 30 days in the herd of origin is a reasonable period. The CFIA suggests the residency period for imported animals remains to 60 days.”**

MAF Response

MAF has decided to amend the clause to state:

“Donors that were imported to the exporting country must have lived continuously in the exporting country for at least 60 days and in the herd of origin for at least 30 days prior to embryo collection for export to New Zealand.”

14.3. **“Article 13: There is questioning about the mandatory requirement to have the donor cows maintained in isolation in the approved embryo collection facility until testing specified in the standard is completed. The rationale of maintaining donor cows in isolation away from animals not of an equivalent status is to provide confirmation no changes in the health status of the donors have take place since collection. A period of 21 days is considered enough to reach this confirmation. Past this period, it should be optional for the owner to have his animal in contact with other animals with the possibility to fail a test due to such contact. The CFIA suggest that maintenance in isolation in the approved embryo collection centre is limited to 21 days.”**

MAF Response

See 1.4

14.4. **“Article 15: There is a logical reason to ask that the herd of origin remains free from any quarantine restrictions for a certain period before the first embryo collection for the consignment to NZ. This 90 days period required is long and should be at the maximum 60 days, which is more than the double of incubation period of majority of quarantine diseases. A period of 60 days is the actual requirement to export bovine embryos to NZ. The CFIA suggests the quarantine restrictions period in the herd of origin and the approved embryo collection facility remains as it actually is, 60 days preceding the collection of the first embryo for the consignment until completion of testing.”**

MAF Response

MAF has decided to amend the clause to state:

“The donors must not be resident in any establishment that is subject to quarantine restrictions, for at least the 60 days before the first embryo collection for the consignment to New Zealand until completion of the testing of the donors as required by this standard.”

- 14.5. **“Article 17: The CFIA suggest that the second indent reads as follows to exclude IBR/IPV as this disease is not transmitted by bovine embryos when they are treated with trypsin in accordance with the IETS Manual (article 20):
o “was collected and processed at a semen collection centre that fully complies with the current OIE Code chapter on collection and processing of bovine semen, except IBR/IPV which is optional;”**
This precision for frozen semen is in line with the requirements where natural service is used, in which case neither the donor cow nor the donor bull are tested for IBR/IPV.”

MAF Response

The IHS is aligned with the OIE Code (Article 4.7.4) that stipulates that semen used to artificially inseminate donors should comply with the OIE chapter on collection and processing of semen.

- 14.6. **“Article 21: Most Canadian embryo collection teams if not all, use media and solutions for collection, processing, washing or storage of embryos purchased from commercial sources that are offering their products internationally. These supply companies have their products screened for the presence of pathogenic organisms, including pestiviruses. These products also contain antibiotics. A regular inspection of embryo collection teams is done by CFIA trained officers as per the Canadian Embryo Export Approval Program and there is verification of media and solutions used at this moment. This comment is to precise this requirement is fulfilled under the Canadian program and the CFIA veterinarian who signs the export certificate relies on this procedure.”**

MAF Response

Noted that this requirement is satisfied by the Canadian program.

- 14.7. **“Article 22: No code is allowed to identify embryos collected in Canada; the IETS code of the collection team, identification of the donor along with collection date are mandatory and must follow IETS straw identification standards.”**

MAF Response

See 1.10

- 14.8. **“Article 30: The CFIA never provided copy of tests to NZ nor any other destination country as the Canadian Privacy Act prevents CFIA to do so. Instead, a summary of all tests is provided in a table which is part of the certificate. In Canada collection of samples may be either done by the approved embryo team veterinarian or a CFIA staff and are sent to a CFIA laboratory; laboratory reports are received electronically by the CFIA district officer and the laboratory report system belong to the CFIA. The accession number reference is not relevant as all results are within the CFIA laboratory system. Only in very rare occasions, CFIA may allow for a test in a laboratory other than CFIA.”**

MAF Response

See 3.5

- 14.9. **“Borna disease (BD): 3 certification options, article 31 to 33.OK
Article 31: no reported case in countries of residence of embryo donors. BD is an immediately notifiable disease in Canada and no case has ever been reported. As**

some donors can be of USA origin but collected in Canada, the USA also never reported a case of Borna virus. So this option can be used for now.

Article 32: confirmation the embryo donor have resided since its birth, in herds (this includes centres) where no BD case has been reported for the 5 years before embryo collection until conclusion of collection for export to NZ. The period of 5 years is arbitrary and should be revisited. This virus is not proven to have tropism for reproductive organs; the extrapolation for data collected on rats to cattle should not use as an impediment to trade.

Article 33: testing option for embryo/oocytes, collection fluids and /or washing fluids for the presence of the virus. Testing is not available at the moment on a regular basis in Canada. Test is to be approved by NZ, as there is no OIE guideline for tests.

Conclusion on Borna Disease:

Actually Canada can use the 1st option (article 31) as this disease was never reported in Canada. Some Canadian donor cows are sourced in the USA which also never reported Borna disease. In the case Borna disease is further reported in Canada or the USA, the requirement to qualify the embryo donors for the 5 years before the embryo collection is excessive and should be revisited as there is no demonstration this virus can be spread by embryos. There is no OIE reference concerning Borna disease, neither in the Code or the Manual, so testing would be problematic. The CFIA questions the pertinence of this requirement.”

MAF Response

See 8.7 for the changes to the risk management measures for Borna disease.

14.10. “Bovine viral diarrhoea type 2 (BVD2): 2 certification options, articles 34 to 36..... TBN

Article 34: option country freedom. This option cannot be used by Canada as BVD is endemic in Canada.

Article 35: option centre freedom during collection destined to NZ.

The requirement is not clear for embryo donors as it is copied directly from the situation of semen donors. As there is no such pre-entry procedure for embryo donors, the requirement is not clear concerning prescribed test prior to entry into pre-entry isolation and during pre-entry isolation. The unique requirement is an isolation period of 30 days in an approved embryo collection facility (ref: article 14). The requirement mentioned at the 1st indent needs explanation as it seems that two sets of BVD-antibodies and antigen tests are required before the donor cow is allowed to enter in the isolation facility for the collection of embryos.

Furthermore seropositive donor cows must have samples of embryos/oocytes, collection fluids and/or washing fluids of all embryo collections examined for the presence of the BVD virus before dispatch while seronegative donor cows must be tested negative to an antibody test after embryo collection. In the latter case the number of tests required is not clear but as the plural form is used, this could mean at least 2 tests in total or one test following each embryo collection. These requirements exceed by far the OIE recommendations in Chapter 4.7 of the Terrestrial OIE Code. The CFIA requests that the actual requirement to export bovine embryos to NZ continues to be applied as before; this actual requirement asks for a BVD virus screening test of a pool of samples of embryos/oocytes, collection fluids and/or washing fluids of each donor cow whose embryos are exported to NZ. **Article 36:** samples of embryos/oocytes, collection fluids and/or washing fluids of all embryo collections performed on each donor cow that have been less than 3 years on the embryo collection facility must be tested by BVDV2

virus isolation test. This requirement is an addition to those mentioned in article 35. This test will have to be done at all times on both seronegative and seropositive donor cows as no permanent embryo collection facilities are in existence in Canada for the purpose to collect embryos destined to NZ due to the very small NZ market. This test also exceeds by far OIE recommendations. This requirement should not apply to seronegative donor cows. Several farms have BVD vaccination program and seropositivity is due to vaccination and in no case related to the presence of the disease; vaccination should be taken into account as regard to BVD-SN positive results. The 3 year period is arbitrary and should be revisited for BVD-SN positive donor cows. The CFIA request this requirement is dropped as seropositive donor cows are already tested before dispatch of embryos for the presence of the BVD virus in collections and washing fluids and seronegative cows tested for presence of antibodies after the conclusion of embryo collection for export to NZ (article 34, 3rd and 4th indent).

Conclusion on BVD:

As Canada cannot use the country freedom option, articles 35 and 36 apply all together. The BVD testing regime suggested by NZ requires that donor cows are tested several times using antibody and antigen tests. The requirements are not clear and extend over several years. These requirements are in excess of the OIE Code and excessive. Vaccination of donor cows is not taken into consideration. Furthermore it is excessive to require a post collection test for donor cows that tested negative. The CFIA suggests that a unique and ultimate test is done for each donor cow and this test should be a BVD virus screening test of a pool of samples of embryos/oocytes, collection fluids and/or washing fluids of each donor cow whose embryos are exported to NZ, as per the OIE Code.”

MAF Response

See 1.12 for the changes to the risk management measures for BVDV.

The revised measures do provide an option of virus screening of a pooled sample of embryos/oocytes, collection fluids, and/or washing fluids for BVDV.

14.11. “Crimean Congo haemorrhagic fever (CCHF): 3 certification options, articles 37 to 39..... TBN

Article 37: the disease must be notifiable and no case reported in the 21 days before and during collection. There is a problem as CCHF is not notifiable in Canada but was never reported (OIE, WAHID 2009). This disease does not exist in North America. It should be sufficient to have this disease not reported in Canada without an obligation from NZ to have this disease being notifiable.

Article 38: option of treatment for ticks with acaricide and tick freedom of the centre. This option is not very practical.

Article 39: test option; this test is not offered for regular diagnostic in Canada; test will have to be implemented for a disease which is exotic to Canada.

Conclusion for CCHF:

This disease does not exist in North America. There is no confirmation this disease is transmitted by embryos. It should be sufficient to have this disease not reported in Canada without the requirement to have this disease being notifiable. According to article 7 of the IHS, it seems that CCHF is not notifiable in NZ, even it is exotic; if this is true, NZ should not require this disease is notifiable in Canada. It seems that both NZ and Canada are in the same situation concerning CCHF. Further discussion with NZ would be needed to accept freedom of this disease never reported, even though this disease is not notifiable.”

MAF Response

MAF determined CCHF to be a notifiable organism on 21/01/2010. Clause 7 of the IHS will be amended to reflect this.

See 8.4 for the changes to the risk management measures for CCHF. The amended measures allow for recognition that CCHF has not been reported in Canada.

- 14.12. **“Foot and Mouth Disease (FMD): 2 certification options, articles 40 to 41OK
Article 40: option of 3 months country freedom without vaccination before embryo collection. Canada qualifies as a country free of FMD without vaccination in accordance with the OIE code. The other option is not considered.”**

MAF Response

Noted

- 14.13. **“Lumpy skin disease (LSD): 3 certification options, articles 42 to 44OK
Article 42: option of 6 months country freedom as defined by OIE before embryo collection. Canada qualifies as a country free of LSD in accordance with the OIE code. Other options not considered.”**

MAF Response

Noted

- 14.14. **“Rift Valley fever (RVF): 3 certification options, articles 45 to 47OK
Article 45: option of 3 months country freedom before and during embryo collection. Canada qualifies as a country free of RVF in accordance with the OIE code. Other options not considered.”**

MAF Response

Noted

- 14.15. **“Vesicular stomatitis (VS): 3 certification options, articles 48 to 50.....OK
Article 48: option of country freedom in accordance with the OIE code. Canada qualifies as a country free of VS in accordance with the OIE code. Other options not considered.”**

MAF Response

Noted

- 14.16. **“Bovine tuberculosis: 2 certification options, articles 51 to 53OK
Article 51: option of donors kept in a country or zone free since birth. Canada is considered free country in accordance with the OIE Code.
Article 52: option of herd of origin with no clinical signs plus article 53 as follows;
Article 53: herd free as per the OIE Code and TB test during the 30 days of mandatory isolation before embryo collection. This option allows for qualification of USA origin donor bulls resident in Canadian herds.
Conclusion on bovine tuberculosis:
The CFIA agrees to both options with covers for Canadian origin and USA origin donor cows.”**

MAF Response

Noted

See 1.15 for the changes to the risk management measures for tuberculosis.

- 14.17. **“Contagious bovine pleuropneumonia (CBPP): 2 certification options, articles 54 to 57.....OK**
Article 54: option of country freedom in accordance with the OIE code. Embryo donors must be born and continuously resident in a free country. Canada qualifies as a country free of CBPP in accordance with the OIE code. The USA also qualifies as a CBPP free country. Other option not considered (articles 55, 56 and 57).”

MAF Response

Noted.

MAF will amend the risk management measure for CBPP to state:

“Donors were born in, and have been continuously resident in, a country that is free from CBPP i.e. there have been no cases of CBPP for at least 3 years;”

This would still allow entry of germplasm from countries that are free of CBPP, yet are not recognised as free from CBPP according to the OIE Code. The guidance document will provide details on how MAF will assess a country’s determination of country freedom to CBPP.

- 14.18. **“Mycoplasma bovis: 3 certification options, articles 58 to 61..... TBN**
Article 58: requires that donor cows never recorded a positive test for Mycoplasma bovis in addition of one of the 3 options mentioned below;
Article 59 option to test donor cows post collection.
Article 60: option to test each embryo collection using a sample of embryos/oocytes, collection fluids and/or washing fluids.
Article 61: option to random test the herd of origin before/after 6 months of embryo collection destined to NZ. Antibiotics are present in collection and washing fluids and they play a similar role than in semen. But control of Mycoplasma bovis is not proven as important as in semen. Serological testing of donor cows is not done in Canada and a test will have to be validated. The simplest option would be to examine samples of embryos/oocytes, collection fluids and/or washing fluids of all embryo collections performed on each donor cow.
Conclusion on Mycoplasma bovis
The CFIA suggests that a unique and ultimate test is done for each donor cow and this test should be a screening of Mycoplasma bovis from a pool of samples of embryos/oocytes, collection fluids and/or washing fluids of each donor cow whose embryos are exported to NZ, as suggested by the OIE Code.”

MAF Response

See 3.10 and 4.9 for the changes to the risk management measures for *Mycoplasma bovis*.

The IHS does provide an option of testing pooled samples of embryos/oocytes, collection fluids and/or washing fluids of each donor cow. The proviso is that the test be validated for pooled samples

- 14.19. **“Q fever: 3 certification options, articles 62 to 65.....OK**
Article 62: requires that donor cows never recorded a positive test for Q-fever in addition of one of the 3 options mentioned below;
Article 63: option to test donor bulls post collection.
Article 64: option to test each collection using a sample of embryos/oocytes, collection fluids and/or washing fluids.
Article 65: option to random test the herd of origin before/after 6 months of embryo collection destined to NZ.

Conclusion for Q-fever:

The CFIA recognizes that NZ is free of Q-fever; thus testing is accepted. There is no scientific evidence that Q-fever is transmitted by embryos. The unique serological test available in CFIA laboratory for Q-fever is the CF test. The CFIA agrees to test all embryo donors after collection using the CF test.”

MAF Response

Noted

See the Import Risk Analysis for the rationale behind this measure.

15. Canadian Food Inspection Agency (CFIA) – Semen IHS

Note that codes used with regard to each disease:

TBN = conditions for this disease have to be negotiated

OK = this disease is not a concern for Canada.

15.1. “Article 7: Mycoplasma bovis is not a notifiable disease in NZ.”

MAF Response

See 14.1

15.2. “Article 11: The CFIA raises the point that imported donor bulls from the USA must lived for 90 days in Canada prior to entering in a semen collection centre. It is regular practice in Canada to import donor bulls directly into the pre-entry isolation facility of a centre. In such case the testing prior to entering pre-entry isolation facility done in the USA; these animals do not live in any Canadian herd before entry to avoid commingling and potential contamination. After a period of 60 days, an imported animal becomes a Canadian animal. The reference to the 90 days residency period in the exporting country and in the herd of origin for 30 days prior to entering a Canadian semen collection centre should be adapted to the North American situation where bulls can enter directly in the pre-entry isolation facility of a centre.”

MAF Response

MAF has decided to amend the clause to state:

“Donors that were imported to the exporting country must have lived continuously in the exporting country for at least 90 days and in the herd of origin for at least 30 days, prior to semen collection for export to New Zealand.” If a donor has been on the semen centre for more than 90 days, then the semen centre can be deemed to be the herd of origin.

15.3. “Article 15: this requirement is not clear. There is no logical reason to ask that both the herd of origin and the centre remain free from any quarantine restrictions from 90 days before the first semen collection for the consignment to NZ until completion of the testing of donor animals. When the donor animal has resided more than 90 days in the centre before collection, this requirement should apply only to the centre and not any more to the farm of origin. After 90 days of residence in the centre, including the pre-entry isolation period, there is no reason to still link the donor animal to the herd of origin. As an example, in the case of a donor bull who entered in the centre at the age of 10 months and collected at 7 year of age (more than 6 years after entry in the centre), it is absolutely not relevant to confirm that herd of origin is not under quarantine restrictions. This information is not available and not pertinent. The CFIA suggest that the

following amendment is included in the text: “The herd (s) of origin of the donor males and/or the semen collection centres must...”.”

MAF Response

If a donor has been on the semen centre for more than 90 days, then the semen centre can be deemed to be the herd of origin, and hence the quarantine restrictions would only apply to the semen collection centre.

MAF has decided to amend the clause to state:

“The donors must not be resident in any establishment that is subject to quarantine restrictions, for at least the 90 days before the first semen collection for this consignment to New Zealand, until completion of the testing of the donors as required by this standard.”

15.4. “Article 16: In Canada semen production centres are placed under the supervision of centre veterinarians. These centre veterinarians are not always present when the bulls are collected as they have trained the staff who collect the semen to pay attention to any unusual signs concerning the donor bulls. When the centre staff note something unusual, the centre veterinarian examines the animal and decides about the collection and semen collected. So it will be difficult to certify that each donor bull has been inspected by the centre veterinarian on each collection day. The CFIA suggests the following: “Each donor animal was regularly inspected by the approved semen collection centre veterinarian and ...”.”

MAF Response

See 2.3

15.5. “Article 24: The CFIA never provided copy of tests to NZ nor any other destination country as the Canadian Privacy Act prevents CFIA to do so. Instead, a summary of all tests is provided in a table which is part of the certificate. In Canada it is CFIA staff that collect samples which are sent to CFIA laboratory; laboratory reports are received electronically and the laboratory report system belong to the CFIA. The accession number reference is not relevant as all results are within the CFIA laboratory system. Only in very rare occasions, CFIA may allow for a test in a laboratory other than CFIA.”

MAF Response

See 3.5

15.6. “Bluetongue (BT): 5 certification options, articles 25 to 29. TBN Article 25: option country free; reference to the OIE code in place when semen collection is done. Canada does not comply as a BT free country as per OIE Code 2010; so this option cannot be used. Discussion with NZ to know if NZ recognizes Canada BT freedom before 1987, year where BT has been firstly isolated in Canada. Article 26: option of semen donors in a BT virus free zone for 100 days prior to semen collection, with BT virus free zone as defined in the OIE Code. Since 2004, this option is used to certify semen from Canada, but without reference to the OIE Code. Over time the presence of the BT virus has only been demonstrated a few times in the Okanagan valley and regionalization of the Okanagan valley in Canada has been accepted by trading partners. NZ should accept that semen actually eligible for export to NZ continues to be eligible for export to NZ if a new import rule applies. Surveillance as per the OIE Code is still not in place in Canada but should be in the near future. Discussion with NZ is

required if actual export conditions can be maintained until surveillance is put in place.

Article 27: option BT virus seasonally free zone as defined in the OIE Code. This option cannot be used as seasonally free zoning for BT is not officially in place in Canada.

Article 28: option post-collection testing with C-ELISA test or AGID authorized tests between 28 and 60 days after last semen collection included in the shipment; OIE code. Post collection testing not included in the AI program, so extra testing would be required.

Article 29: option of mini-stud, where donor tested before, during and after semen collection destined to NZ; virus isolation test or PCR on blood; OIE code. PCR not available in CFIA labs so only virus isolation at every 7 days can be used. This could be done but very demanding.

Conclusion for BT:

1. Semen actually considered eligible for export to NZ should be maintained eligible. All inventory semen which is now certified using article 26, but without reference to the OIE code, would not qualify for BT as per strict application of options offered. This would be a great loss for industry as this semen now qualifies for export to NZ and would not be considered eligible when these new conditions are in place. No semen exported to NZ or any other destination country has ever been incriminated about BT transmission. Only new semen collected would be eligible for NZ if options in articles 27, 28 and 29 are used.

2. There is no credit for the semi-annual BT testing done by CFIA on all animals in semen collection centres, nor for BT testing required by OIE (2010) Chapter 4.6, "Collection and processing of bovine, small ruminants and porcine semen" prior to entering pre-entry isolation facility and in the pre-entry isolation facility (articles 4.6.2.1 and 4.6.2.2). This regular testing along with exclusion of any suspect/reactor animal from the centres, if any found, should be taken into consideration to qualify semen collected in centres, at least for the semen where a negative test is available after the collection, up to 6 months, taking in account that all the residents and teasers are tested every 6 months. This would at least qualify immediate previous semen production done before a semi-annual test. An equivalence should be discussed with NZ taking into consideration the particular situation of Canada, where the virus has never be reported outside a very specific localisation (Okanagan valley) and regular testing done on all animals in semen production centres."

MAF Response

See 2.6 for the changes to the risk management measures for BTV.

The amended clause allows recognition by MAF of the localised nature of BTV in Canada.

The eligibility of semen produced under the previous IHS requirement will be resolved during bilateral negotiations.

- 15.7. **"Borna disease (BD): 3 certification options, article 30 to 32.....OK**
Article 30: no reported case in countries of residence of semen donors. BD is an immediately notifiable disease in Canada and no case has ever been reported. The USA also never reported a case of Borna virus. The same situation applies to the USA. So this option can be used for now. Article 31: confirmation the semen donor have resided since its birth, in herds (this includes centres) where no BD case has been reported for the 5 years before semen collection until conclusion of semen collection collected for export to NZ. As this requirement applies for the 5 years before and during collection; this means that this requirement should not apply

since birth for animals which have resided more than 5 years in semen collection centre where no case has occurred. This requirement to check on the herd of residence should be limited to the semen donors only having less than 5 years residence in such centre. The reference period should be limited only to the 5 years before commencement of semen collection destined to NZ. Furthermore, the period of 5 years is arbitrary and should be revisited. This virus is not proven to have tropism for reproductive organs; the extrapolation for data collected on rats to cattle should not be used as an impediment to trade.

Article 32: testing option for blood sample of semen donors or semen itself tested for the virus. Testing is not available at the moment on a regular basis in Canada. Test is to be approved by NZ, as there is no OIE guideline for tests. Also not clear in the requirements when and how often animals or semen should be tested.

Conclusion on Borna Disease:

Actually Canada can use the 1st option (article 30) as this disease was never reported in Canada. Several Canadian donor bulls are sourced in the USA which also never reported Borna disease. In the case Borna disease is further reported in Canada or the USA, the requirement to qualify the semen donors for the 5 years before the semen collection is excessive and should be revisited as there is no demonstration this virus can be spread by semen. There is no OIE reference concerning Borna disease, neither in the Code or the Manual, so testing would be problematic. The CFIA questions the pertinence of this requirement.”

MAF Response

See 8.7 for the changes to the risk management measures for Borna disease.

15.8. “**Bovine viral diarrhoea type 2 (BVD2): 2 certification options, articles 33 to 35..... TBN**
Article 33: option country freedom. This option cannot be used by Canada as BVD is endemic in Canada.

Article 34: option centre freedom during collection destined to NZ. BVD tests (BVD-IP and BVD-SN), annual re-test for BVD-SN negative residents and semen tests for BVD-SN positive residents before initial semen dispatch (first 3 indents) are OIE recommendations (Chapter 4.6) and included in the CFIA Artificial program. But NZ requires a BVD-SN test for BVD-SN negative residents after the collection of semen destined to NZ (4th indent); this is an extra test which exceeds OIE recommendations in Chapter 4.6 of the Code. After semi-annual testing, all semen collected before from these bulls will qualify, but not the semen collected after the semi-annual test; this would be an important restriction for centres.

Article 35: all collection dates exported to NZ from either BVD-SN positive or BVD-SN negative donors must be tested using a virus isolation test when they were resident in the centre for less than 3 years; this requirement is an addition to those mentioned in article 34. This test exceeds OIE recommendations. This requirement should not apply to seronegative bulls. Several centres vaccinate bulls against BVD and seropositivity is due to vaccination and in no case related to the presence of the disease; vaccination should be taken into account as regard to BVD-SN positive results. The 3 year period is arbitrary and should be revisited for BVD-SN positive bulls.

Conclusion on BVD:

As Canada cannot use the country freedom option, articles 34 and 35 apply all together. Even though all Canadian centres comply with the BVD requirements mentioned in the OIE Code Chapter 4.6 “Collection and processing of bovine, small ruminants and porcine semen”, NZ requires that seronegative bulls are

tested post-collection and that all the semen from bulls resident less than 3 years in a centre must be tested. These requirements are in excess of the OIE Code and excessive. Vaccination of bulls is not taken into consideration when such extra testing is required from BVD-SN positive donor bulls. Furthermore it is excessive to require a post collection test for donor bulls regularly tested negative as per the OIE recommendations in the case of Canada, this test on seronegative bulls is done every semi-annually.”

MAF Response

See 2.7 for the changes to the risk management measures for BVDV.

- 15.9. **“Crimean Congo haemorrhagic fever (CCHF): 3 certification options, articles 36 to 38.....TBN**
Article 36: the disease must be notifiable and no case reported in the 21 days before and during collection. There is a problem as CCHF is not notifiable in Canada but was never reported (OIE, WAHID 2009). This disease does not exist in North America. It should be sufficient to have this disease not reported in Canada without an obligation from NZ to have this disease being notifiable.
Article 37: option of treatment for ticks with acaricide and tick freedom of the centre. This option is not very practical.
Article 38: test option; this test is not offered for regular diagnostic in Canada; test will have to be implemented for a disease which is exotic to Canada.
Conclusion for CCHF:
This disease does not exist in North America. There is no confirmation this disease is transmitted by semen. It should be sufficient to have this disease not reported in Canada without the requirement to have this disease being notifiable. According to article 7 of the IHS, it seems that CCHF is not notifiable in NZ, even it is exotic; if this is true, NZ should not require this disease is notifiable in Canada. It seems that both NZ and Canada are in the same situation concerning CCHF. Further discussion with NZ would be needed to accept freedom of this disease never reported, even though this disease is not notifiable.”

MAF Response

MAF determined Crimean Congo haemorrhagic fever to be a notifiable organism on 21/01/2010. Clause 7 of the IHS will be amended to reflect this.

See 8.4 for the changes to the risk management measures for CCHF.

The amended measures allow for recognition that CCHF has not been reported in Canada.

- 15.10. **“Foot and Mouth Disease (FMD): 2 certification options, articles 39 to 41.....OK**
Article 39: option of 3 months country freedom without vaccination before semen collection. Canada qualifies as a country free of FMD without vaccination in accordance with the OIE code. The other option (articles 40 and 41) is not considered.”

MAF Response

Noted

- 15.11. **“Bovine herpes virus abortifacient strains (IBR/IPV): 2 certification options, articles 42 & 43..... TBN**
Article 42: option centre IBR free during collection destined to NZ, as per the OIE code, including IBR negative test on farm and in isolation for all animals and annually afterwards for donor bulls. But the requirement also includes an IBR

negative test after the semen collection. This is an extra test in addition of the semi-annual testing done on all animals resident in an IBR free semen centre as per the Canadian Artificial insemination program; for sure the next semi-annual test qualifies all the semen collected before from donor bulls but semen collected since the last semi-annual test will required an extra test. The program already goes farther than OIE recommendations asking for a semi-annual test on all animals in the centre instead of an annual test; this extra test which follows collection is not considered necessary in this case and exceeds the OIE recommendations. This requirement should be revisited to follow OIE recommendations.

Article 43: option semen virus isolation test. NZ required an equivalent of 0.05 ml of raw semen from each collection of semen exported to NZ. The requirement to test each collection date follows the OIE Terrestrial Code for serologically positive donor bulls as per articles 4.6.2 and 11.11.7. But NZ only refers to raw semen for the test while the OIE Manual (2008) Chapter 2.4.13. on IBR/IPV, section virus isolation from semen (a prescribed test for international trade) clearly mentions that suitable samples can be either 0.05 ml of extended semen or 0.02 ml of raw semen; for extended semen, an approximation should be made to ensure that the equivalent of 0.05 ml raw semen is examined. The CFIA wants to refer to the OIE Terrestrial Manual for testing procedures and sample type. CFIA would appreciate a clarification that test is also allowed on extended semen as permitted by international reference, as it was the case in the past.

Conclusion for IBR/IPV:

The post collection test required by NZ is in excess of the OIE recommendations when semen donors are resident in an IBR free semen production centre where all animals are tested as per the OIE terrestrial Code on farm, in isolation and annually afterwards as residents. Canada already goes farther than the OIE requirements as a semi-annual testing of all animals is required by the Canadian Artificial Insemination program instead of an annual test. The CFIA considers that the semi-annual test coupled with biosecurity measures in place in semen production centres as per the Canadian Artificial insemination program gives sufficient guaranties that semen donors stay negative throughout their semen production period. The CFIA considers that requirements for IBR should be in accordance with the OIE recommendations. Concerning the semen virus isolation test, the CFIA also consider that testing requirements should be in accordance with the OIE and the use of extended semen confirmed.”

MAF Response

See 2.8 for the changes to the risk management measures for BHV.

The amended measures provided post-collection serological testing as a separate option. In addition the semen test may be done on raw or extended semen.

15.12. “Lumpy skin disease (LSD): 3 certification options, articles 44 to 46OK

Article 44: option of 6 months country freedom as defined by OIE before semen collection. Canada qualifies as a country free of LSD in accordance with the OIE code. Other options not considered.”

MAF Response

Noted

15.13. “Rift Valley fever (RVF): 3 certification options, articles 47 to 49OK

Article 47: option of 3 months country freedom before and during semen

collection. Canada qualifies as a country free of RVF in accordance with the OIE code. Other options not considered.”

MAF Response

Noted

- 15.14. “Vesicular stomatitis (VS): 3 certification options, articles 50 to 52.....OK
Article 50: option of country freedom in accordance with the OIE code. Canada qualifies as a country free of VS in accordance with the OIE code. Other options not considered.”

MAF Response

Noted

- 15.15. “Bovine brucellosis: 2 certification options, articles 53 & 54OK
Article 53: option of donors kept in a country or zone free since birth. Canada is considered free country in accordance with the OIE Code.
Article 54: option centre free as per the OIE Code. All Canadian centres also qualify according to these conditions. This option allows for qualification of USA origin donor bulls resident in Canadian centres.”

MAF Response

Noted

- 15.16. “Bovine tuberculosis: 2 certification options, articles 55 & 56OK
Article 55: option of donors kept in a country or zone free since birth. Canada is considered free country in accordance with the OIE Code.
Article 56: option centre free as per the OIE Code. All Canadian centres also qualify according to these conditions. This option allows for qualification of USA origin donor bulls resident in Canadian centres.”

MAF Response

Noted

See 5.1 for the changes to the risk management measures for tuberculosis.

- 15.17. “Contagious bovine pleuropneumonia (CBPP): 2 certification options, articles 57 to 60.....OK
Article 57: option of country freedom in accordance with the OIE code. Semen donors must be born and continuously resident in a free country. Canada qualifies as a country free of CBPP in accordance with the OIE code. The USA also qualifies as a CBPP free country. Other option not considered (article 58, 59 and 60).”

MAF Response

See 14.17 for the changes to the risk management measures for CBPP.

- 15.18. “Mycoplasma bovis: 3 certification options, articles 61 to 63 TBN
Article 61: option to test donor bulls post collection.
Article 62: option to test each collection using raw semen.
Article 63: option to random test the centre population once a year.
A scientific paper (Shin S.J., Lein D.H., Patten V.H. and Ruhnke H.L., A new antibiotic combination for frozen bovine semen, 1. Control of Mycoplasmas,

Ureaplasmas, Campylobacter fetus subsp. Venerealis and Haemophilus somnus, Theriogenology, March 1988, vol. 29, no 3. 577-591) was published concerning the control of several bacteria in the semen, including Mycoplasma bovis, by addition of antibiotics in extenders. The mixture of gentamicin, tylosin and lincomycin-spectinomycin (lincospectin) has been proved enough efficient to be adopted by the OIE Code since several years as the reference antibiotic mixture (gentamicin, tylosin, lincomycin-spectinomycin: GTLS) for addition in the semen to control these bacteria as mentioned in Chapter 4.6, article 4.5.7. The OIE Code recommends that a mixture of these antibiotics is added to each ml of frozen semen. As addition of proven antibiotics is now a standard followed in the Canadian bovine semen production centres and imposed by the CFIA as per the Artificial Insemination program, there is absolutely no need to test donor bulls or semen for Mycoplasma bovis. This testing requirement from NZ must be revised to take in account the mitigating measures obtained by addition of reference antibiotic mixture to all semen produced in Canada.

Conclusion on Mycoplasma bovis

An appropriate mixture of antibiotics (GTLS) is added to all semen produced in Canadian centres and such procedure is controlled by the CFIA. This mitigating measure is sufficient for the control of Mycoplasma bovis. No test should be required by NZ concerning Mycoplasma bovis in accordance with the OIE Code.”

MAF Response

See 3.10 and 4.9 for the changes to the risk management measures for *Mycoplasma bovis*. As stated above, the issues associated with the usage of antibiotics as sanitisers in semen extenders means that alternative risk management measures are required.

15.19. “Q fever: 3 certification options, articles 64 to 66.....OK

Article 64: option to test donor bulls post collection.

Article 65: option to test each collection using raw semen.

Article 66: option to random test the centre population once a year.

Conclusion for Q-fever:

The CFIA recognizes that NZ is free of Q-fever; thus testing as per options offered is accepted. The unique test available in CFIA laboratory for Q-fever is the CF test.”

MAF Response

Noted

16. US Government – Semen IHS

16.1. “Documentation accompanying the consignment

The US veterinary infrastructure includes a two-tier review of veterinary health documents used for export. USDA accredited veterinarians draw samples, order the diagnostic tests and review original copies of the test results. The accredited veterinarian issues the veterinary health certificate, according to the NZ import requirements, and submits all documents (including original laboratory reports) to USDA Animal and Plant Health Inspection Service (APHIS) Veterinary Services (VS). VS reviews all documents, including original laboratory reports, and endorses correctly completed veterinary health export certificates. Foreign government review of original laboratory reports from the US is unnecessary.”

MAF Response

See 3.5

- 16.2. **“The US can certify to freedom from Borna disease, Crimean Congo haemorrhagic fever, foot and mouth disease, lumpy skin disease, Rift Valley fever and contagious bovine pleuropneumonia. The US Code of Federal Regulations Title 9, Part 161.4 (f) mandates that accredited veterinarians report suspicious signs of foreign animal diseases (FAD) to the APHIS Area Veterinarian in Charge or State animal health officials.”**

MAF Response

Noted

- 16.3. **“Bluetongue (BT):
25, 26, 27, 28, 29 The US agrees with the NZ risk analysis that, in the absence of the competent vector, BT “risk management measures are not justified.” The US respectfully suggests minimal requirements for BT risk management.”**

MAF Response

While reasonable from a risk and import cost perspective, abolishment of measures against bluetongue virus for imported bovine semen could create disruption in trade because of a lack of alignment with the requirements of other countries. For simplicity the measures have been aligned with OIE Code requirements.

- 16.4. **“Bovine viral diarrhea type 2 (BVD2):
33. Semen already collected and in storage may come from donors which only were tested for BVD type 1. The US respectfully requests that semen currently in storage and qualified to export to NZ remain qualified for export to NZ.
34. The US respectfully requests NZ to accept BVD disease management program of the Certified Semen Services (CSS) as described at http://www.naab-css.org/about_css/disease_control-2002.html) as equivalent to OIE requirements. The US notes that NZ’s recommended options do not match the 2010 World Organization for Animal Health (OIE) Terrestrial Animal Health Code in two places. One, Chapter 4.6 provides a scheme that accommodates seroconversion during pre-entry isolation. Two, the OIE Code does not specify the timing of annual retesting (i.e., samples collected after semen is collected for export).
35. The US believes the suggested requirement for testing donors that have been on the semen collection center for less than 3 years is not scientifically based and, therefore, is an unwarranted barrier to trade. The potential length of time that virus can be shed is irrelevant to trading bovine semen: Persistently infected animals are identified by testing and removed. There is no scientific basis to extend a requirement for testing beyond the six months originally offered in the NZ risk management proposal. Additionally, OIE Code does not require testing donors on the basis of the residence time at the center.”**

MAF Response

See 2.7 for the changes to the risk management measures for BVDV.

The risk management measures have been amended to align with OIE Code requirements.

The eligibility of semen produced under the previous IHS requirement will be resolved during bilateral negotiations.

- 16.5. **“Infectious bovine rhinotracheitis/Infectious pustular vulvovaginitis (IBR/IPV):**
42. Article 11.11.7. of the OIE Terrestrial Animal Health Code recommends an international veterinary certificate for frozen semen attesting that: the donor animals were kept in an IBR/IPV free herd; or the donor animals were held in isolation and tested; or an aliquot of semen was tested. NZ appears to be applying the OIE requirement that define a herd free from IBR to bovine semen donors: OIE requirements for herd freedom are different than OIE requirements for trade in bovine semen. Herd freedom is only one of three options recommended by OIE. The US respectfully suggests that NZ’s recommendations in the risk management proposal be clarified accordingly.
43. As written, NZ asks for 0.05 ml of raw semen to be tested. Chapter 2.4.13 of the OIE Terrestrial Manual, B. 1. b) (2008) prescribes “One straw, 0.5 ml, of extended semen or 0.02 ml of raw semen ... For extended semen, an approximation should be made to ensure that the equivalent of 0.05 ml raw semen is examined.” The US respectfully suggests that NZ clarify the wording to allow either extended semen or raw semen to be tested in the amounts indicated by OIE.”

MAF Response

See 2.8 for the changes to the risk management measures for BHV.
The amended measures are aligned with OIE Chapter 11.11.7.

- 16.6. **“Vesicular stomatitis (VS):**
No comment.”

MAF Response

Noted

- 16.7. **“Bovine brucellosis:**
54. Chapter 4.6. of the OIE Code (2010) recommends country or zone freedom (augmented by testing) prior to pre-entry isolation; serological testing during pre-entry isolation; and annual testing. The OIE Code (Article 11.3.5.) allows for animals to originate in a “herd officially free from bovine brucellosis.” NZ has adapted that to a “herd officially free from bovine brucellosis in accordance with the OIE Code.” The US understands that the APHIS VS program for brucellosis control and eradication provides the basis for certification of a herd officially free from bovine brucellosis. As written, the health standard implies that official freedom is determined by OIE code as opposed to a program administered by the competent authority.”

MAF Response

See 8.5 for changes to the risk management measures for bovine brucellosis
The amended measures are aligned with the OIE Code.

- 16.8. **“Bovine tuberculosis**
56. **The US has an official program for the control and eradication of bovine tuberculosis and can make veterinary health certifications to that effect.”**

MAF Response

See 5.1 for the changes to the risk management measures for tuberculosis.

- 16.9. **“Mycoplasma bovis
61.,62., 63. Mycoplasma bovis in bovine semen is controlled through the use of antibiotics in the semen extender (Shin, et al, Thierogenology, March 1988, Vol. 29, No. 3, pp. 577-591). Requirements for testing semen donors for Mycoplasma bovis are not warranted.”**

MAF Response

See 3.10 and 4.9 for the changes to the risk management measures for *Mycoplasma bovis*. As stated above, the issues associated with the usage of antibiotics as sanitisers in semen extenders mean that alternative risk management measures are required.

- 16.10. **“Q fever: No comment”**

MAF Response

Noted

17. US Government – Embryo IHS

- 17.1. **“Documentation accompanying the consignment:**

The US veterinary infrastructure includes a two-tier review of veterinary health documents used for export. USDA accredited veterinarians draw samples, order the diagnostic tests and review original copies of the test results. The accredited veterinarian issues the veterinary health certificate, according to the NZ import requirements, and submits all documents (including original laboratory reports) to USDA Animal and Plant Health Inspection Service (APHIS) Veterinary Services (VS). VS reviews all documents, including original laboratory reports, and endorses correctly completed veterinary health export certificates. Foreign government review of original laboratory reports from the US is unnecessary.”

MAF Response

See 3.5

- 17.2. **“The US can certify to freedom from Borna disease, Crimean Congo haemorrhagic fever, foot and mouth disease, lumpy skin disease, Rift Valley fever and contagious bovine pleuropneumonia. The US Code of Federal Regulations Title 9, Part 161.4 (f) mandates that accredited veterinarians report suspicious signs of foreign animal diseases (FAD) to the APHIS Area Veterinarian in Charge or State animal health officials.”**

MAF Response

Noted

- 17.3. **“Vesicular stomatitis (VS): No comment.”**

MAF Response

Noted

- 17.4. **“Bovine tuberculosis: No comment.”**

MAF Response

Noted

- 17.5. **“Mycoplasma bovis:**
Mycoplasma bovis can be controlled through the use of antibiotics (Shin, et al, Thierogenology, March 1988, Vol. 29, No. 3, pp. 577-591). Requirements for testing donors for Mycoplasma bovis are not warranted.”

MAF Response

See 3.10 and 4.9 for the changes to the risk management measures for *Mycoplasma bovis*. As stated above, the issues associated with the usage of antibiotics as sanitisers in semen extenders mean that alternative mitigation measures are required.

- 17.6. **“Q fever: No comment.”**

MAF Response

Noted

18. European commission – Semen IHS

- 18.1. **Part B, Point 11. - Donor eligibility**
OIE Code/EU-NZ Agreement: EU-NZ Agreement

EU request to NZ:

- **to change "in the exporting country for at least 90 days" for "within the European Union for at least 90 days";**
Rational:
- **The recognition of the EU as whole in the EU-NZ Agreement.**

MAF Response

The IHS describes the risk management measures for all countries. This detail can be incorporated into the zoosanitary certificate negotiated for the import of germplasm from the European Union into New Zealand.

- 18.2. **Part B, Point 13. - Isolation period**
OIE Code/EU-NZ Agreement: Point 2 of Article 4.6.2. of the OIE Code; Annex V to the EU-NZ Agreement

EU request to NZ:

- **to replace "30 days" by "28 days";**
Rational:
- **OIE Code requires 28 days;**
- **practical importance for the organisation of animal movements on weekly basis.**

MAF Response

See 2.2

- 18.3. **Part C, Points 26 and 27. - Bluetongue**
OIE Code/EU-NZ Agreement: Points 1 (a) of Articles 8.3.9 and 8.3.10 of the OIE Code

EU request to NZ:

- **to replace "100 days" by "60 days"**
Rational:
- **OIE Code requires 60 days**

MAF Response

See 2.6 for the changes to the risk management measures for BTV.

18.4. Part C, Point 28. - Bluetongue

OIE Code/EU-NZ Agreement: Point 1 (b) of Article 8.3.11. of the OIE Code; Annex V to the EU-NZ Agreement

EU request to NZ:

- to replace "28-60 days" by "21-60 days"
Rational:
- OIE Code requires 21-60 days;
- practical importance for the organisation of animal testing on weekly basis.

MAF Response

See 2.6 for the changes to the risk management measures for BTV.

18.5. Part C, Points 30-32. - Borna Disease

OIE Code/EU-NZ Agreement: The OIE Code does not provide any requirements as regards this disease; Annex V to the EU-NZ Agreement does not provide any additional certification requirements as regards this disease

EU request to NZ:

- to delete the requirement, or
- to provide evidence that this disease in clinically healthy animals present an animal health risk to NZ.
Rational:
- OIE does not consider this disease to be a risk;
- not an OIE listed disease.

MAF Response

See 8.7 for the changes to the risk management measures for Borna disease.

18.6. Part C, Points 33-35. - Bovine viral diarrhoea type 2 (BVDV2)

OIE Code/EU-NZ Agreement: Point 2 (b) of Article 4.6.2 of the OIE Code; Annex V to the EU-NZ Agreement

EU request to NZ:

- to delete Point 35
Rational:
- Point 34 already ensures that there is no virus circulation in semen collection centre.

MAF Response

See 2.7 for the changes to the risk management measures for BVDV.

18.7. Part C, Point 42. - IBR/IPV

OIE Code/EU-NZ Agreement: Point 3 (g) of Article 4.6.2 of the OIE Code; Annex V to the EU-NZ Agreement

EU request to NZ:

- to consider adding an option for certifying country IBR/IPV freedom;

- to delete the negative post-collection serology on donor bulls from which semen is certified for export to NZ.

Rational:

- In accordance with OIE Code, annual (negative) serology is considered sufficient.

MAF Response

Only BHV1.2b has been isolated in New Zealand, so MAF has decided to add the clause that provides the option of certifying freedom to the strains not present in New Zealand. See 2.8 for the changes to the risk management measures for BHV.

**18.8. Part C, Point 57 - Contagious bovine pleuropneumonia (CBPP)
OIE Code/EU-NZ Agreement: Article 11.8.3. of the OIE Code**

EU request to NZ:

- to adapt the requirement to the recommendations in Article 11.8.3. of the OIE Code

Rational:

- Neither NZ nor the EU, except PT, are in the OIE list.

MAF Response

See 14.17 for the changes to the risk management measures for CBPP.

18.9. Part C, Points 61-63. - Mycoplasma bovis

OIE Code/EU-NZ Agreement: The OIE Code does not provide any requirements as regards this pathogen.; Annex V to the EU-NZ Agreement does not provide any additional certification requirements as regards this pathogen.

EU request to NZ:

- to delete the requirements concerning testing for Mycoplasma bovis
- If the requirement is kept, criteria for country freedom should be provided.

Rational:

- OIE does not consider this pathogen to be a risk;
- compulsory addition of antibiotics to the semen is preventing the spreading of Mycoplasma bovis;
- specific evidence is required that the antibiotics commonly used for processing semen are not effective against this organism;
- NZ should provide information, how it is concluded that NZ is free of the Mycoplasma bovis.

MAF Response

See 3.10 and 4.9 for the changes to the risk management measures for *Mycoplasma bovis*.

18.10. Stocks of semen.

OIE Code/EU-NZ Agreement: NA

EU request to NZ:

- to clarify which conditions will apply to the stocks of embryos collected, processed and stored before new requirements enter into force

MAF Response

The eligibility of semen produced under the previous IHS requirement will be resolved during bilateral negotiations.

19. European commission – Embryo IHS

19.1. Part B, Point 11. - Donor eligibility

OIE Code/EU-NZ Agreement: EU-NZ Agreement

EU request to NZ:

- to change "in the exporting country for at least 90 days" for "within the European Union for at least 90 days".

Rational:

- The recognition of the EU as whole in the EU-NZ Agreement.

MAF Response

See 18.1

19.2. Part B, Points 13-14. - Embryo collection facility and pre-entry isolation.

OIE Code/EU-NZ Agreement: The OIE Code does not provide such a requirement; Annex V to the EU-NZ Agreement does not provide any additional certification requirements in this respect and requirements for the collection of embryos have already been recognised as equivalent to NZ standards in this respect.

EU request to NZ:

- to clarify the meaning of "embryo collection facility", in particular with a view to allow collection of embryos on the holdings/farms.

Rational:

- a bespoke facility is not required under OIE Code;
- most embryos are collected on holdings/farms, by approved embryo collection teams with mobile laboratories or who have access to permanently sited laboratories. Therefore, such a facility created on a holding/farm should be acceptable, as long as the donors can be isolated there from animals which are not of an equivalent health status.

MAF Response

See 1.2 and 1.4

19.3. Part B, Point 20. - Embryo collection, processing, storage and transport

OIE Code/EU-NZ Agreement: NA

EU request to NZ:

- to clarify whether a biopsed embryo be eligible for exports to NZ provided that the biopsy is taken after the requirements described in Point 20 have been fulfilled.

MAF Response

MAF has decided to add an additional clause into the IHS stating:

“Any micro-manipulation that causes a breach of the zona pellucida is to be done as per the procedures described in the OIE code and IETS manual. These include specifications on the facilities used and require that micro-manipulation only be carried out on an embryo having an intact zona pellucida and that it be done subsequent to the last wash and examination of the embryo.”

19.4. Part C, Points 31-33. - Borna Disease

OIE Code/EU-NZ Agreement: The OIE Code does not provide any requirements as regards this disease and it is also not an OIE listed disease; Annex V to the EU-NZ Agreement does not provide any additional certification requirements as regards this disease

EU request to NZ:

- to delete the requirement, or
- to provide evidence that this disease in clinically healthy animals present an animal health risk to NZ.

Rational:

- OIE does not consider this disease to be a risk;
- not an OIE listed disease.

MAF Response

See 8.7 for the changes to the risk management measures for Borna disease.

19.5. Part C, Points 34-36. - Bovine viral diarrhoea type 2 - (BVDV2)

OIE Code/EU-NZ Agreement: Annex V to the EU-NZ Agreement

EU request to NZ:

- to consider reviewing Points 35 and 36 as follows:
 - to adapt Point 35 in order to provide for a negative VI or antigen ELISA on the donor female on the day of collection of embryos or a negative serology 21 days after collection of embryos;
 - to replace the "AND " between Points 35 and 36 by "OR" to provide for an optional negative VI or PCR test on dead/non-viable embryos/washing/flushing fluid from first collection (Point 36 refers).

Rational:

- No EU MS is currently recognised as free (Annex V of agreement refers), so points 35 and 36 would apply.
- Points 35 and 36 mirror what has been proposed for bovine semen. Nevertheless, embryos are not collected from donor females at a bespoke collection facilities (see our comment to points 13-14) like in the case of semen, so the requirements for tests prior to entering the pre-isolation, during pre-isolation and annually in the embryo collection facility are not realistic, and in any case, unnecessarily complex.

MAF Response

See 1.12 for the changes to the risk management measures for BVDV.

19.6. Part C, Point 54. - Contagious bovine pleuropneumonia (CBPP)

OIE Code/EU-NZ Agreement: Article 11.8.3. of the OIE Code

EU request to NZ:

- to adapt the requirement to the recommendations in Article 11.8.3. of the OIE Code

Rational:

- Neither NZ nor the EU, except PT, are in the OIE list.

MAF Response

See 14.17 for the changes to the risk management measures for CBPP.

19.7. **Part C, Points 58-61. - Mycoplasma bovis**

OIE Code/EU-NZ Agreement: The OIE Code does not provide such a requirement; Annex V to the EU-NZ Agreement does not provide any additional certification requirements in this respect.

EU request to NZ:

- **to delete the requirements concerning testing for Mycoplasma bovis**
If the requirement is kept:
 - **criteria for country freedom should be provided;**
 - **evidence is required that M. bovis is transmissible through in-vivo derived IETS processed embryos;**
 - **to clarify whether point 58 implies a compulsory surveillance for M. bovis to be in place;**
 - **to consider whether serological testing for M. bovis of the donor animals on the holding 21-120 days after flushing is sufficient.**

Rational:

- **OIE does not consider this pathogen to be a risk. Mycoplasma sp. in cattle is currently in IETS Category IV;**
- **compulsory addition of antibiotics to the embryos is preventing the spreading of Mycoplasma bovis;**
- **specific evidence is required that the antibiotics commonly used for processing embryos are not effective against this organism;**
- **NZ should provide information, how it is concluded that NZ is free of the Mycoplasma bovis.**

MAF Response

See 3.10 and 4.9 for the changes to the risk management measures for *Mycoplasma bovis*.

19.8. **Part C, Points 62 to 65. - Q fever**

OIE Code/EU-NZ Agreement: NA

EU request to NZ:

- **to clarify whether Point 62 implies a compulsory surveillance for Q-fever to be in place;**
- **to consider whether the options in Points 63, 64 and 65 are not sufficient if carried out on the donor animals on a holding/farm.**

Rational:

- **According to Part B Point 15, the tests should be done at the embryo collection facility. This is not relevant and causes problems in the practice.**

MAF Response

The IHS does not require that compulsory surveillance for Q fever be in place – this measure is included due to the tendency of infected animals to be long term carriers of the disease. Serological testing of the donor can be done either while the donor is resident in the embryo collection herd (the resident herd at the time of embryo collection) or another establishment. The herd serological test is required to be done on the embryo collection herd.

The measures for Q fever have been amended to:

“Donors have never recorded a positive test for Q fever;

AND EITHER

Donors were subjected to a MAF approved serological test for Q fever, on a sample collected between 21 and 120 days after each embryo collection for export to New Zealand, with negative results;

OR

A sample of embryos/oocytes, collection fluids and/or washing fluids from each embryo collection for export to New Zealand was tested for Q fever by a MAF approved PCR test, with negative results;

OR

Within the 6 month period before or after embryo collection for export to New Zealand, the embryo collection herd has been tested for Q fever, with negative results. This testing can be a MAF approved serological test done on either the whole herd or a random sample of at least 60 animals (whichever is the lesser number); AND
The embryo collection herd has been isolated for the period between embryo collection and diagnostic sampling.”

19.9. Stocks of embryos

OIE Code/EU-NZ Agreement: NA

EU request to NZ:

- **to clarify which conditions will apply to the stocks of embryos collected, processed and stored before new requirements enter into force.**

MAF Response

The eligibility of embryos produced under the previous IHS requirement will be resolved during bilateral negotiations.

20. Denmark – Ministry of Food, Agriculture and Fisheries – Semen IHS

20.1. **“13. The isolation period should according to the OIE be 28 days”**

MAF Response

See 2.2

20.2. **“16. The provision that the centre veterinarian should do an individual clinical inspection of the donor animals should be questioned from a practical point of view. The important thing must be that the health of the animals is monitored and recorded on the day of collection. It should be considered sufficient whether done by the centre veterinarian or a skilled lay person. See also 88/407 annex C 1. a “Semen must be obtained from animals which: a show no clinical signs of disease on the day the semen is collected “”**

MAF Response

See 2.3 for the change to who may be responsible for the health inspection of the donor.

20.3. **“20. Is there any documentation supporting the requirement for separate storage? The only risk which has been suggested is that of contaminated liquid nitrogen**

which is excluded since only fresh nitrogen is to be used (OIE Animal Health Code).”

MAF Response

See 2.5

- 20.4. **“BVDV - 34. The OIE requirements should be sufficient since it is applied to all animals at the SCC. This ensures that there is no virus circulation at the SCC. It is interesting that the post collection antibody test (bullet point 4) can be taken even the day after semen collection which makes it irrelevant!**
35. The time the animal has spent at the SCC does not influence the reliability of the tests mentioned under 34. Should be excluded!”

MAF Response

See 2.7 for the changes to the risk management measures for BVDV.

- 20.5. **“Bovine herpes virus abortifacient strains (IBR/IPV) - We kindly request same initial text as under BVDV 33 as option “At the time of collection of semen to New Zealand, the exporting country was free from IBR/IPV, i.e. there have been no cases of IBR/IPV for at least 3 years”**
42. The OIE requirements should be sufficient since it is applied to all animals at the SCC. This ensures that there is no virus circulation at the SCC. It is interesting that the post collection antibody test (bullet point 4) can be taken even the day after semen collection which makes it irrelevant!”

MAF Response

See 2.8 and 18.7 for the changes to the risk management measures for BHV.

21. Denmark – Ministry of Food, Agriculture and Fisheries – Embryo IHS

- 21.1. **“13. Exclude on farm embryo collection with a mobile laboratory”**

MAF Response

The intent of the IHS is to allow on-farm collection of embryos. See 1.4.

- 21.2. **“17. Will any semen fulfilling EU Directive 88/407 be possible to use?”**

MAF Response

See 14.5.

The reference to overseas country legislation will be managed within the bilateral negotiation process as an equivalence.

- 21.3. **“20. Would a biopsied embryo be eligible for NZ provided the biopsy is taken after proper washing according to IETS and examination of the zona pelucida?”**

MAF Response

See 19.3

- 21.4. **“35. To ensure that the embryo donor is not infected during embryo collection either virus detection at the time of flushing or antibody testing \geq 21 days after should be sufficient.**
36. Since very few, if any, animals would spend their entire lives at an embryo

collection facility this would be applicable to all donors. The time an animal has spent at the facility does not influence the reliability of the tests mentioned under 35 nor regarding the suggested alternative. Should be deleted!"

MAF Response

See 1.12 for the changes to the risk management measures for BVDV.

21.5. "58 and 62. Tests for *Mycoplasma bovis* and Q fever 21 – 120 days after flushing are possible but the provision that the samples should be taken at the ET facility is irrelevant (item 15.). Are these diseases a threat provided the embryos have been washed and trypsin treated?"

MAF Response

See 3.10 and 4.9 for the changes to the risk management measures for *Mycoplasma bovis*.
See 19.8 for the changes to the risk management measures for Q fever.

22. Australia – Biosecurity Australia – Semen IHS

22.1. "Bluetongue

25. BTV (not just BT)

26. Recommend amendment to include bolded, underlined words :

Semen donors were kept in a BT virus free zone, as defined by the OIE Code or recognised by NZ MAF, for at least the 60 days immediately prior.....New Zealand"

- 100 days was a transitory OIE code aberration. It reverted back to 60 days a few years ago taking into account the evidence regarding duration of BT viraemia.

- We've observed the recent changes to the OIE code BTV code chapter with dismay. The bluetongue Code chapter is now no longer supported by Australia as it is unscientific and disregards the epidemiology of this viral infection in parts of the world outside Europe. The long-established and credible Australian BTV free zone that met OIE Code requirements for many years is now not able to meet the updated BTV code chapter, yet it is still as credible as it ever was, perhaps even more so with accumulating data and constant refinement.

In particular, Article 8.3.3.3 in the 2010 Code chapter is of concern.

Article 8.3.3.3 :

"A BTV free country or zone in which surveillance has found evidence that Culicoides are present will not lose its free status through the importation of vaccinated or seropositive animals from infected countries or infected zones, provided: ...

b) the animals are not vaccinated and, at least 60 days prior to dispatch, are demonstrated to have specific antibodies against the bluetongue virus serotypes whose presence has been demonstrated in the exporting country or zone."

This change is also reflected in Article 8.3.8.5.

BA interprets this to mean that BTV susceptible animals moving from our zone of possible BTV transmission into the free zone must be tested to confirm they have antibodies to all BTV serotypes in the "exporting zone" before they are moved into the free zone. This implies that movement restrictions should be in place between the transmission and free zones. We continue to argue strongly that movement restrictions relating to BTV are unnecessary in this country because there are insufficient populations of competent culicoides vectors in the free zone to transmit BTV. Note that the OIE Code chapter no longer makes the important distinction between competent Culicoides vectors and Culicoides which are irrelevant as it

simply refers to *Culicoides* (8.3.3.1b).

As NZ MAF would be aware from past discussions with us, non-competent species of *Culicoides* (e.g. *C. victoriae*) are present in Victoria, SA, Tasmania and the southwest of WA. Very small numbers of vectors, blown over long distances from populations within the zone of possible virus transmission, are occasionally trapped in the free and surveillance zones in the absence of any evidence that cattle are seroconverting to bluetongue. We've pointed this out to many trading partners (most of whom accept BTV zoning in Australia), to the EC (who has not yet accepted our free zone for reasons which we can speculate about) and to the OIE Commission. It is also documented in our BTV zoning submission (p8) which we regularly update. Latest version attached for information.

<<Blu Zoning_Aug10.doc>>

We request that NZ MAF amends the proposed BTV requirement, which currently exclusively requires compliance with the OIE Code, to permit recognition of Australia's BTV free zone.

27. 60 days as above

28. We no longer allow AGID for BTV for imports. (See p60 of BTV review - http://www.daff.gov.au/__data/assets/pdf_file/0007/1656493/2010_16_BTV_Policy_Review.pdf

<http://www.daff.gov.au/__data/assets/pdf_file/0007/1656493/2010_16_BTV_Policy_Review.pdf>

29. What would constitute a MAF approved PCR test for BTV? See p61 of http://www.daff.gov.au/__data/assets/pdf_file/0007/1656493/2010_16_BTV_Policy_Review.pdf

<http://www.daff.gov.au/__data/assets/pdf_file/0007/1656493/2010_16_BTV_Policy_Review.pdf>”

MAF Response

See 2.6 for the changes to the risk management measures for BTV.

22.2. “FMD

For information, in Australia's case imports of FMD susceptible animals and their products are not permitted from countries which have not been approved by BSG as FMD free countries where import requirements stipulate FMD country or zone freedom. (BSG is Biosecurity Services Group - includes AQIS and BA).

MAF NZ's current proposal does not appear to have a similar exclusion with regard to FMD and import of bovine genetic material, though in practice we may not have a significantly different approach (noting clause 41 requiring verification activities). NZ's current IHS for bovine semen from EU - clause 1.2.2 under Sanitary information - has been of some interest to us in this respect.”

MAF Response

Noted

22.3. “IBR

Your proposal interests us as we recently updated our IBR import requirements for bovine semen from EU and North America. For context, NZ and Australia have similar health status with regard to BHV1 i.e. only the relatively benign subtype BHV1.2b, whereas most other countries have all 3 subtypes - BHV1.1, 1.2a and 1.2b. (BHV1.1 and 1.2a being more virulent and abortigenic).

Regarding NZ MAF's proposal, the final antibody test after collection seems excessive, providing your prior requirements have sufficient rigour with regard to

isolation and tests. It is also not in line with current OIE recs and adds to the cost of the trade - it could be deleted. I suspect you will be getting similar comment from CFIA.”

MAF Response

See 2.8 for the changes to the risk management measures for BHV.

22.4. “Sexed semen

We made a number of recommendations to the OIE code concerning use of sexed semen about a year ago. The OIE Code adopted the following (Chapter 4.6):

Sperm sorting

Equipment used for sex-sorting sperm should be clean and disinfected between animals according to the recommendations of the licencer of the system.

Where seminal plasma, or components thereof, is added to sorted semen prior to cryopreservation and storage, it should be derived from animals of same or better health status.

In addition, we have:

Where reproductive material was removed from containers for further processing or aggregation with other reproductive material at an approved centre or laboratory, the dates of transfer, reason for transfer (e.g. for sex sorting), name of the approved centre of laboratory and the Approved Veterinarian must be listed against the containers. The unique serial number of each shipping container must be included in this documentation. (extracted from ICON - bovine semen from EU).”

MAF Response

The intent of the IHS is to include entry of sexed semen.

MAF has decided to amend the clause describing semen processing to state:

“Semen must be collected, handled, prepared, processed and stored under the supervision of the approved semen centre veterinarian and in accordance with the OIE Code.”

In order to maximise the assurance that PCR testing will confirm the absence of microorganisms, it will be required that PCR testing be done on sexed semen prior to the sorting process (unless otherwise validated).

MAF has decided to add the clause describing testing of sexed semen:

“Any PCR testing of sexed semen is to be done on a representative semen sample prior to the sorting process, unless evidence is provided to MAF demonstrating that the PCR process is valid for sorted sexed semen.”

MAF has decided to amend the clause describing semen centre requirements to state:

“Bovine semen must be collected, handled, prepared, processed and stored at semen centres approved for export by the veterinary authority. The semen centres must be subject to regular inspection by an Official Veterinarian, and under the supervision of a semen centre veterinarian approved by the veterinary authority. The name and approval numbers of these semen centres must be recorded on the zoosanitary certificate.”

22.5. “Scope

On page 3 of IHS - "... bovine semen being semen derived from any member of the sub-family Bovinae".

This subfamily is quite broad. We're interested in why you elected to nominate the

scope as "any member of the sub-family Bovinae" as we've been pondering this issue ourselves (informally) .

For example, would you import bison semen from North America under the same conditions as (domestic) cattle semen from North America?

As an example, Australia's conditions for import of bovine embryos from NZ currently state: These conditions allow the import of embryos derived from domestic cattle (*Bos taurus* and *Bos indicus*), and breeds derived from these species only."

MAF Response

The intent of the IHS is to be generic and provide the legal framework allowing entry of semen derived from any member of the sub-family *Bovinae*. In reality this would only apply to *Bos taurus* and *indicus* species, but MAF would consider other species if suitable test validation data had been supplied.

The guidance document will record that when zoosanitary standards vary, this will be reflected in the specific zoosanitary certificate.

23. Australia – Biosecurity Australia – Embryo IHS

23.1. **"17. The semen used to produce the embryos in this consignment either: Met the minimum health standards for semen imported into the exporting country.**

Our general policy regarding use of semen imported from a third country for fertilising embryos for export to Australia is that the health conditions under which the semen was imported must be demonstrably equivalent to conditions for import of that semen directly into Australia. However, In NZ's case, for bovine embryos to Australia, we have (for the time being) accepted a slightly different approach taking into account a number of relevant factors . As would be the case in NZ and any other importing country, import conditions can come under review if circumstances change and the situation warrants a review."

MAF Response

MAF has decided to amend the options for the semen used to produce embryos to state:

The semen used to produce the embryos in the consignment either:

- was imported directly from New Zealand or is eligible for export to New Zealand; OR
- must be collected and processed at a semen collection centre that fully complies with the current OIE Code chapter on collection and processing of bovine semen; OR
- where natural service or fresh semen was used, donor males must be inspected, and found free from clinical evidence of infectious diseases transmissible in semen, and are of an equivalent isolation and tested health status to the donor females.

23.2. **"23 The embryos for export were stored in the frozen state for at least 28 days before shipment to New Zealand...**

We assume this requirement would not apply for embryos from Australia."

MAF Response

See 13.4

23.3. **"As a general enquiry, it's not entirely clear to me how this generic IHS will be incorporated into a bilaterally agreed health certificate. As indicated above, some requirements would be excessive to needs (and current practice), eg storage of**

embryos from Australia for 28 days before export, or if not amended will be likely to cause problems eg BTV free zone as per current OIE code.”

MAF Response

The intent of the IHS is to be generic and provide the legal framework describing risk management measures for organisms and diseases deemed to be a hazard to New Zealand. It is anticipated that options could be selected from the IHS for incorporation into a bilaterally agreed zoosanitary certificate.

24. Canadian Food Inspection Agency, Government of Canada - Dr. Alain Moreau, - Senior Veterinary Officer – Embryo IHS

24.1. “The purpose of this reply is simply to mention that obligation to identify the straw itself instead of using gummed labels and plugs would contravene to the IETS recommendations, mentioned in Chapter 9, Certification and identification of embryos, 4th edition 2010, page 89, subsection "Labelling straws". first paragraph.

Less and less ET teams write by hand on the straws as manipulation very often causes disappearance of information.

Only ET teams linked to a semen production centre or having a contract to print straws in advance use laser printed straws such as used for semen.

Extension plugs are now extensively used internationally and also gummed labels. It would be unfortunate that NZ restricts methods internationally approved by IETS and OIE to label embryos straws.”

MAF Response

See 1.10

Appendix 1 Copies of Submissions – Bovine Germplasm Import Health Standard

1. CRV AmBreed N Z; Robert Courtney – Embryo & Semen - 26/07/2010

Dear Mey

On behalf of CRV AmBreed I wish to make submissions on Import Health Standards for Bovine Semen, bovshed.gen and Import Health Standards for Bovine Embryos, bovmid.gen

Regards

Rob C

Robert Courtney B.V.Sc

Centre Veterinarian

CRV AmBreed N Z.

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e: rob.courtney@crv4all.co.nz

w: www.crv4all.co.nz

Submissions import health standards for bovine embryo

This IHS should include in-vitro embryo production even though there are some references within this draft IHS to ova. It appears that this draft has been a cut and paste of the semen draft where isolation is a requirement. Donor isolation is not a recommendation of embryo production in EU directives, OIE recommendation or IETS guides. In my opinion semen and embryo production are totally different. Semen and embryo IHS should not follow the same template. For disease freedom assurance, other ways of insuring freedom must be applied other than part reliance on isolation. OIE Article 4.8.6, Risk Management should form the basis of developing embryo disease assurances.

Clause 12: Additional wording required to meet the needs of international embryo trade ***“and in accordance of Directive 89/556/EEC and subsequent amendments (if in the European Union) and following recommendations of the current Manual of the International Embryo Transfer Society (IETS). “***

Clause 13& 14: These clauses are not consistent with the OIE code article 4.7.2, Directive 89/556/EEC nor recommendations of the IETS Manual and should be removed. In my opinion under Article 5.3 of the WTO Agreement on Sanitary and Phytosanitary Measures, both these clauses do not meet the accepted criteria of this agreement. Isolation is not a mandatory requirement of embryo production.

Clause 16: This clause is too restrictive and should be replaced with wording similar to OIE article 4.7.1 **At the time of collection, the donor animals should be clinically inspected by the team veterinarian, or by a veterinarian responsible to the team veterinarian and certified to be free of clinical signs of diseases that could be transmitted in embryos.**

Clause 18: Should have provision for in-vitro embryo production. Replace embryo with ***ova/embryo*** and ***“processing of in vivo/ in-vitro derived embryo”***

Clause 19 ***“were fertilised in vivo/ in-vitro”***

Clause 20: remove identified as not possible, as can not identify an embryo, as doesn't have identification per say. Containers can but not embryos. Additional statement that ***if in-vitro embryo produced, then each embryo must be washed with fresh media separately and treated with fresh trypsin separately*** , Theriologenology 2003 Nov60(8): Bovine

herpesvirus-1 associated with single, trypsin treated embryos was not infective for uterine tubal cells. Additional assurance for IBR, if donor not maintained from official IBR herd may also be gained by adding. ***Donors have a sample of non viable embryos/oocytes, collection fluids and/or wash fluids from each collection (samples as per OIE and IETS recommendations) in the consignment tested for IBR using virus isolation or validated transcriptase polymerase chain reaction with negative results***

Clause 22: this clause is not strong. ***Indelible*** should be added “***clearly indelibly marked***”

Clause 28: additional wording required *in vivo/in-vitro*

Clause 35: This is embryo production so the statement relating to artificial insemination centre must be deleted. The bullet points are not applicable to ova/embryo collection facilities and are a cut and paste from the semen draft. This should all be replaced by ***donor/s tested with BVD antigen /PCR for the detection of active infection at time of collection.***

Ova/embryo harvesting, unlike semen collection does not tend to be a continuous harvest. This has the consequence that it is possible to test for active BVD infection at the very time of collection. The effect of this is that an isolation phase is not required to establish the BVD status of the ova/embryo. Additional safeguards are provided by ensuring viral testing in clause 36 is done.

Clause 36: I can not see where the validity of the 3 years residency comes in as any exposed animal can become infected and shed, 3 years of residency doesn't imply resistance.

This clause should read ***Donors have a sample of non viable embryos/oocytes, collection fluids and/or wash fluids from each collection (samples as per OIE and IETS recommendations) in the consignment tested for BVDV2 using virus isolation or validated transcriptase polymerase chain reaction with negative results***

Clause 52: remove this clause as already covered in clause 16. “24 hours” in this clause is not valid and makes no sense in the epidemiology of Tuberculosis. Is it possible some “Flag”? may show at 24 hours pre collection that is an indicator of TB?, that would not be indicated by clause 16. This I am not aware of.

Clause 53: remove reference to isolation. Should read..... ***during the 30 days prior to collection of embryos for consignment to New Zealand*** (may be 60 days to allow for repeat collection as not valid test if repeated at 30 days as commercially oocyte/embryo collections can be repeated within 60 days) ***else a post collection tuberculin test within 365 days***

Additional disease statement required as not covered in part C and be consistent with OIE and EU directive.

Donors must come from herds that are:

officially brucellosis free,

enzootic bovine leucosis free or no clinical case of enzootic bovine leucosis during the past 3 years and negative to enzootic bovine leucosis serological test at time of collection.

During previous year they must not have been in a herd(or herds) which have shown any clinical sign of infectious bovine rhinotracheitis/infectious pustular vulvovaginitis

CHAPTER 5.3.

OIE PROCEDURES RELEVANT TO THE AGREEMENT ON THE APPLICATION OF SANITARY AND PHYTOSANITARY MEASURES OF THE WORLD TRADE ORGANIZATION

Article 5.3.1.

The Agreement on the Application of Sanitary and Phytosanitary Measures and role and responsibility of the OIE

The Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) encourages the Members of the World Trade Organization to base their sanitary measures on international standards, guidelines and recommendations, where they exist. Members may choose to adopt a higher level of protection than that provided by international texts if there is a scientific justification or if the level of protection provided by the relevant international texts is considered to be inappropriate. In such circumstances, Members are subject to obligations relating to risk assessment and to a consistent approach of risk management.

Submission Import health Standards for Bovine Semen-07-2010

The proposed standard will if approved in its present form, would essential curtail bovine semen imports into New Zealand. Clauses such as, centre veterinarian being required to inspect donor animals on the day of collection and semen storage requirement are not the norm in many countries that we currently trade with.

Clause 13: Why 30 days OIE code section 4.5.2.2 states 28 days. Even though 88/407/ECC Laying down the animal health requirements applicable to intra-community trade in and import of semen of domestic animals of the bovine species states 30 days.

Suggested change **28 days**

Clause 16: This clause is too restrictive as centre veterinarian may not be present and inspect donor on day of collection. NZ OAP clause 6.14.1.b *states on day of collection, the animal being collected from must not show any evidence of infectious disease that will compromise the integrity of the semen*

88/407/ECC annex C. semen must be obtained by animals which: show no clinical signs of disease on the day semen is collected.

Suggested change: **On day of collection, the animal being collected from must not show any evidence of infectious disease that will compromise the integrity of the semen**

In New Zealand it is accepted that this can be by the centre veterinarian or skilled person under the supervision of the centre veterinarian.

Clause 19. "Clearly marked" Not strong enough as markings may be lost

Suggested change: **indelibly marked**

Clause 20 "stored with semen and embryo that is eligible for export to New Zealand" This is too restrictive as in a large centre not practicable because of storage issues.

No evidence that infection can spread in storage tanks.

Canadian paper 2005 Apr;50(2):206-10.

Non-transmission of bacterial and viral microbes to embryos and semen stored in the vapour phase of liquid nitrogen in dry shippers.

[Cryobiology](#). 2003 Apr;46(2):146-52. **Microbial contamination of embryos and semen during long term banking in liquid nitrogen.** [Bielanski A](#), [Bergeron H](#), [Lau PC](#), [Devenish J](#).

The only risk during storage is if contaminated nitrogen used. This risk is excluded as only fresh nitrogen used.

As New Zealand has additional testing than the standard tests required in the EU in particular, this storage should only include storage with the standard EU testing regime. Equivalent health status should only involve these tests. Not Q fever or M bovis and other non standard diseases as specified in Import Health Standards.

Suggested change: remove clause as under both OIE and 88/407/ECC directives only fresh nitrogen allowed or **stored in storage that only fresh nitrogen has been used. Or stored with germplasm of equivalent health status.**

Bluetongue

These clause need to be consistent with OIE section 8.3.10 etc

Clause 26 why 100 days OIE section 8.3.9.1 states 60 days

Clause 27 why 100 days OIE section 8.3.10.1 states 60 days

Clause 28 why 28 days OIE section 8.3.11.b states 21 days

BVD

Clause 35/36 difficult to understand why both 35 and 36 are required Should be a “or” not a “and” statement. Clause 36, not sound scientifically in my opinion. Very difficult to extrapolate to the requirement for 3 years if on centre as any animal could shed if infected if there is a breakdown on centre. No where in the paper can I see how by virtue of being on a centre greater than 3 years you can not become infected. All donors should have there first frozen collection viral tested but not all ejaculates in a consignment unless there is a change of BVD serological status in any donor on centre. In this case all ejaculates in consignment must be tested. An infected non antibody positive animal will consistently shed so repeated testing not warranted. By doing a semen test on the first collection of all donors this would detect negative serological BVD shedders.

Vet Microbiol. 2009 Oct 20;139(1-2):42-51. Epub 2009 May 3. **Epidemiology of prolonged testicular infections with bovine viral diarrhoea virus.**

Results of this research demonstrated that prolonged testicular infections could result in detection of viral RNA in semen for 2.75 years with infectious virus grown from testicular tissue 12.5 months after viral exposure

IBR

Clause 42 4th bullet point: The post collection antibody test interval for sampling following collection should be stated. This interval should be greater than 21 days per European Food Safety Authority- AHAW Panel

“Definition of a BoHV-1-free animal and a BoHV-1-free holding, and the procedures to verify and maintain this status.” EFSA-Q-2005-018 2005

2. CRV BV, and other Dutch AI organisations (Alta, AI Samen and AI Kampen); Jan Venneman – Semen & Embryo - 26/07/2010

Arnhem, 22-07-2010

Dear Mey Chan,

On behalf of CRV BV, and the other Dutch AI organisations (Alta, AI Samen and AI Kampen), I send you hereby our comments regarding the new proposed requirements for the export of bovine semen and bovine embryo's to New Zealand.

Most probably the Dutch authorities, and/or the EU authorities, will react as well.

I would like to ask you to take our comments into serious consideration, while redrafting the current requirements.

In case our comments are not clear, do not hesitate to approach me.

Best regards,
Jan Venneman
PECS/CRV BV
Director International Relations

Comments to the draft import health standards for bovine semen and bovine embryo's of New Zealand.

Bovine semen

1. In general the requirements are beyond the EU requirements for the import of semen from NZ to countries in the EU and also beyond the OIE requirements for the import /export of bovine semen.
2. Article 13: according the EU regulations and the OIE code the period of isolation should be at least 28 days (in stead of 30).
3. Article 16: this requirement is too rigid; in our opinion the center veterinarian is responsible for the clinical inspection of the donor animals at the days of semen collection. This can be done by the center veterinarian or a skilled person supervised by the center veterinarian. See also 88/407 annex C 1. a "Semen must be obtained from animals which: a show no clinical signs of disease on the day the semen is collected "
4. Is there any documentation supporting the requirement for separate storage? The only risk which has been suggested is that of contaminated liquid nitrogen which is excluded since only fresh nitrogen is to be used (OIE Animal Health Code).
5. Article 24 (second and third dot): sending summaries of the lab tests and copies of lab reports goes far beyond the regulations of the EU and the OIE code; import/export by means of international health certificates is based on trust between veterinary authorities of individual countries; requiring the sending of all mentioned documents will be considered as a disqualification of the veterinary authorities of exporting countries
6. Article 26: in the EU regulations, as well in the OIE, code 60 days are mentioned (in stead of 100 days).
7. Article 27: in the EU regulations, as well in the OIE, code 60 days are mentioned (in stead of 100 days).
8. Article 28: in the EU regulations, as well in the OIE code 21 days are mentioned (in stead of 28 days).
9. Article 34: in regard to sero-positive donors the NZ requirements are going far beyond the EU regulations and the OIE code (testing prior to (every) initial dispatch to NZ versus prior to (only) the first general dispatch ; NZ is asked to follow the recommendations in the OIE code for sero-positive donors.

10. Article 35: this article goes far beyond the EU regulations and the OIE code and is therefore not acceptable.
11. Article 41: the sentence in which NZ requires the use of a NZ approved semen collection personnel is going too far.
12. Articles 61, 62 and 63: these articles are neither mentioned in the EU regulations, nor in the OIE code; besides, the exported semen is treated with antibiotics for *Mycoplasma bovis*.

Bovine embryo's

1. In general the requirements are beyond the EU requirements for the import of embryo's from NZ to countries in the EU and also beyond the OIE requirements for the import of bovine embryo's.
2. Article 13 and 14: in these articles an approved/registered embryo collection facility is mentioned; however, embryo collection in the whole world is based on collection by approved embryo collection teams; in general donors are not isolated from other animals; articles 13 and 14 should therefore be deleted.
3. Article 18: what is the reason that only in vivo derived embryo's can be exported to NZ? It should be possible to export in vitro derived embryo's as well.
4. Article 30: sending of a summaries of lab tests and copies of lab reports goes far beyond the regulations of the EU and the OIE code; import/export by means of international health certificates is based on trust between veterinary authorities of individual countries; requiring the sending of all mentioned documents will be considered as a disqualification of the veterinary authorities of exporting countries.
5. Article 35: this article is completely copied from the draft import requirements for bovine semen; it does not make sense for bovine embryo's; it is more logical to maintain the requirements in the current health certificate.
6. Article 36: this article goes far beyond the EU regulations and the OIE code and is therefore not acceptable.
7. Article 41: the sentence in which NZ requires the use of a NZ approved embryo collection personnel is going too far.
8. Article 53: we can do the tuberculosis test but we do not isolate the donor animals; see the comments to article 13 and 14.
9. Article 58, 59, 60 and 61: these articles are neither mentioned in the EU regulations, nor in the OIE code.

Jakomien Noordman, Jaap Bosch and Jan Venneman
CRV BV

3. Genex, Billings Montana (via LIC); Dr. Harry Michael - 03/08/2010

Mat,

Attached is a comment from Dr. Harry Michael DVM, who is SCC veterinarian for Genex, Hawkeye West, Billings Montana,
..... Harry has identified a problem in the wording of the Tb requirements as it relates to Tb control in USA

"Bovine Tuberculosis

There is a problem with the wording in No. 56 Re: Tuberculosis which would be the only one we could qualify under. The sub statement would be better suited to the USA if it said, as it does in the Brucellosis statement, as follows: "Prior to entry into pre-isolation the donor Bulls were either from a country or zone that is free from Tuberculosis in accordance with the OIE Code"

Without a change in this statement it will be difficult for Hawkeye to qualify for semen shipments of either Yak or Bovine semen. The addition of the wording or zone is important as it fits the way the USDA controls Tuberculosis. The USA controls Tuberculosis on a State basis. Is it possible there was an unintentional omission of the statement? If this statement cannot be changed would it be possible for us to ask for a special dispensation"

.....

Cheers, Ken

4. Embryoplus (South Africa); Dr Robert Treadwell – 02/08/2010

Dear dr. Chang

A partner of mine, Dr. Ronnie de la Rey, visited with you in New Zealand more or less 2 years ago to discuss the possible exports of south African embryos to your country.

We examined your draft Import Health Standards and also asked our Government officials to make the necessary proposals to you. Unfortunately they are extremely busy at the moment with other protocols being negotiated currently and I took the liberty of forwarding our request directly to you for your consideration in order to meet the deadline.

I'm also currently the secretary of SAVSEG (South African Semen and Embryo Group) which assists and work with our Department of animal Health regarding these issues.

Best regards
Robert Treadwell

From: Dr Robert Treadwell
Sent: 13 July 2010 04:27 PM
To: JuliaP@daff.gov.za; JuliaP
Cc: info
Subject: New Zealand Draft IHS for Bovine Semen and Embryos
Importance: High

Dear Dr. Julia

Please see below links to a draft Import Health standards for Bovine semen and embryos for New Zealand, asking for comment before August 2nd ..

I have circulated the message amongst the SAVSEG committee members and will forward any recommendations received to you.

Our comment was on point 46 of the Embryo Standard on RVF , where we thought that they could add as possible alternative

“OR

All donor animals have been vaccinated against RVF with a modified live virus vaccine at least 30 days prior to movement to a quarantine facility.”

which is basically the same as the proposed amendment to the Brazilian protocol.

Could you possibly contact dr. Chang with any comments/proposals from your side as well as confirmation of SA's official status as being free of:

Borna disease

FMD (Zonal freedom)

Vesicular Stomatitis

CBPP

Q fever (listed under point 7 of the standard for Bovine embryos)

Thanks for your time and efforts.

Best regards
Robert

5. New Zealand Hereford Association; Natalie Campbell – 03/08/2010

Hello,

Please find attached a submission from the New Zealand Hereford Association regarding the draft import standard for bovine embryos and semen.

Acknowledgment that this message has been received would be appreciated please.

Regards,

Natalie Campbell

General Manager

New Zealand Hereford Association

PO Box 503

Feilding

Ph 06) 323 4484

Fax 06) 323 3878



2 August 2010

To Whom It May Concern,

RE: Submission on the Draft Import Standard for Bovine Embryos and Semen

The New Zealand Hereford Association wishes to acknowledge the tremendous efforts MAF has shown in keeping dangerous organisms out of New Zealand.

We commend the proposal to link protocols with international guidelines, standards and recommendations and the use of different alternative tests as an option on semen and embryos.

We would like to ask that you explore the case for allowing on farm collection of embryos in North America and Australia, providing the protocols you have outlined are met, and the service is carried out by approved providers.

By limiting collection to approved centres, we feel it is creating a monopoly and another layer of cost. We believe on-farm testing will relieve this cost, while testing protocols and approved operators would negate any risk.

We were not able to obtain a 'list of approved countries' from which export, in the guidance document (section C as described), but wish to enquire on the status of Uruguay as an exporting country for bovine genetic material as it has been free of Foot and Mouth for some time and contains a world class, state of the art bovine collection centre that several NZ Hereford Association board members can attest to.

Uruguay has some world class genetics that could be beneficial to the New Zealand beef industry and so depending on Uruguay's existing status we urge you to investigate further the possibility of Uruguay upgrading its status to an approved export country for bovine material.

Yours sincerely

A handwritten signature in black ink, appearing to read 'N Campbell', written in a cursive style.

Natalie Campbell
General Manager
New Zealand Hereford Association.

6. World Wide Sires NZ (on behalf of Select Sires and Accelerated Genetics, USA); Judy Hope – 03/08/2010

Hello Mey

Please find attached submissions from our suppliers, Select Sires and Accelerated Genetics, in the US. I realise they are a day late but I hope that they will still be considered.

Select Sires is the largest AI company for bovine semen globally and between Select Sires and Accelerated Genetics, they supply over 50% of the US market, so I think that their input is valuable.

Thank you and best wishes

Judy Hope
General Manager
World Wide Sires NZ

Below, please find the comments we have received concerning the proposed health protocol changes in New Zealand from Select Sires and Accelerated:

BVD comments:

BVD- They still are looking for on-farm BVD testing- why is this necessary? These bulls are tested for BVD through CSS on the farm (SN, Capture Elisa or IP), in isolation (SN & virus isolation) (all SN+ animals have to have a semen virus isolation test before release for sale) and every 6 months for semi-annual testing (virus isolation). Then they want post test for negative animals. They have added semen testing to bull that have not been in stud for more than 3 years, the current regs allow for in stud 6 months or less.

Adding Type 2 to their BVD regulations causes another issue. Many labs typically only test for Type 1 unless Type 2 is requested. The BVD recommendations will affect all previously stored semen for most places, so is there a grandfather type scenario? If not, I bet every code will have to be tested for M. bovis and BVD type 2.

IBR

IBR- This follows EEC isolation testing, the extra addition here is the post test or you can test the semen. Why can't we have a statement like Australia-"kept in an "IBR/IPV free herd", as defined in OIE Terrestrial Animal Health Code, at the time of collection of the semen." No post test. Also, it mentions BHV5- I checked with the labs, they don't run for BHV5, just BHV1. The labs mentioned they don't have reagents for BHV5.

The IBR recommendations will make any non-EU bull unavailable for export and for us it will not allow for any non-EU herd resident to be exported (no beef bulls).

IBR neg antibody tests after time of collection - gives no time frame like have in the past for a post test, how far can we dare go after the collection? Unlimited usually isn't an option.

Vesicular stomatitis

Vesicular stomatitis would now 100km radius instead of AI center which makes no sense. How can we validate this statement? We don't have knowledge or control of all the animals

in a 100km radius. We cannot certify this. The other option of insect free premises is ridiculous but luckily Ohio is a long way from Arizona.

Crimean Congo Haemorrhagic Fever

It doesn't appear to be in the North American continent. Mostly, Africa, Asia, China, South Africa, Uganda areas. The US labs do not have a test for this. Maybe need to suggest this as country freedom statement. APHIS will have to sign off on it too.

TB & Brucellosis

TB- US is not free from TB, our bulls come from all different states with different TB status. All bulls are TB tested before coming into stud, but not all herds have had a whole herd TB test to come into stud based on their state status. OIE discusses the options for herd free status etc. I can't see making these herds do a whole herd TB test just to bring a bull into stud when the state doesn't require it. I don't know how many states this could effect. How each herd manages this testing is up to each state and their status and where they are selling animals to. I would like to see this statement stay as the donor bull was tested 30 days prior to departure to semen collection center. This may be the same for Brucellosis being from an officially free herd.

Mycoplasma bovis

Mycoplasma bovis- Per our CSS protocol, antibiotics are added to provide effective microbiological control of mycoplasma, ureaplasma, etc. If we were to have to test as they are recommending, it would be very costly as sending raw semen, eliminates how much processed semen we can produce for sale on one ejaculate. We couldn't pre-qualify unless we submitted serology testing. This could limit how many bulls we could offer NZ.

Testing for some of their added disease are not quality tests : M. bovis, borna, etc. Not to mention, the actual possibility of transmitting these diseases thru frozen semen doesn't seem to be taken into consideration at all.

Bluetongue

We would like to see a BTV PCR on semen as a possible option.

Lab test results

Point 24- This asks for test results for the health paper, the next part, are they asking for test results for the isolation(qualification to enter) and semi-annual testing. It is enough to have to provide test results for the health paper test date but to add isolation & semi-annual testing too is much. They would be getting a book for each bull. The other sections that refer to pre-entry for the various test- I hope they don't want the copies of test to go with it either. It would take days to get the documents together for one health paper if this is what they are wanting! Finally, we should strive to get away from sending tests results with the health certificate and they appear to be asking for more! An accredited veterinarian signs the paper attesting the health testing as well as the federal veterinarian but they want to see the actual test results.

Thank you for the opportunity to provide comments.

Kristy Scott
World Wide Sires Ltd

7. Kaitoa polled Herefords; Philip Barnett – 03/08/2010

Submission on the Draft Import Standard for Bovine Embryos and semen

1/08/2010

Firstly I wish to acknowledge the tremendous efforts MAF has shown in keeping dangerous organisms out of New Zealand.

I commend the proposal to link protocols with international guidelines, standards and recommendations and the use of different alternative tests.

I wish to submit there is a case for on farm collection of embryo's in North America/ Australia providing the protocols you have outlined are met, and the service is carried out by approved providers . By limiting collection to approved centers it is creating a monopoly and another layer of cost.

Finally I failed to obtain` list of approved countries from which to export in the guidance document.

Philip Barnett
Kaitoa polled Herefords
R.D.9
Dannevirke

8. Livestock and Animal Germplasm Trade Association; Jim Edwards - 03/08/2010

Dear Mey

Please find attached a submission from the Livestock and Animal Germplasm Association.

Kind regards
Jim Edwards
Secretary

LAGTA Submission on the draft "Import Health Standard for Bovine Embryos" Page 1
Livestock and Animal Germplasm Trade Association

2 August 2010

Submission on the draft "Import Health Standard for Bovine Embryos"

BACKGROUND:

New Zealand has been importing embryos from a selection of approved countries for nearly 40 years. To date there have been no reported incidents or incursions relating to biosecurity or disease transmission from this method of germplasm movement

The OIE Terrestrial Animal Health Code 2010 Article 4.7.5 on Risk Management states:

"With regard to disease transmission, transfer of in vivo derived embryos is a very low risk method for moving animal genetic material."

SUBMISSIONS:

1. Part B, paragraph 13:

"During the collection of embryos for consignment to New Zealand, and until the testing specified in this standard was completed, donors were held in a veterinary authority approved and registered embryo collection facility. During this time they were isolated from animals not of an equivalent health status."

The requirement to hold donors in an approved embryo collection facility does not accord with either the OIE or the OAP.

The definition of embryo collection facility (centre) refers only to the place of collection and in fact there is no definition of a collection of facilities that incorporates a holding facility to perform the donor hormone programming regime (during which time supposed isolation would take place).

The new OAP made this very clear with a specific definition of collection facility 8.5.1.b so the requirement in section 13 of the IHS is inconsistent with the OAP definition as well as the definition in the OIE glossary.

The phrase "*During the collection of embryos*" quite clearly refers to the period when the veterinarian or technician is collecting the embryos from the donor in the approved facility for this purpose.

The only reference in the OIE to embryo collection is in fact 4.7.4.1.c which stipulates donors are to be inspected for signs of disease by a veterinarian at the time of collection.

The OIE Terrestrial Animal Health Code, Article 4.7.4, paragraph 1.b, states only that "the donor animals should not be situated in a herd/flock subject to veterinary restrictions for OIE listed disease or pathogens for relevant species (see Chapter 1.2. of the Terrestrial Code), other than those that are in IETS Category 1 for the species of embryos being collected (see Article 4.7.14. and footnote1)."

Article 4.7.2 requires that the embryo team be supervised by a "specifically approved" team veterinarian, and goes on to state that:

"The collection team should have adequate facilities and equipment for:

- a. collecting embryos;
- b. processing and treatment of embryos at a permanent site or mobile laboratory;
- c. storing embryos.

These facilities need not necessarily be at the same location."

Nowhere in the OIE Code Chapter 4.7. "Collection and Processing of *in-vivo* derived Embryos from Livestock and Horses" is there a requirement for the donors to be resident on a registered

embryo collection facility, so this is clearly an anomaly that is open to misinterpretation by overseas competent authorities.

Similarly, MAF Biosecurity's "Revised Official Assurance Programme - Live Animals and Germplasm" does not require donors to be resident in a registered embryo collection facility. Part 8 of the OAP, "Requirements for Embryo Teams" states that "this part sets out the requirements for New Zealand embryo teams to be approved for collecting, processing and storing embryos from ruminants, equidae and other species for export" and that "these requirements are based, in part, on the recommendations related to collection, processing and storage of embryos in the OIE Code and IETS Manual, and will be used when auditing embryo teams."

The Livestock and Germplasm Trade Association therefore considers that the imposition, by the draft IHS, of having to hold donors in a registered embryo collection facility cannot be justified and in fact that MAFBNZ have confused terminology and have proposed requirements inconsistent with both the OIE, IETS and their own OAP.

The Association submits that it would be sufficient to require that donors be isolated from any other animals of a non-equivalent health status from the time of pre-collection testing until the embryo collections have been completed.

Recent communication from Dr Stone indicated that this requirement was related to the risk analysis for BVD type 2.

However the recommendation was related more to semen centres and the attempt to align embryo collection with semen collection, as far as donor isolation, should not necessarily follow.

2. Part B, paragraph 13:

"During the collection of embryos for consignment to New Zealand, and until the testing specified in this standard was completed, donors were held in a veterinary authority approved and registered embryo collection facility. During this time they were isolated from animals not of an equivalent health status."

The LAGTA submits that keeping donors in isolation after the collection of the embryos, and until the completion of any post-collection health testing, is not necessary from a biosecurity viewpoint. Once the embryos have been collected and frozen, there is no risk to them from the donors being in contact with animals of a lesser health status.

The risk of the donors becoming sero-positive after contact with these animals, and thus failing a post-collection health test, is purely a commercial risk on the part of the owner of the donors. Further, there is no requirement for such mandatory post collection isolation in either the OIE guidelines, the IETS manual or the NZ OAP.

3. Part B, Paragraph 14:

"Prior to collection of embryos for this consignment the donors must be subject to a period of isolation of at least 30 days in accommodation specifically approved for this purpose by the veterinary authority of the exporting country.

During this time they were isolated from animals not of an equivalent health status". There is no requirement for any mandatory donor isolation in either the OIE guidelines, the IETS manual or the NZ OAP.

There appears to be concern within MAFBNZ related to the risk of BVD2 infection related to embryos, and this has been promulgated as the reason for the imposition of this inconsistent request. The LAGTA submits that there may be adequate biosecurity reasons for pre-collection isolation for importations from countries where this or other diseases may present a risk.

However, this does not currently apply to the main regions (the EU, Canada and Australia) from which most embryos are being imported. The requirement for pre-collection isolation of donors should therefore not be mandatory, but should be decided on a country by country basis.

Article 4.7.5 of the OIE code related to risk management involving in vivo derived embryos states in section 3 that risk mitigation for diseases not included in IETS Category 1 should be based on:

- a) post collection surveillance of donors
- b) testing of embryo fluids etc and or blood samples which appears to be related to the post collection period and relative incubation periods of disease agents

4. Paragraph 16:

This paragraph is not consistent with OIE guidelines. It should reflect the wording in OIE section 4.7.4.1.c

5. Paragraph 17:

Given the LAGTA submission number 3, above, bullet point 3 may need to be changed to reflect changes to donor isolation requirements.

6. Paragraph 19:

It is not possible to identify embryos other than by DNA testing. The wording of this paragraph should be changed so that it is the straw containing the embryos that are identified, not the embryos themselves.

7. Paragraph 22:

There should be reference to indelible labeling of the actual straw or ampoule. If an attached plug is used for a label, or if gummed labels are used, these must be permanently attached but the straw itself should also be indelibly labeled, at least with a cipher or code and an individual straw number.

The IETS also requires an individual straw identification for every straw.

8. Paragraph 30: bullet point #3

The LAGTA submits that it should not be necessary for copies of laboratory reports to be included in the accompanying documentation if the Team Veterinarian has signed an ED or export certificate or health certificate which has been sighted and signed over by the exporting country competent veterinary authority prior to export. This appears to be overkill and certainly is not consistent with the NZ OAP and export procedures. This paragraph also refers to donors "resident on a collection facility", which is inconsistent with the LAGTA submission number 1 above.

9. Paragraph 53

This paragraph refers to a mandatory donor isolation period which is inconsistent with submission number 3 above.

10. Part C Specific Requirements for Identified Risk Organisms.

There is inconsistency between testing requirements for donor testing and isolation, particularly between BVD2 and *M. bovis*. The former is an IETS category 3 disease, yet has a more stringent pre-entry requirement than *M. bovis*, which is a category 4 disease. This appears to be without logic and there is no link between IETS categories and the requirement for mandatory donor isolation as per semen IHS, in fact quite the contrary. The LAGTA submits that isolation and testing requirements for BVD2 should be more in line with those for *M. bovis* and Q Fever, namely post collection serological testing and / or post collection PCR testing of collection or washing fluids.

11. Inconsistency with trading partners

The sections in the Draft IHS related to disease testing and embryo donor mandatory isolation are not consistent with those in the Import Health Standards for embryos imported into Australia. For example, the requirements for BVD2 testing of donor cows and donor isolation. Submitted on behalf of the Livestock and Animal Germplasm Association

J D Edwards

Secretary

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9. Federated Farmers of New Zealand; David Burt – 02/08/2010

Good afternoon Mey,

Please find attached the Federated Farmers Submission on the Bovine Semen [“bovsemid.gen”] and Bovine Embryo [“bovemid.gen”] Draft Import Health Standards, comment on which is due today.

Regards,

Dave Burt

DAVID BURT
POLICY ADVISOR, MEAT & FIBRE

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SUBMISSION TO BIOSECURITY NEW ZEALAND ON TWO DRAFT IMPORT HEALTH STANDARDS “BOVINE SEMEN” AND “BOVINE EMBRYOS” 1. FEDERATED FARMERS CONCERNS

Federated Farmers is supportive of the move towards a two level system to more effectively manage Import Health Standards – generic IHS documents that focus on identified risks (independent of specific markets) complemented by market focused “guidance measures” that identify how the identified risks will be managed.

One exception to our support is the wording of the IHS Clause concerning the negotiation of the content of Zoosanitary Certificates. While it is accepted that this will involve a dialogue with the veterinary authorities in countries wishing to export bovine germplasm to New Zealand, the proposed wording (*MAF ... will negotiate ...*) implies that MAF could potentially accept measures that do not fully mitigate identified risks. Replacing “negotiate” with “MAF ... will determine” would ensure that decisions around risk mitigation remain with the New Zealand authorities.

A number of other changes to the wording of the two IHS documents are also suggested. We would be pleased to discuss these matters with you in more detail should you believe this is necessary. Please contact David Burt, Policy Advisor Meat & Fibre [dburt@fedfarm.org.nz; DDI 04 494 9182] in the first instance.

2. BACKGROUND

Our Submission is in accordance with the request for comment on the above draft documents [“bovsemid.gen” (Bovine Semen, 21 June 2010) and “bovemid.gen” (Bovine Embryos, 21 June 2010)] by the Senior Advisor, Animal Imports, in an e-mail dated 22 June 2010.

In addition, a draft document referenced in the e-mail “Risk management proposal: Bovine semen and embryos FOR PUBLIC CONSULTATION” (21 June 2010) was also read.

3. GENERAL COMMENTS

3.1 Streamlining of the IHS process

Federated Farmers understands that IHS documents will become more generic in nature - rather than market focused as they are now - and that the mechanism(s) to be used to meet

IHS requirements around the importation of animal material are to be detailed in separate, market specific, “guidance documents”.

The Federation is supportive of this change, with the proviso that a process exists to ensure the relevant guidance and other documents are updated appropriately when the underpinning IHS documents are amended.

3.2 Negotiation of Zoosanitary certificate content [PART A: Outcomes, Clause #9]

The standards state that “*MAF and the veterinary authority of the exporting country will negotiate*” and, later, “... *Upon conclusion of the negotiations ...*”

An alternative, stronger wording is suggested for the first sentence of this section:

“*MAF will, in conjunction with the competent veterinary authority of the exporting country, determine how the relevant identified risks are to be managed.*”

3.3 Alignment of the two IHS [“bovsemid.gen” (Bovine Semen, 21 June 2010) and “bovemid.gen” (Bovine Embryos, 21 June 2010)] documents

The structure and content of these documents is, as might be expected, very similar.

Examining the two documents however, there are a number of differences in the wording not attributable to the different (semen/embryo) foci. For example, the wording of clause relating to the disinfection of transport containers (#’s 21 and 25 for semen and embryos respectively) is different, with requirements around the disinfection process specified for the latter but not the former.

It is recommended that the two documents – if it is not feasible to combine them – should be examined to ensure that, where appropriate, the wording used is consistent and current.

[Page 3 of the draft Risk Management Proposal document notes that “... *the import health standards for bovine semen and embryos are presented in a single standard ...*”. Does this mean that they are to be published as one document?]

3.4 Document phrasing

The preamble (eg Part A) of the documents – correctly - frequently uses “imperative” phrasing, such as “... *the requirements that must be met ...*” [Scope, #4, page 3], but a number of the [Part C] “Requirements” are written as “... *must have been ...*” [eg #’s 17 – 19 (Semen)] or “... *were*” [eg #’s 19 – 20 (Embryos)]. It is recommended that the requirements to be met are written in “*must be*” form.

4. SPECIFIC COMMENTS

4.1 Part B: Donor and centre health status

Clause #16 includes the sentence that ends “... *evidence of infectious diseases caused by micro-organisms transmissible in semen.*” be rewritten as “*evidence of diseases of concern.*”

4.2 Part B: Semen collection, processing storage and transport

Clause #20 of the Semen IHS requires that semen “*must have been stored only with other embryos or semen that is eligible for export to New Zealand*”. How is this requirement reconciled with the need to effectively quarantine/store semen while it is undergoing testing – the results of which may make it (in)eligible for export to New Zealand?

4.3 Part C: Specific requirements – Bovine viral diarrhoea type 2

4.3.1 The terminology used is inconsistent in that this disease is referred to both as “BVD2” and “BVDV2”.

4.3.2 The draft “Risk management proposal” document refers, in respect of this disease, to the need for a “validated RT-PCR” (page 7), but the requirement for a validated test is omitted in the Semen IHS [**Clause #35**].

4.3.3 In a similar vein, in discussing this disease, the draft “Risk management proposal” notes (paragraph 2, page 7) that “*at present there is no validated VI or RT-PCR test that could be used for germplasm*”. In this case, should both the VI and RP-CR tests have a requirement for a validated test in the IHS?

4.4 Part C: Specific requirements - Crimean Congo haemorrhagic fever

4.4.1 The wording of both the IHS is, in part, ambiguous, in that **Clause #37 (Semen) or #38 (Embryos)** refers to “*Verification of tick freedom ... at least monthly where no ticks were found.*” This statement could usefully be reworded as “... *at least monthly with negative results*”.

4.4.2 **Clause #38 (Semen)** refers to “... *until 21 to 60 days after the conclusion of embryo collection ...*”. Should this instead be “... *semen collection ...*”?

4.5 Part C: Specific requirements – Foot and mouth disease

Clause #41 (Semen, Embryos) states “... MAF ... or require any other measures deemed necessary to ensure compliance with facility and operating standards upon which the approval is based.” This statement could usefully be made stronger by restating it as “... MAF ... take any other measures necessary to ensure the conditions on which the approval is based are met.”

4.6 Part C: Specific requirements – Vesicular stomatitis

Clause #51 (Semen) states “... until 30 days after collection for export to New Zealand”. Should this instead state “... until 30 days after collection of semen for export ...”

4.6 Part C: Specific requirements – Bovine brucellosis

Clause #7 of the Semen IHS identifies several Brucellosis organisms of concern (*B. abortus*, *B. melitensis*, *B. suis*), but **Clause #53**, refers only to *B abortus*. Is this intentional?

4.7 Part C: Specific requirements – *Mycoplasma bovis*

Clause #61 (Semen) states “... on a sample collected between 21 and 120 days after the last collection of germplasm ...”. Should this be rewritten as “... after each collection” as is the case in Clause #59 of the Embryos IHS?

4.8 Risk Management Proposal document - Other Mollicutes

Under the “Other risk management considerations” heading (page 15), there is a highlighted word apparently requiring comment.

4.9 Risk Management Proposal document – Leptospirosis

It is accepted that the identified risks around this disease (pp 16 – 17) are addressed by the inclusion of measures included in the general text [Part B] of the IHS. Nevertheless, if the audience for the publications under discussion is intended to encompass people who may not have a good technical level of understanding of the subject, it would be useful to include (eg as a footnote in the Risk Management Proposal document), a comment referring readers to where in the IHS documents this risk is dealt with.

5. ABOUT FEDERATED FARMERS OF NEW ZEALAND

5.1 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.

5.2 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.

10. Beef + Lamb New Zealand Ltd & Meat Industry Association; Chris Houston - 02/08/2010

Dear Mey,

Please find attached a copy of a joint submission from ourselves and the Meat Industry Association on the draft IHSs for bovine germplasm and associated documents. Please confirm receipt.

Best wishes,
Chris

Chris Houston | Senior Advisor - Technical Policy

beef + lamb new zealand ltd

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SUBMISSION TO MAF BIOSECURITY NEW ZEALAND

On the consultation documents:

**Import Health Standards: 'Bovine Semen', 'Bovine Embryos'
and the 'Risk management proposal :
Bovine semen and embryos'**

**By Beef + Lamb New Zealand Ltd and the Meat
Industry Association 02 August 2010**

1. Introduction

1.1 Beef + Lamb New Zealand Ltd (B+LNZ) and the Meat Industry

Association (MIA) welcome the opportunity to make a submission on the documents: "Draft Import Health Standard for Bovine Semen", Draft Import Health Standard for Bovine Embryos "and "Risk management proposal : Bovine semen and embryos".

1.2 B+LNZ is an industry-good body funded under the Commodity

Levies Act through a levy paid by producers on all cattle and sheep slaughtered in New Zealand. B+LNZ's activities aim to increase preference for New Zealand beef and sheep meat internationally and domestically; to maintain and extend trade access for New Zealand red meat; and to fund research and development to help improve the profitability of New Zealand farmers.

1.3 B+LNZ's contact for this submission is:

Ben O'Brien

Beef + Lamb New Zealand Ltd

P O Box 121

Wellington

Phone: (04) 474 0839

Fax: (04) 474 0800

Email: Ben.OBrien@beeflambnz.com

1.4 The Meat Industry Association of New Zealand Inc (MIA) is a voluntary trade association representing New Zealand meat processors, marketers and exporters. It

is an incorporated society (owned by members) that represents companies' supplying the majority of New Zealand sheep meat exports and all beef exports.

1.5 MIA's contact for this submission is:

Kevin Cresswell

Meat Industry Association

P.O Box 345

Wellington

Phone: (04) 4958377

Fax: (04) 473 1731

Email: kevin.cresswell@mia.co.nz

2. General comments

2.1. B+LNZ and the MIA support the provision of new streamlined IHSs for bovine germplasm as, well managed, this pathway generally represents a lower risk of the import of risk organisms than live animals.

2.2. The absence of clear information indicating how and why the current proposals differ, both materially and in respect to consequential risk, from the current status quo has made meaningful review of these drafts challenging. B+LNZ and MIA strongly recommend that such information be provided as part of future consultation rounds for these types of documents.

2.3. Point 2.2 above is exacerbated by the fact that specific arrangements will be negotiated bilaterally at some future point, hence limiting the understanding achievable by reviewers of the proposed future risk management regimes. This is further complicated by the omission of the approved countries list that is referenced to the guidance document for the standards themselves.

2.4. Ease of review would be facilitated by providing the guidance document that is intended to accompany the standards.

2.5. The level of expertise available to B+LNZ and MIA for undertaking critical review of these documents is limited. Accordingly, and acknowledging MAF's mandate in this area, both organisations place a high level of trust in the judgement of officials to maintain appropriate levels of risk management for all potential pathways for the entry of risk organisms into New Zealand.

2.6. We note that post-border traceability of germplasm imports is governed by Regulations 6, 7 and 8 of the Biosecurity (Imported Animals, Embryos, and Semen Information) Regulations 1999. We trust that MAF will provide adequate regulatory oversight and audit compliance with these regulations, taking appropriate action where non-compliance is found.

2.7. B+LNZ and MIA appreciate the opportunity to provide comment on these documents. Please do not hesitate to contact us should you require clarification of any of the points raised above.

11.DairyNZ and DCANZ; Fiona Hutchinson - 06/08/2010

Dear Mey,

Please find attached comments from DairyNZ and DCANZ on the draft IHS for bovine semen and embryos. Please accept my apologies for this late submission – as you will see from the attached submission we found the process of developing our comments to be more time-consuming than anticipated. Please pass on our thanks to Mark Mirkin for letting put in a late submission.

Regards,
Fiona.

Fiona Hutchinson
Senior Policy Analyst

DairyNZ

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Import Health Standards: Bovine Semen, Bovine Embryos and Risk Management Proposal – Bovine Semen and Embryos

Submission from DairyNZ and DCANZ 6 August 2010

Summary

1 DairyNZ and the Dairy Companies Association of New Zealand (DCANZ) welcome the opportunity to comment on the Draft Import Health Standard for Bovine embryos and semen and the Risk Management Proposal for Bovine Semen and Embryos. We support the establishment of a new process for managing the development of new Import Health Standards (IHSs), and their basis being technical risk analysis undertaken to identify the hazards, assess the risks, and determine suitable risk management options where justified.

2 DairyNZ and DCANZ have a number of serious concerns regarding the IHSs and the Risk Management Proposal (RMP). No reference is made in these documents to the risk mitigation steps applied by the New Zealand bovine germplasm processing industry in relation to endemic diseases they currently manage. We would contend that these or equivalent measures should be referenced in the IRA and included in the IHSs.

3 The IHS and RMP must be amended to make it explicit that the commodities being considered are frozen semen and in vivo derived frozen embryos from healthy cattle.

4 Comparison of the Import Risk Analysis and subsequent RMP with the accompanying IHSs has identified some changed positions in relation to identified hazards, risk assessment and or risk management measures. The consultation documents do not provide an adequate explanation of the rationale supporting these changed positions. We have initial comments in relation to 15 of these changed positions. However, these comments should be regarded as preliminary only and

further discussion is required between MAF BNZ and the *production* animal industry technical staff must occur before DairyNZ and DCANZ are able to provide their final views on the proposed documents.

Introduction

5 DairyNZ and DCANZ welcome the opportunity to comment on the Draft Import Health Standard for Bovine embryos and semen and the Risk Management Proposal for Bovine Semen and Embryos.

6 DairyNZ is the industry good organisation representing New Zealand's dairy farmers. Funded by a levy on milksolids and through government investment, our purpose is to secure and enhance the profitability, sustainability and competitiveness of New Zealand dairy farming. We deliver value to farmers through leadership, influencing, investing, partnering with other organisations and through our own strategic capability. Our work includes research and development to create practical on-farm tools, leading on-farm adoption of best practice farming, promoting careers in dairying and advocating for farmers with central and regional government. For more information, visit www.dairynz.co.nz

7 DCANZ represents the collective views of the dairy industry on relevant public policy issues. DCANZ members currently include Fonterra Co-operative Group, Westland Milk Products, Tatua Co-operative Dairy Company, Goodman Fielder, NZ Dairies, Fonterra Brands NZ, Open Country Dairy and Synlait Milk.

8 This submission has been prepared by the Policy and Advocacy team of DairyNZ and DCANZ technical advisors. The primary contact for this issue is:

Fiona Hutchinson
Senior Policy Analyst
DairyNZ
PO Box 10002
Wellington 6143

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Fax (04) 471 6909
e-mail: fiona.hutchinson@dairynz.co.nz

Comments

9 DairyNZ and DCANZ support the establishment of a new process for managing the development of new Import Health Standards (IHSs), and their basis being technical risk analysis undertaken to identify the hazards, assess the risks, and determine suitable risk management options where justified.

10 We recognise the strong value proposition that importation of germplasm makes to the New Zealand dairy industry and also other sectors of the cattle industry. We accept that germplasm importation properly managed should present less risk than live animal importation in relation to the introduction of diseases exotic to New Zealand. When considering risk management for imported germplasm it must also be recognised that other options exist rather than current direct widespread dissemination of germplasm once imported. Examples of this would include the use of quarantine herds and then subsequent multiplication and dissemination of animals and/or germplasm when

absence of pathogens has occurred. These may be of some value when considering how risks are managed for identified diseases where some degree of uncertainty exists regarding the adequacy of pre-border risk mitigation measures.

11 The Ministry of Agriculture and Forestry's Import Risk Analysis (IRA): Cattle germplasm from all countries ISBN 978-0-478-3316-4, 13 February 2009, is an excellent document and sets out clearly the details regarding hazards, and risk mitigation steps including commentary on their adequacy, for diseases exotic to New Zealand and where diseases endemic to New Zealand are under official management, e.g. bovine tuberculosis. No reference is made in this or the consultation documents to the risk mitigation steps applied by the New Zealand bovine germplasm processing industry in relation to endemic diseases they currently manage. We would contend that current domestic measures are designed to ensure bovine germplasm does not transmit diseases of economic significance to the cattle industry and these or equivalent measures should be referenced in the IRA and included in the IHSs. If the issue is one of the risk management measures used domestically not being 'Officially Mandated' by MAF BNZ, then consideration needs to be given to rectifying this situation.

12 Section 4 of the IRA under Commodity Definition states that the commodities being considered are frozen semen and *in vivo* derived frozen embryos from healthy cattle. Neither the Risk Management Proposal (RMP), 21 June 2010, nor the IHSs refer to this statement. The draft IHSs must be explicitly defined as only applying to these commodities and not covering fresh semen, *in vitro* derived embryos, and cloned embryos. An additional assumption in the IRA is that the commodities '*be stored in a frozen state for at least 28 days before shipment to New Zealand and that during this time the donor animals and all animals in contact with them will have remained healthy and free from any diseases that are considered to be of non non-negligible risk in this risk analysis.*' This statement along with appropriate measures designed to demonstrate freedom from the specified diseases needs to be reflected in the IHSs. The current drafts do not appear to reflect this situation adequately.

13 Initial comparison of the IRA and subsequent RMP with the accompanying IHSs has identified some changed positions in relation to identified hazards, risk assessment and or risk management measures. The consultation documents do not provide an adequate explanation of the rationale supporting these changed positions. The following sets out our initial comments in regard to these and also in relation to some of the initial risk management measures proposed. These should be regarded as preliminary only and requiring greater clarification from the authors of the IRA and IHSs documents:

- a. **Bluetongue:** Agreement with the proposed IHS measures and their justification even though the IRA describes the risk as negligible.
- b. **Borna disease:** We require more information about why a more general MAF approved test is specified in the IHS instead of the specific methods stated in the IRA.
- c. **BVD:** Specific requirements solely relating to BVDV 2 are not accepted as adequate. It is our view that other strains of BVD including endemic strains are of economic importance and must not be present in imported (and domestically produced) germplasm. Risk management steps must be in place to ensure BVDV is not present. In our view it is reasonable to require the germplasm collection premise to be free of BVDV in accordance with the OIE Code.

- d. **Crimean Congo Haemorrhagic Fever (CCHF):** Additional detail is sought in regard to why both 37 and 38 should not be combined to effectively manage the risks in countries where the disease is present.
- e. **Foot and Mouth disease:** Greater detail is required to provide assurances that the proposed management measures in the IHSs relating to countries where FMD is present will adequately mitigate the risk. Given the very significant impact FMD would have on sectors of New Zealand's livestock industry our strongly preferred position is that imports only occur from countries recognised as FMD free. The IRA clearly states; *'in the view of the extreme seriousness of the disease and the catastrophic consequences that could result from the introduction of FMDV, it could be considered that the OIE recommendations for bovine germplasm are not sufficient to provide the appropriate level of protection against this hazard and importation of germplasm from countries that are infected with foot-and-mouth disease could be prohibited.'*
- f. **IBR/IPV:** The proposed measures are supported.
- g. **Lumpy Skin Disease:** Information is requested in regard to the sensitivity of the current validated PCR tests.
- h. **Rift Valley fever:** We would question the achievability of the proposed management measure of holding donor animals in mosquito free premises. Evidence is sought that this has been achieved and that it has consistently managed the hazard.
- i. **Vesicular stomatitis:** As for Rift Valley Fever.
- j. **Bovine brucellosis:** The management proposals are supported
- k. **Bovine tuberculosis:** Clarification is required in regard to the OIE Tb freedom requirements as stated in the IHSs. If it is a period prevalence of < 0.2% but the disease is still present in cattle in the exporting country then additional testing requirements for donors may need to be applied.
- l. **Contagious bovine pleuropneumonia:** It is recommended that consideration be given to adding a post collection test of the donor animal to those already proposed.
- m. **Mycoplasma bovis and other Mollicutes:** We accept the requirements proposed for Mycoplasma bovis but question the justification for not including the other exotic Mollicutes identified in the IRA as causing disease conditions of economic significance in cattle, and the fact that likelihood of transfer by semen or embryos is considered non negligible.
- n. **Exotic Salmonella:** The justification for not including management requirements for exotic salmonella, specifically S. Dublin and S.typhimurium DT104 is not accepted. The cost of culture is not regarded as significant relative to the hazard being managed and potential impact of introduction of these species spp within the New Zealand cattle population.
- o. **Q fever:** The proposed management measures are supported.

14 Given the issues set out above we believe it is essential that a meeting occur between the *production* animal industry technical staff and BNZ technical staff to allow sharing of technical information and viewpoints. We acknowledge that previous consultation has occurred between BNZ and industry technical staff, however this occurred primarily with those associated with the processing and/or importation of germplasm. We believe that further joint discussions would allow all parties to establish what is technically feasible and reasonable and also complies with New

Zealand's international obligations under the WTO SPS agreement and international technical standards.

15 DairyNZ would like to thank MAF BNZ for the opportunity to comment on the Draft Import Health Standard for Bovine embryos and semen and the Risk Management Proposal for Bovine Semen and Embryos. We look forward with engaging with MAF BNZ on these standards as they move forward.

12.Canadian Food Inspection Agency (CFIA) – Embryo & Semen – 20/08/2010

To: New Zealand SPS Notification Authority and Enquiry Point
From: Canadian Enquiry Point

Attached you will find comments from Canada on notification G/SPS/N/NZL/440, which concerns three documents: New Zealand's *Import Health Standard for bovine semen*; *Import Health Standard for bovine embryos*; and *Risk management proposal: Bovine semen and embryos*. (The notification in question is enclosed for your convenience.)

We ask that you kindly respond directly to Mr. Daniel Burgoyne of the Canadian Food Inspection Agency (CFIA), and copy the Canadian Enquiry Point in your reply. Please send the copy to enquirypoint@scc.ca and to aspencer@scc.ca. Below is Mr. Burgoyne's contact information:

Mr. Daniel Burgoyne
A/Director, Bilateral Relations and Market Access Division
International Policy Directorate
Canadian Food Inspection Agency (CFIA)
1400 Merivale Road, Tower 1, Floor 5, Room 256
Ottawa, Ontario K1A 0Y9
Telephone: 613-773-6072
Fax: 613-773-6088
E-mai: Daniel.Burgoyne@inspection.gc.ca

Your acknowledgement of receiving the attached comments would be greatly appreciated. Please send the acknowledgement to enquirypoint@scc.ca and to aspencer@scc.ca.

Please do not hesitate to communicate with me should you have any questions.

Warmest regards,
Andrea Spencer
Coordinator, Enquiry Point / Coordonnatrice, Point d'information (Canada)
Standards Council of Canada / Conseil canadien des normes
Tel/Tél: (613) 238-3222 ext./poste 479
Fax/Télé: (613) 569-7808
E-mail/Courriel: aspencer@scc.ca

Sally Jennings
Coordinator
SPS New Zealand
PO Box 2526
Wellington, New Zealand

**SUBJECT: CANADA'S COMMENTS ON WORLD TRADE ORGANIZATION (WTO)
NOTIFICATION G/SPS/N/NZL/440**

Dear Mrs. Sally Jennings,

Canada appreciates the opportunity to comment on the above notification, dated June 24, 2010 concerning New Zealand's draft Import Health Standard (IHS) for bovine semen, IHS for bovine embryos, and Risk Management proposal for bovine semen and embryos.

This notification, outlines proposals for two IHS to provide New Zealand with mitigation measures for a number of diseases related to bovine semen and embryos. Please find attached to this letter, two documents with Canada's comments on New Zealand's IHS for bovine semen and IHS for embryos.

These comments reflect the practice and programs in Canada and we submit them to you for your consideration and in order to help facilitate future trade in these products.

Yours truly,



Daniel Burgoyne
A/Director, Bilateral Relations and Market Access Division
International Policy Directorate
Canadian Food Inspection Agency

Attachments:

CFIA comments on New Zealand Import Health Standard (IHS) for bovine semen
CFIA comments on New Zealand Import Health Standard (IHS) for bovine embryos

Canada

Document commented: Import Health Standard (IHS) for bovine embryos

Short name: bovemid.gen, dated June 21, 2010

Part A. BACKGROUND, SCOPE AND OUTCOMES

Article 7: *Mycoplasma bovis* is not a notifiable disease in NZ.

Part B. GENERAL REQUIREMENTS

Article 11: The CFIA raises the point that after a period of 60 days, an imported animal becomes a Canadian animal. The reference to the 60 days residency period in the exporting country is actually included in certification of bovine embryos from Canada to NZ and there is no scientific reason to augment this period to 90 days. Animals are regularly imported from the USA and a period of 60 days is sufficient to evaluate the health status of an imported

animal. Furthermore, a change in the period could compromise eligibility of embryos that are presently or were collected for NZ. The period of 30 days in the herd of origin is a reasonable period. The CFIA suggests the residency period for imported animals remains to 60 days.

Article 13: There is questioning about the mandatory requirement to have the donor cows maintained in isolation in the approved embryo collection facility until testing specified in the standard is completed. The rationale of maintaining donor cows in isolation away from animals not of an equivalent status is to provide confirmation no changes in the health status of the donors have take place since collection. A period of 21 days is considered enough to reach this confirmation. Past this period, it should be optional for the owner to have his animal in contact with other animals with the possibility to fail a test due to such contact. The CFIA suggest that maintenance in isolation in the approved embryo collection centre is limited to 21 days.

Article 15: There is a logical reason to ask that the herd of origin remains free from any quarantine restrictions for a certain period before the first embryo collection for the consignment to NZ. This 90 days period required is long and should be at the maximum 60 days, which is more than the double of incubation period of majority of quarantine diseases. A period of 60 days is the actual requirement to export bovine embryos to NZ. The CFIA suggests the quarantine restrictions period in the herd of origin and the approved embryo collection facility remains as it actually is, 60 days preceding the collection of the first embryo for the consignment until completion of testing.

Article 17: The CFIA suggest that the second indent reads as follows to exclude IBR/IPV as this disease is not transmitted by bovine embryos when they are treated with trypsin in accordance with the IETS Manual (article 20):

o “was collected and processed at a semen collection centre that fully complies with the current OIE Code chapter on collection and processing of bovine semen, except IBR/IPV which is optional;”

This precision for frozen semen is in line with the requirements where natural service is used, in which case neither the donor cow nor the donor bull are tested for IBR/IPV.

Article 21: Most Canadian embryo collection teams if not all, use media and solutions for collection, processing, washing or storage of embryos purchased from commercial sources that are offering their products internationally. These supply companies have their products screened for the presence of pathogenic organisms, including pestiviruses. These products also contain antibiotics. A regular inspection of embryo collection teams is done by CFIA trained officers as per the Canadian Embryo Export Approval Program and there is verification of media and solutions used at this moment. This comment is to precise this requirement is fulfilled under the Canadian program and the CFIA veterinarian who signs the export certificate relies on this procedure.

Article 22: No code is allowed to identify embryos collected in Canada; the IETS code of the collection team, identification of the donor along with collection date are mandatory and must follow IETS straw identification standards.

Article 30: The CFIA never provided copy of tests to NZ nor any other destination country as the Canadian Privacy Act prevents CFIA to do so. Instead, a summary of all tests is provided in a table which is part of the certificate. In Canada collection of samples may be either done by the approved embryo team veterinarian or a CFIA staff and are sent to a CFIA laboratory; laboratory reports are received electronically by the CFIA district officer and the laboratory report system belong to the CFIA. The accession number reference is not relevant as all results are within the CFIA laboratory system. Only in very rare occasions, CFIA may allow for a test in a laboratory other than CFIA.

Part C. SPECIFIC REQUIREMENTS FOR IDENTIFIED RISK ORGANISMS

Codes used with regard to each disease:

TBN = conditions for this disease have to be negotiated

OK = this disease is not a concern for Canada.

Borna disease (BD): 3 certification options, article 31 to 33.OK

Article 31: no reported case in countries of residence of embryo donors. BD is an immediately notifiable disease in Canada and no case has ever been reported. As some donors can be of USA origin but collected in Canada, the USA also never reported a case of Borna virus. So this option can be used for now.

Article 32: confirmation the embryo donor have resided since its birth, in herds (this includes centres) where no BD case has been reported for the 5 years before embryo collection until conclusion of collection for export to NZ. The period of 5 years is arbitrary and should be revisited. This virus is not proven to have tropism for reproductive organs; the extrapolation for data collected on rats to cattle should not use as an impediment to trade.

Article 33: testing option for embryo/oocytes, collection fluids and /or washing fluids for the presence of the virus. Testing is not available at the moment on a regular basis in Canada. Test is to be approved by NZ, as there is no OIE guideline for tests.

Conclusion on Borna Disease: Actually Canada can use the 1st option (article 31) as this disease was never reported in Canada. Some Canadian donor cows are sourced in the USA which also never reported Borna disease. In the case Borna disease is further reported in Canada or the USA, the requirement to qualify the embryo donors for the 5 years before the embryo collection is excessive and should be revisited as there is no demonstration this virus can be spread by embryos. There is no OIE reference concerning Borna disease, neither in the Code or the Manual, so testing would be problematic. The CFIA questions the pertinence of this requirement.

Bovine viral diarrhoea type 2 (BVD2): 2 certification options, articles 34 to 36.....
TBN

Article 34: option country freedom. This option cannot be used by Canada as BVD is endemic in Canada.

Article 35: option centre freedom during collection destined to NZ.

The requirement is not clear for embryo donors as it is copied directly from the situation of semen donors. As there is no such pre-entry procedure for embryo donors, the requirement is not clear concerning prescribed test prior to entry into pre-entry isolation and during pre-entry isolation. The unique requirement is an isolation period of 30 days in an approved embryo collection facility (ref:article 14). The requirement mentioned at the 1st indent needs explanation as it seems that two sets of

BVD-antibodies and antigen tests are required before the donor cow is allowed to enter in the isolation facility for the collection of embryos. Furthermore seropositive donor cows must have samples of embryos/oocytes, collection fluids and/or washing fluids of all embryo collections examined for the presence of the BVD virus before dispatch while seronegative donor cows must be tested negative to an antibody test after embryo collection. In the latter case the number of tests required is not clear but as the plural form is used, this could mean at least 2 tests in total or one test following each embryo collection. These requirements exceed by far the OIE recommendations in Chapter 4.7 of the Terrestrial OIE Code. The CFIA requests that the actual requirement to export bovine embryos to NZ continues to be applied as before; this actual requirement asks for a BVD virus screening test of a pool of samples of embryos/oocytes, collection fluids and/or washing fluids of each donor cow whose embryos are exported to NZ.

Article 36: samples of embryos/oocytes, collection fluids and/or washing fluids of all embryo collections performed on each donor cow that have been less than 3 years on the embryo collection facility must be tested by BVDV2 virus isolation test.

This requirement is an addition to those mentioned in article 35. This test will have to be done at all times on both seronegative and seropositive donor cows as no permanent embryo collection facilities are in existence in Canada for the purpose to collect embryos destined to NZ due to the very small NZ market. This test also exceeds by far OIE recommendations.

This requirement should not apply to seronegative donor cows. Several farms have BVD

vaccination program and seropositivity is due to vaccination and in no case related to the presence of the disease; vaccination should be taken into account as regard to BVD-SN positive results. The 3 year period is arbitrary and should be revisited for BVD-SN positive donor cows. The CFIA request this requirement is dropped as seropositive donor cows are already tested before dispatch of embryos for the presence of the BVD virus in collections and washing fluids and seronegative cows tested for presence of antibodies after the conclusion of embryo collection for export to NZ (article 34, 3rd and 4th indent).

Conclusion on BVD:

As Canada cannot use the country freedom option, articles 35 and 36 apply all together. The BVD testing regime suggested by NZ requires that donor cows are tested several times using antibody and antigen tests. The requirements are not clear and extend over several years. These requirements are in excess of the OIE Code and excessive. Vaccination of donor cows is not taken into consideration. Furthermore it is excessive to require a post collection test for donor cows that tested negative. The

CFIA suggests that a unique and ultimate test is done for each donor cow and this test should be a BVD virus screening test of a pool of samples of embryos/oocytes, collection fluids and/or washing fluids of each donor cow whose embryos are exported to NZ, as per the OIE Code.

Crimean Congo haemorrhagic fever (CCHF): 3 certification options, articles 37 to 39.....
TBN

Article 37: the disease must be notifiable and no case reported in the 21 days before and during collection. There is a problem as CCHF is not notifiable in Canada but was never reported (OIE, WAHID 2009). This disease does not exist in North America. It should be sufficient to have this disease not reported in Canada without an obligation from NZ to have this disease being notifiable.

Article 38: option of treatment for ticks with acaricide and tick freedom of the centre. This option is not very practical.

Article 39: test option; this test is not offered for regular diagnostic in Canada; test will have to be implemented for a disease which is exotic to Canada.

Conclusion for CCHF:

This disease does not exist in North America. There is no confirmation this disease is transmitted by embryos. It should be sufficient to have this disease not reported in Canada without the requirement to have this disease being notifiable. According to article 7 of the IHS, it seems that CCHF is not notifiable in NZ, even it is exotic; if this is true, NZ should not require this disease is notifiable in Canada. It seems that both NZ and Canada are in the same situation concerning CCHF. Further discussion with NZ would be needed to accept freedom of this disease never reported, even though this disease is not notifiable.

Foot and Mouth Disease (FMD): 2 certification options, articles 40 to 41

.....OK

Article 40: option of 3 months country freedom without vaccination before embryo collection. Canada qualifies as a country free of FMD without vaccination in accordance with the OIE code. The other option is not considered.

Lumpy skin disease (LSD): 3 certification options, articles 42 to 44.....OK

Article 42: option of 6 months country freedom as defined by OIE before embryo collection. Canada qualifies as a country free of LSD in accordance with the OIE code. Other options not considered.

Rift Valley fever (RVF): 3 certification options, articles 45 to 47OK

Article 45: option of 3 months country freedom before and during embryo collection. Canada qualifies as a country free of RVF in accordance with the OIE code. Other options not considered.

Vesicular stomatitis (VS): 3 certification options, articles 48 to 50.....OK

Article 48: option of country freedom in accordance with the OIE code. Canada qualifies as a country free of VS in accordance with the OIE code. Other options not considered.

Bovine tuberculosis: 2 certification options, articles 51 to 53OK

Article 51: option of donors kept in a country or zone free since birth. Canada is considered free country in accordance with the OIE Code.

Article 52: option of herd of origin with no clinical signs plus article 53 as follows;

Article 53: herd free as per the OIE Code and TB test during the 30 days of mandatory isolation before embryo collection. This option allows for qualification of USA origin donor bulls resident in Canadian herds.

Conclusion on bovine tuberculosis:

The CFIA agrees to both options with covers for Canadian origin and USA origin donor cows.

Contagious bovine pleuropneumonia (CBPP): 2 certification options, articles 54 to 57.....OK

Article 54: option of country freedom in accordance with the OIE code. Embryo donors must be born and continuously resident in a free country. Canada qualifies as a country free of CBPP in accordance with the OIE code. The USA also qualifies as a CBPP free country.

Other option not considered (articles 55, 56 and 57).

Mycoplasma bovis: 3 certification options, articles 58 to 61 TBN

Article 58: requires that donor cows never recorded a positive test for *Mycoplasma bovis* in addition of one of the 3 options mentioned below;

Article 59 option to test donor cows post collection.

Article 60: option to test each embryo collection using a sample of embryos/oocytes, collection fluids and/or washing fluids.

Article 61: option to random test the herd of origin before/after 6 months of embryo collection destined to NZ.

Antibiotics are present in collection and washing fluids and they play a similar role than in semen. But control of *Mycoplasma bovis* is not proven as important as in semen. Serological testing of donor cows is not done in Canada and a test will have to be validated. The simplest option would be to examine samples of embryos/oocytes, collection fluids and/or washing fluids of all embryo collections performed on each donor cow.

Conclusion on *Mycoplasma bovis*

The CFIA suggests that a unique and ultimate test is done for each donor cow and this test should be a screening of *Mycoplasma bovis* from a pool of samples of embryos/oocytes, collection fluids and/or washing fluids of each donor cow whose embryos are exported to NZ, as suggested by the OIE Code.

Q fever: 3 certification options, articles 62 to 65.....OK

Article 62: requires that donor cows never recorded a positive test for Q-fever in addition of one of the 3 options mentioned below;

Article 63: option to test donor bulls post collection.

Article 64: option to test each collection using a sample of embryos/oocytes, collection fluids and/or washing fluids.

Article 65: option to random test the herd of origin before/after 6 months of embryo collection destined to NZ.

Conclusion for Q-fever:

The CFIA recognizes that NZ is free of Q-fever; thus testing is accepted. There is no scientific evidence that Q-fever is transmitted by embryos. The unique serological test available in CFIA laboratory for Qfever is the CF test. The CFIA agrees to test all embryo donors after collection using the CF test.

Document commented: Import Health Standard (IHS) for bovine semen

Short name: bovsemid.gen, dated June 21, 2010

Part A. BACKGROUND, SCOPE AND OUTCOMES

Article 7: *Mycoplasma bovis* is not a notifiable disease in NZ.

Part B. GENERAL REQUIREMENTS

Article 11: The CFIA raises the point that imported donor bulls from the USA must live for 90 days in Canada prior to entering in a semen collection centre. It is regular practice in Canada to import donor bulls directly into the pre-entry isolation facility of a centre. In such case the testing prior to entering pre-entry isolation facility done in the USA; these animals do not live in any Canadian herd before entry to avoid commingling and potential contamination. After a period of 60 days, an imported animal becomes a Canadian animal. The reference to the 90 days residency period in the exporting country and in the herd of origin for 30 days prior to entering a Canadian semen collection centre should be adapted to the North American situation where bulls can enter directly in the pre-entry isolation facility of a centre.

Article 15: this requirement is not clear. There is no logical reason to ask that both the herd of origin and the centre remain free from any quarantine restrictions from 90 days before the first semen collection for the consignment to NZ until completion of the testing of donor animals. When the donor animal has resided more than 90 days in the centre before collection, this requirement should apply only to the centre and not any more to the farm of origin. After 90 days of residence in the centre, including the pre-entry isolation period, there is no reason to still link the donor animal to the herd of origin. As an example, in the case of a donor bull who entered in the centre at the age of 10 months and collected at 7 year of age (more than 6 years after entry in the centre), it is absolutely not relevant to confirm that herd of origin is not under quarantine restrictions. This information is not available and not pertinent. The CFIA suggest that the following amendment is included in the text: "The herd (s) of origin of the donor males **and/or** the semen collection centres must...".

Article 16: In Canada semen production centres are placed under the supervision of centre veterinarians. These centre veterinarians are not always present when the bulls are collected as they have trained the staff who collect the semen to pay attention to any unusual signs concerning the donor bulls. When the centre staff note something unusual, the centre veterinarian examines the animal and decides about the collection and semen collected. So it will be difficult to certify that each donor bull has been inspected by the centre veterinarian on each collection day. The CFIA suggests the following: "Each donor animal was regularly inspected by the approved semen collection centre veterinarian and ...".

Article 24: The CFIA never provided copy of tests to NZ nor any other destination country as the Canadian Privacy Act prevents CFIA to do so. Instead, a summary of all tests is provided in a table which is part of the certificate. In Canada it is CFIA staff that collect samples which are sent to CFIA laboratory; laboratory reports are received electronically and the laboratory report system belong to the CFIA. The accession number reference is not relevant as all results are within the CFIA laboratory system. Only in very rare occasions, CFIA may allow for a test in a laboratory other than CFIA.

Part C. SPECIFIC REQUIREMENTS FOR IDENTIFIED RISK ORGANISMS

Codes used with regard to each disease:

TBN = conditions for this disease have to be negotiated

OK = this disease is not a concern for Canada.

Bluetongue (BT): 5 certification options, articles 25 to 29. TBN

Article 25: option country free; reference to the OIE code in place when semen collection is done. Canada does not comply as a BT free country as per OIE Code 2010; so this option cannot be used. Discussion with NZ to know if NZ recognizes Canada BT freedom before 1987, year where BT has been firstly isolated in Canada.

Article 26: option of semen donors in a BT virus free zone for 100 days prior to semen collection, with BT virus free zone as defined in the OIE Code. Since 2004, this option is used to certify semen from Canada, but without reference to the OIE Code. Over time the presence of the BT virus has only been demonstrated a few times in the Okanagan valley and

regionalization of the Okanagan valley in Canada has been accepted by trading partners. NZ should accept that semen actually eligible for export to NZ continues to be eligible for export to NZ if a new import rule applies. Surveillance as per the OIE Code is still not in place in Canada but should be in the near future. Discussion with NZ is required if actual export conditions can be maintained until surveillance is put in place.

Article 27: option BT virus seasonally free zone as defined in the OIE Code. This option cannot be used as seasonally free zoning for BT is not officially in place in Canada.

Article 28: option post-collection testing with C-ELISA test or AGID authorized tests between 28 and 60 days after last semen collection included in the shipment; OIE code. Post collection testing not included in the AI program, so extra testing would be required.

Article 29: option of mini-stud, where donor tested before, during and after semen collection destined to NZ; virus isolation test or PCR on blood; OIE code. PCR not available in CFIA labs so only virus isolation at every 7 days can be used. This could be done but very demanding.

Conclusion for BT:

1. Semen actually considered eligible for export to NZ should be maintained eligible. All inventory semen which is now certified using article 26, but without reference to the OIE code, would not qualify for BT as per strict application of options offered. This would be a great loss for industry as this semen now qualifies for export to NZ and would not be considered eligible when these new conditions are in place. No semen exported to NZ or any other destination country has ever been incriminated about BT transmission. Only new semen collected would be eligible for NZ if options in articles 7, 28 and 29 are used.

2. There is no credit for the semi-annual BT testing done by CFIA on all animals in semen collection centres, nor for BT testing required by OIE (2010) Chapter 4.6, "Collection and processing of bovine, small ruminants and porcine semen" prior to entering pre-entry isolation facility and in the pre-entry isolation facility (articles 4.6.2.1 and 4.6.2.2). This regular testing along with exclusion of any suspect/reactor animal from the centres, if any found, should be taken into consideration to qualify semen collected in centres, at least for the semen where a negative test is available after the collection, up to 6 months, taking in account that all the residents and teasers are tested every 6 months. This would at least qualify immediate previous semen production done before a semi-annual test. An equivalence should be discussed with NZ taking into consideration the particular situation of Canada, where the virus has never be reported outside a very specific localisation (Okanagan valley) and regular testing done on

all animals in semen production centres.

Borna disease (BD): 3 certification options, article 30 to 32.OK

Article 30: no reported case in countries of residence of semen donors. BD is an immediately notifiable disease in Canada and no case has ever been reported. The USA also never reported a case of Borna virus. The same situation applies to the USA. So this option can be used for now.

Article 31: confirmation the semen donor have resided since its birth, in herds (this includes centres) where no BD case has been reported for the 5 years before semen collection until conclusion of semen collection collected for export to NZ. As this requirement applies for the 5 years before and during collection; this means that this requirement should not apply since birth for animals which have resided more than 5 years in semen collection centre where no case has occurred. This requirement to check on the herd of residence should be limited to the semen donors only having less than 5 years residence in such centre. The reference period should limited only to the 5 years before commencement of semen collection destined to NZ. Furthermore, the period of 5 years is arbitrary and should be revisited. This virus is not proven to have tropism for reproductive organs; the extrapolation for data collected on rats to cattle should not use as an impediment to trade.

Article 32: testing option for blood sample of semen donors or semen itself tested for the virus. Testing is not available at the moment on a regular basis in Canada. Test is to be approved by NZ, as there is no OIE guideline for tests. Also not clear in the requirements when and how often animals or semen should be tested.

Conclusion on Borna Disease:

Actually Canada can use the 1st option (article 30) as this disease was never reported in Canada. Several Canadian donor bulls are sourced in the USA which also never reported Borna disease. In the case Borna disease is further reported in Canada or the USA, the requirement to qualify the semen donors for the 5 years before the semen collection is excessive and should be revisited as there is no demonstration this virus can be spread by semen. There is no OIE reference concerning Borna disease, neither in the Code or the Manual, so testing would be problematic. The CFIA questions the pertinence of this requirement.

Bovine viral diarrhoea type 2 (BVD2): 2 certification options, articles 33 to 35.....
TBN

Article 33: option country freedom. This option cannot be used by Canada as BVD is endemic in Canada.

Article 34: option centre freedom during collection destined to NZ. BVD tests (BVD-IP and BVD-SN), annual re-test for BVD-SN negative residents and semen tests for BVD-SN positive residents before initial semen dispatch (first 3 indents) are OIE recommendations (Chapter 4.6) and included in the CFIA Artificial program. But NZ requires a BVD-SN test for BVD-SN negative residents after the collection of semen destined to NZ (4th indent); this is an extra test which exceeds OIE recommendations in Chapter 4.6 of the Code. After semi-annual testing, all semen collected before from these bulls will qualify, but not the semen collected after the semi-annual test; this would be an important restriction for centres.

Article 35: all collection dates exported to NZ from either BVD-SN positive or BVD-SN negative donors must be tested using a virus isolation test when they were resident in the centre for less than 3 years; this requirement is an addition to those mentioned in article 34. This test exceeds OIE recommendations. This requirement should not apply to seronegative bulls. Several centres vaccinate bulls against BVD and seropositivity is due to vaccination and in no case related to the presence of the disease; vaccination should be taken into account as regard to BVD-SN positive results. The 3 year period is arbitrary and should be revisited for BVD-SN positive bulls.

Conclusion on BVD:

As Canada cannot use the country freedom option, articles 34 and 35 apply all together. Even though all Canadian centres comply with the BVD requirements mentioned in the OIE Code Chapter 4.6

“Collection and processing of bovine, small ruminants and porcine semen”, NZ requires that seronegative bulls are tested post-collection and that all the semen from bulls resident less than 3 years in a centre must be tested. These requirements are in excess of the OIE Code and excessive. Vaccination of bulls is not taken into consideration when such extra testing is required from BVD-SN positive donor bulls. Furthermore it is excessive to require a post collection test for donor bulls regularly tested negative as per the OIE recommendations in the case of Canada, this test on seronegative bulls is done every semi-annually.

Crimean Congo haemorrhagic fever (CCHF): 3 certification options, articles 36 to 38.....
TBN

Article 36: the disease must be notifiable and no case reported in the 21 days before and during collection. There is a problem as CCHF is not notifiable in Canada but was never reported (OIE, WAHID 2009). This disease does not exist in North America. It should be sufficient to have this disease not reported in Canada without an obligation from NZ to have this disease being notifiable.

Article 37: option of treatment for ticks with acaricide and tick freedom of the centre. This option is not very practical.

Article 38: test option; this test is not offered for regular diagnostic in Canada; test will have to be implemented for a disease which is exotic to Canada.

Conclusion for CCHF:

This disease does not exist in North America. There is no confirmation this disease is transmitted by semen. It should be sufficient to have this disease not reported in Canada without the requirement to have this disease being notifiable. According to article 7 of the IHS, it seems that CCHF is not notifiable in NZ, even it is exotic; if this is true, NZ should not require this disease is notifiable in Canada. It seems that both NZ and Canada are in the same situation concerning CCHF. Further discussion with NZ would be needed to accept freedom of this disease never reported, even though this disease is not notifiable.

Foot and Mouth Disease (FMD): 2 certification options, articles 39 to 41

.....OK

Article 39: option of 3 months country freedom without vaccination before semen collection. Canada qualifies as a country free of FMD without vaccination in accordance with the OIE code. The other option (articles 40 and 41) is not considered.

Bovine herpes virus abortifacient strains (IBR/IPV): 2 certification options, articles 42&43..TBN

Article 42: option centre IBR free during collection destined to NZ, as per the OIE code, including IBR negative test on farm and in isolation for all animals and annually afterwards for donor bulls. But the requirement also includes an IBR negative test after the semen collection. This is an extra test in addition of the semi-annual testing done on all animals resident in an IBR free semen centre as per the Canadian Artificial insemination program; for sure the next semi-annual test qualifies all the semen collected before from donor bulls but semen collected since the last semi-annual test will required an extra test. The program already goes farther than OIE recommendations asking for a semi-annual test on all animals in the centre instead of an annual test; this extra test which follows collection is not considered necessary in this case and exceeds the OIE recommendations. This requirement should be revisited to follow OIE recommendations.

Article 43: option semen virus isolation test. NZ required an equivalent of 0.05 ml of raw semen from each collection of semen exported to NZ. The requirement to test each collection date follows the OIE Terrestrial Code for serologically positive donor bulls as per articles 4.6.2 and 11.11.7. But NZ only refers to raw semen for the test while the OIE Manual (2008) Chapter 2.4.13. on IBR/IPV, section virus isolation from semen (a prescribed test for international trade) clearly mentions that suitable samples can be either 0.05 ml of extended semen or 0.02 ml of raw semen; for extended semen, an approximation should be made to ensure that the equivalent of 0.05 ml raw semen is examined. The CFIA wants to refer to the OIE Terrestrial Manual for testing procedures and sample type. CFIA would appreciate a clarification that test is also allowed on extended semen as permitted by international reference, as it was the case in the past.

Conclusion for IBR/IPV:

The post collection test required by NZ is in excess of the OIE recommendations when semen donors are resident in an IBR free semen production centre where all animals are tested as per the OIE terrestrial Code on farm, in isolation and annually afterwards as residents. Canada already goes farther than the OIE requirements as a semi-annual testing of all animals is required by the Canadian Artificial Insemination program instead of an annual test. The CFIA considers that the semi-annual test coupled with biosecurity measures in place in semen production centres as per the Canadian Artificial insemination program gives sufficient guaranties that semen donors stay negative throughout their semen production period. The CFIA considers that requirements for IBR should be in accordance with the OIE recommendations. Concerning the semen virus isolation test, the CFIA also consider that

testing requirements should be in accordance with the OIE and the use of extended semen confirmed.

Lumpy skin disease (LSD): 3 certification options, articles 44 to 46OK

Article 44: option of 6 months country freedom as defined by OIE before semen collection. Canada qualifies as a country free of LSD in accordance with the OIE code. Other options not considered.

Rift Valley fever (RVF): 3 certification options, articles 47 to 49OK

Article 47: option of 3 months country freedom before and during semen collection. Canada qualifies as a country free of RVF in accordance with the OIE code. Other options not considered.

Vesicular stomatitis (VS): 3 certification options, articles 50 to 52.....OK

Article 50: option of country freedom in accordance with the OIE code. Canada qualifies as a country free of VS in accordance with the OIE code. Other options not considered.

Bovine brucellosis: 2 certification options, articles 53 & 54OK

Article 53: option of donors kept in a country or zone free since birth. Canada is considered free country in accordance with the OIE Code. Article 54: option centre free as per the OIE Code. All Canadian centres also qualify according to these conditions. This option allows for qualification of USA origin donor bulls resident in Canadian centres.

Bovine tuberculosis: 2 certification options, articles 55 & 56OK

Article 55: option of donors kept in a country or zone free since birth. Canada is considered free country in accordance with the OIE Code. Article 56: option centre free as per the OIE Code. All Canadian centres also qualify according to these conditions. This option allows for qualification of USA origin donor bulls resident in Canadian centres.

Contagious bovine pleuropneumonia (CBPP): 2 certification options, articles 57 to 60.....OK

Article 57: option of country freedom in accordance with the OIE code. Semen donors must be born and continuously resident in a free country. Canada qualifies as a country free of CBPP in accordance with the OIE code. The USA also qualifies as a CBPP free country. Other option not considered (article 58, 59 and 60).

Mycoplasma bovis: 3 certification options, articles 61 to 63 TBN

Article 61: option to test donor bulls post collection.

Article 62: option to test each collection using raw semen.

Article 63: option to random test the centre population once a year.

A scientific paper (Shin S.J., Lein D.H., Patten V.H. and Ruhnke H.L., A new antibiotic combination for frozen bovine semen, 1. Control of Mycoplasmas, Ureaplasmas, *Campylobacter fetus* subsp. *Venerealis* and *Haemophilus somnus*, *Theriogenology*, March 1988, vol. 29, no 3. 577-591) was published concerning the control of several bacteria in the semen, including *Mycoplasma bovis*, by addition of antibiotics in extenders. The mixture of gentamicin, tylosin and lincomycin-spectinomycin (lincospectin) has been proved enough efficient to be adopted by the OIE Code since several years as the reference antibiotic mixture (gentamicin, tylosin, lincomycin-spectinomycin: GTLS) for addition in the semen to control these bacteria as mentioned in Chapter 4.6, article 4.5.7. The OIE Code recommends that a mixture of these antibiotics is added to each ml of frozen semen. As addition of proven antibiotics is now a standard followed in the Canadian bovine semen production centres and imposed by the CFIA as per the Artificial Insemination program, there is absolutely no need to test donor bulls or semen for *Mycoplasma bovis*. This testing requirement from NZ must be revised to take in account the mitigating measures obtained by addition of reference antibiotic mixture to all semen produced in Canada.

Conclusion on *Mycoplasma bovis*

An appropriate mixture of antibiotics (GTLS) is added to all semen produced in Canadian centres and such procedure is controlled by the CFIA. This mitigating measure is sufficient

for the control of *Mycoplasma bovis*. No test should be required by NZ concerning *Mycoplasma bovis* in accordance with the OIE Code.

Q fever: 3 certification options, articles 64 to 66.....OK

Article 64: option to test donor bulls post collection.

Article 65: option to test each collection using raw semen.

Article 66: option to random test the centre population once a year.

Conclusion for Q-fever:

The CFIA recognizes that NZ is free of Q-fever; thus testing as per options offered is accepted. The unique test available in CFIA laboratory for Q-fever is the CF test.

13.US Government – Semen & Embryo – 20/08/2010

Hi Sally - Pls see USG comments below. Can you pls forward to the appropriate person and also share their contact information as I would like to follow up. Thanks, Laura

This provides comments on the World Trade Organization notification, , dated 24 June 2010, regarding New Zealand's (NZ) Import Health Standard for bovine semen; Import Health Standard for bovine embryos; and Risk management proposal: Bovine semen and embryos. We understand these to be generic measures and that individual model Zoosanitary Certificates will be negotiated with the United States of America (US) among other countries. We provide comments on the Import Health Standards for Bovine Semen and Bovine Embryos, as follows.

BOVINE SEMEN

PART B. GENERAL REQUIREMENTS

Documentation accompanying the consignment

The US veterinary infrastructure includes a two-tier review of veterinary health documents used for export. USDA accredited veterinarians draw samples, order the diagnostic tests and review original copies of the test results. The accredited veterinarian issues the veterinary health certificate, according to the NZ import requirements, and submits all documents (including original laboratory reports) to USDA Animal and Plant Health Inspection Service (APHIS) Veterinary Services (VS). VS reviews all documents, including original laboratory reports, and endorses correctly completed veterinary health export certificates. Foreign government review of original laboratory reports from the US is unnecessary.

PART C. SPECIFIC REQUIREMENTS FOR IDENTIFIED RISK ORGANISMS

The US can certify to freedom from Borna disease, Crimean Congo haemorrhagic fever, foot and mouth disease, lumpy skin disease, Rift Valley fever and contagious bovine pleuropneumonia. The US Code of Federal Regulations Title 9, Part 161.4 (f) mandates that accredited veterinarians report suspicious signs of foreign animal diseases (FAD) to the APHIS Area Veterinarian in Charge or State animal health officials.

Bluetongue (BT)

25, 26, 27, 28, 29 The US agrees with the NZ risk analysis that, in the absence of the competent vector, BT "risk management measures are not justified." The US respectfully suggests minimal requirements for BT risk management.

Bovine viral diarrhoea type 2 (BVD2):

33. Semen already collected and in storage may come from donors which only were tested for BVD type 1. The US respectfully requests that semen currently in storage and qualified to export to NZ remain qualified for export to NZ.

34. The US respectfully requests NZ to accept BVD disease management program of the Certified Semen Services (CSS) as described at http://www.naab-css.org/about_css/disease_control-2002.html) as equivalent to OIE requirements.

The US notes that NZ's recommended options do not match the 2010 World Organization for Animal Health (OIE) Terrestrial Animal Health Code in two

places. One, Chapter 4.6 provides a scheme that accommodates seroconversion during pre-entry isolation. Two, the OIE Code does not specify the timing of annual retesting (i.e., samples collected after semen is collected for export).

35. The US believes the suggested requirement for testing donors that have been on the semen collection center for less than 3 years is not scientifically based and, therefore, is an unwarranted barrier to trade. The potential length of time that virus can be shed is irrelevant to trading bovine semen: Persistently infected animals are identified by testing and removed. There is no scientific basis to extend a requirement for testing beyond the six months originally offered in the NZ risk management proposal. Additionally, OIE Code does not require testing donors on the basis of the residence time at the center.

Infectious bovine rhinotracheitis/Infectious pustular vulvovaginitis (IBR/IPV)

42. Article 11.11.7. of the OIE Terrestrial Animal Health Code recommends an international veterinary certificate for frozen semen attesting that: the donor animals were kept in an IBR/IPV free herd; or the donor animals were held in isolation and tested; or an aliquot of semen was tested. NZ appears to be applying the OIE requirement that define a herd free from IBR to bovine semen donors: OIE requirements for herd freedom are different than OIE requirements for trade in bovine semen. Herd freedom is only one of three options recommended by OIE. The US respectfully suggests that NZ's recommendations in the risk management proposal be clarified accordingly.

43. As written, NZ asks for 0.05 ml of raw semen to be tested. Chapter 2.4.13 of the OIE Terrestrial Manual, B. 1. b) (2008) prescribes "One straw, 0.5 ml, of extended semen or 0.02 ml of raw semen ... For extended semen, an approximation should be made to ensure that the equivalent of 0.05 ml raw semen is examined." The US respectfully suggests that NZ clarify the wording to allow either extended semen or raw semen to be tested in the amounts indicated by OIE.

Vesicular stomatitis (VS): No comment.

Bovine brucellosis

54. Chapter 4.6. of the OIE Code (2010) recommends country or zone freedom (augmented by testing) prior to pre-entry isolation; serological testing during pre-entry isolation; and annual testing. The OIE Code (Article 11.3.5.) allows for animals to originate in a "herd officially free from bovine brucellosis." NZ has adapted that to a "herd officially free from bovine brucellosis in accordance with the OIE Code." The US understands that the APHIS VS program for brucellosis control and eradication provides the basis for certification of a herd officially free from bovine brucellosis. As written, the health standard implies that official freedom is determined by OIE code as opposed to a program administered by the competent authority.

Bovine tuberculosis

56. The US has an official program for the control and eradication of bovine tuberculosis and can make veterinary health certifications to that effect.

Mycoplasma bovis

61., 62., 63. Mycoplasma bovis in bovine semen is controlled through the use of antibiotics in the semen extender (Shin, et al, Thierogenology,

March 1988, Vol. 29, No. 3, pp. 577-591). Requirements for testing semen donors for *Mycoplasma bovis* are not warranted.

Q fever: No comment

BOVINE EMBRYOS

PART B. GENERAL REQUIREMENTS

Documentation accompanying the consignment

The US veterinary infrastructure includes a two-tier review of veterinary health documents used for export. USDA accredited veterinarians draw samples, order the diagnostic tests and review original copies of the test results. The accredited veterinarian issues the veterinary health certificate, according to the NZ import requirements, and submits all documents (including original laboratory reports) to USDA Animal and Plant Health Inspection Service (APHIS) Veterinary Services (VS). VS reviews all documents, including original laboratory reports, and endorses correctly completed veterinary health export certificates. Foreign government review of original laboratory reports from the US is unnecessary.

PART C. SPECIFIC REQUIREMENTS FOR IDENTIFIED RISK ORGANISMS

The US can certify to freedom from Borna disease, Crimean Congo haemorrhagic fever, foot and mouth disease, lumpy skin disease, Rift Valley fever and contagious bovine pleuropneumonia. The US Code of Federal Regulations Title 9, Part 161.4 (f) mandates that accredited veterinarians report suspicious signs of foreign animal diseases (FAD) to the APHIS Area Veterinarian in Charge or State animal health officials.

Vesicular stomatitis (VS): No comment.

Bovine tuberculosis: No comment.

Mycoplasma bovis

Mycoplasma bovis can be controlled through the use of antibiotics (Shin, et al, *Thierogenology*, March 1988, Vol. 29, No. 3, pp. 577-591). Requirements for testing donors for *Mycoplasma bovis* are not warranted.

Q fever: No comment.

BILATERAL NEGOTIATIONS

The US is prepared to proceed with bilateral negotiations with NZ. We assume that the bilateral negotiations will not be limited by imposing the proposed Import Health Standards by the suggested date of 4 November 2010. If this poses a conflict, the US respectfully suggests a delay in the implementation date until bilateral negotiations can be complete.

Thank you for your consideration of these comments. The US looks forward continuing working collaboratively with NZ during bilateral negotiations to maximize the benefits of trade in bovine germplasm between NZ and the US.

Laura Scandurra

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14. European Commission – Semen & Embryo – 24/08/2010

Dear Madam,

Please find attached the EU comments to the draft regulatory text notified in notice G/SPS/N/NZL/440 concerning the Import Health Standards for bovine semen and embryos.

Kind regards,
Marta Sobieraj



EUROPEAN COMMISSION
HEALTH & CONSUMERS DIRECTORATE-GENERAL

Directorate D - Animal Health and Welfare
D3 - International questions (multilateral)

Brussels, SANCO D3 MSo/ci D(2010) 582772

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EMMERLING THEA	RELEX WTO	DEL GVA
HIVONNET JOELLE		
SITAR OLIVIER		
EU - TBT	ENTR/C3	B100 6/09
VAN GOETHEM BERNARD	SANCO/D	B232 3/85
LADDOMADA ALBERTO	SANCO/D1	F101 3/60
VAN GELDORP PAUL	SANCO/D4	B232 2/94
SANCO SPS	SANCO/D3	F101 2/66
WEIGL ULRICH	TRADE /C1	CHAR 9/32

Subject: EU comments to the Import Health Standards notified in document G/SPS/N/NZL/440

Dear Madam,

Please find attached the European Union comments to the Import Health Standards for bovine semen and embryos notified in document G/SPS/N/NZL/440.

It would be very much appreciated if any reply to this letter be also copied to the EU Delegation Wellington (address above).

Ella Strickland
EU SPS Notification Authority



THE EUROPEAN UNION COMMENTS ON THE IMPORT HEALTH STANDARDS NOTIFIED BY NEW ZEALAND TO THE WTO SECRETARIAT UNDER THE CODE G/SPS/N/NZL/440 RELATED TO IMPORT HEALTH STANDARDS FOR OF BOVINE SEMEN AND EMBRYOS

The European Union (EU) would like to thank New Zealand for the notification G/SPS/N/NZL/440 and for the opportunity to comment on the Import Health Standards for bovine semen and embryos.

The EU would like to transmit the following comments and questions on the content of the aforementioned texts on the basis of the Terrestrial Animal Health Code of the World Organisation for Animal Health (OIE Code) and arrangements laid down in the Agreement between the European Community and New Zealand on sanitary measures applicable to trade in live animals and animal products¹⁸, as approved by Council Decision 97/132/EC¹⁹ (EU-NZ Agreement).

COMMENTS ON BOVINE SEMEN:

NZ Import Health Standard on BOVINE SEMEN	OIE Code/EU-NZ Agreement	EU request to NZ
Part B, Point 11. Donor eligibility	EU-NZ Agreement	to change "in the exporting country for at least 90 days" for "within the European Union for at least 90 days" <u>Rational:</u> The recognition of the EU as whole in the EU-NZ Agreement.
Part B, Point 13. Isolation period	Point 2 of Article 4.6.2. of the OIE Code Annex V to the EU-NZ Agreement	to replace "30 days" by "28 days". <u>Rational:</u> <ul style="list-style-type: none">• OIE Code requires 28 days;• practical importance for the organisation of animal movements on weekly basis.
Part C, Points 26 and 27. Bluetongue	Points 1 (a) of Articles 8.3.9 and 8.3.10 of the OIE Code	to replace "100 days" by "60 days" <u>Rational:</u> OIE Code requires 60 days.
Part C, Point 28. Bluetongue	Point 1 (b) of Article 8.3.11. of the OIE Code Annex V to the EU-NZ Agreement	to replace "28-60 days" by "21-60 days" <u>Rational:</u> <ul style="list-style-type: none">• OIE Code requires 21-60 days;• practical importance for the organisation of animal testing on weekly basis.

¹⁸ OJ L 57, 26.2.1997, p. 5.

¹⁹ OJ L 57, 26.2.1997, p. 4.

NZ Import Health Standard on BOVINE SEMEN	OIE Code/EU-NZ Agreement	EU request to NZ
Part C, Points 30-32. Borna Disease	The OIE Code does not provide any requirements as regards this disease Annex V to the EU-NZ Agreement does not provide any additional certification requirements as regards this disease	<ul style="list-style-type: none"> to delete the requirement, or to provide evidence that this disease in clinically healthy animals present an animal health risk to NZ. <u>Rational:</u> <ul style="list-style-type: none"> OIE does not consider this disease to be a risk; not an OIE listed disease.
Part C, Points 33-35. Bovine viral diarrhoea type 2 (BVDV2)	Point 2 (b) of Article 4.6.2 of the OIE Code Annex V to the EU-NZ Agreement	to delete Point 35 <u>Rational:</u> Point 34 already ensures that there is no virus circulation in semen collection centre.
Part C, Point 42. IBR/IPV	Point 3 (g) of Article 4.6.2 of the OIE Code Annex V to the EU-NZ Agreement	<ul style="list-style-type: none"> to consider adding an option for certifying country IBR/IPV freedom; to delete the negative post-collection serology on donor bulls from which semen is certified for export to NZ. <u>Rational:</u> In accordance with OIE Code, annual (negative) serology is considered sufficient.
Part C, Point 57 Contagious bovine pleuropneumonia (CBPP)	Article 11.8.3. of the OIE Code	to adapt the requirement to the recommendations in Article 11.8.3. of the OIE Code <u>Rational</u> Neither NZ nor the EU, except PT, are in the OIE list.
Part C, Points 61-63. <i>Mycoplasma bovis</i>	The OIE Code does not provide any requirements as regards this pathogen. Annex V to the EU-NZ Agreement does not provide any additional certification requirements as regards this pathogen.	to delete the requirements concerning testing for <i>Mycoplasma bovis</i> If the requirement is kept, criteria for country freedom should be provided. <u>Rational:</u> <ul style="list-style-type: none"> OIE does not consider this pathogen to be a risk; compulsory addition of antibiotics to the semen is preventing the spreading of <i>Mycoplasma bovis</i>; specific evidence is required that the antibiotics commonly used for processing semen are not effective against this organism; NZ should provide information, how it is concluded that NZ is free of the <i>Mycoplasma bovis</i>.
Stocks of semen	NA	to clarify which conditions will apply to the stocks of embryos collected, processed and stored before new requirements enter into force.

COMMENTS ON BOVINE EMBRYOS:

NZ Import Health Standard on BOVINE EMBRYOS	OIE Code/EU-NZ Agreement	EU request to NZ
Part B, Point 11. Donor eligibility	EU-NZ Agreement	to change "in the exporting country for at least 90 days" for "within the European Union for at least 90 days". <u>Rational:</u> The recognition of the EU as whole in the EU-NZ Agreement.
Part B, Points 13-14. Embryo collection facility and pre-entry isolation.	The OIE Code does not provide such a requirement Annex V to the EU-NZ Agreement does not provide any additional certification requirements in this respect and requirements for the collection of embryos have already been recognised as equivalent to NZ standards in this respect.	to clarify the meaning of "embryo collection facility", in particular with a view to allow collection of embryos on the holdings/farms. <u>Rational:</u> <ul style="list-style-type: none"> • a bespoke facility is not required under OIE Code; • most embryos are collected on holdings/farms, by approved embryo collection teams with mobile laboratories or who have access to permanently sited laboratories. Therefore, such a facility created on a holding/farm should be acceptable, as long as the donors can be isolated there from animals which are not of an equivalent health status.
Part B, Point 20. Embryo collection, processing, storage and transport	NA	to clarify whether a biopsed embryo be eligible for exports to NZ provided that the biopsy is taken after the requirements described in Point 20 have been fulfilled.
Part C, Points 31-33. Borna Disease	The OIE Code does not provide any requirements as regards this disease and it is also not an OIE listed disease Annex V to the EU-NZ Agreement does not provide any additional certification requirements as regards this disease	<ul style="list-style-type: none"> • to delete the requirement, or • to provide evidence that this disease in clinically healthy animals present an animal health risk to NZ. <u>Rational:</u> <ul style="list-style-type: none"> • OIE does not consider this disease to be a risk; • not an OIE listed disease.
Part C, Points 34-36. Bovine viral diarrhoea type 2 (BVDV2)	Annex V to the EU-NZ Agreement	to consider reviewing Points 35 and 36 as follows: <ul style="list-style-type: none"> – to adapt Point 35 in order to provide for a negative VI or antigen ELISA on the donor female on the day of collection of embryos or a negative serology 21 days after collection of embryos; – to replace the "AND " between Points 35 and 36 by "OR" to provide for an optional negative VI or PCR test on dead/non-viable embryos/washing/flushing fluid from first collection (Point 36 refers).

NZ Import Health Standard on BOVINE EMBRYOS	OIE Code/EU-NZ Agreement	EU request to NZ
		<p><u>Rational:</u></p> <ul style="list-style-type: none"> No EU MS is currently recognised as free (Annex V of agreement refers), so points 35 <u>and</u> 36 would apply. Points 35 and 36 mirror what has been proposed for bovine semen. Nevertheless, embryos are not collected from donor females at a bespoke collection facilities (see our comment to points 13-14) like in the case of semen, so the requirements for tests prior to entering the pre-isolation, during pre-isolation and annually in the embryo collection facility are not realistic, and in any case, unnecessarily complex.
Part C, Point 54. Contagious bovine pleuropneumonia (CBPP)	Article 11.8.3. of the OIE Code	<p>to adapt the requirement to the recommendations in Article 11.8.3. of the OIE Code</p> <p><u>Rational</u> Neither NZ nor the EU, except PT, are in the OIE list.</p>
Part C, Points 58-61. <i>Mycoplasma bovis</i>	The OIE Code does not provide such a requirement. Annex V to the EU-NZ Agreement does not provide any additional certification requirements in this respect.	<p>to delete the requirements concerning testing for <i>Mycoplasma bovis</i></p> <p>If the requirement is kept:</p> <ul style="list-style-type: none"> – criteria for country freedom should be provided; – evidence is required that <i>M. bovis</i> is transmissible through <i>in-vivo</i> derived IETS processed embryos; – to clarify whether point 58 implies a compulsory surveillance for <i>M. bovis</i> to be in place; – to consider whether serological testing for <i>M. bovis</i> of the donor animals on the holding 21-120 days after flushing is sufficient. <p><u>Rational:</u></p> <ul style="list-style-type: none"> OIE does not consider this pathogen to be a risk. <i>Mycoplasma sp.</i> in cattle is currently in IETS Category IV; compulsory addition of antibiotics to the embryos is preventing the spreading of <i>Mycoplasma bovis</i>; specific evidence is required that the antibiotics commonly used for processing embryos are not effective against this organism; NZ should provide information, how it is concluded that NZ is free of the <i>Mycoplasma bovis</i>.

NZ Import Health Standard on BOVINE EMBRYOS	OIE Code/EU-NZ Agreement	EU request to NZ
Part C, Points 62 to 65. Q fever	NA	<ul style="list-style-type: none"> • to clarify whether Point 62 implies a compulsory surveillance for Q-fever to be in place; • to consider whether the options in Points 63, 64 and 65 are not sufficient if carried out on the donor animals on a holding/farm. <p><u>Rational:</u> According to Part B Point 15, the tests should be done at the embryo collection facility. This is not relevant and causes problems in the practice.</p>
Stocks of embryos	NA	to clarify which conditions will apply to the stocks of embryos collected, processed and stored before new requirements enter into force.

The EU would like to thank New Zealand again for the opportunity to comment on its Import Health Standards and asks for its comments to be taken into account.

15. Denmark – Ministry of Food, Agriculture and Fisheries – Semen & Embryo – 24/08/2010

Dear Sally Jennings,

Please find below the comments from the Danish Veterinary and Food Administration. We have asked Danish exporters of bovine semen to New Zealand to give their comments as well.

The proposals in general goes beyond the OIE requirements. Examples of this is the request for copies of all lab reports and the request for an annex specifying the test dates could be questioned. Additional specific requirements for *Mycoplasma bovis* for the general management e.g. length of isolation period, separate storage etc. is of greater concern and should be revoked.

Bovine Semen

Part B General Requirements

13. The isolation period should according to the OIE be 28 days

16. The provision that the centre veterinarian should do an individual clinical inspection of the donor animals should be questioned from a practical point of view. The important thing must be that the health of the animals is monitored and recorded on the day of collection. It should be considered sufficient whether done by the centre veterinarian or a skilled lay person. See also 88/407 annex C 1. a “Semen must be obtained from animals which: a show no clinical signs of disease on the day the semen is collected “

20. Is there any documentation supporting the requirement for separate storage? The only risk which has been suggested is that of contaminated liquid nitrogen which is excluded since only fresh nitrogen is to be used (OIE Animal Health Code).

Part C Specific requirements for identified risk organisms

BVDV

34. The OIE requirements should be sufficient since it is applied to all animals at the SCC. This ensures that there is no virus circulation at the SCC. It is interesting that the post collection antibody test (bullet point 4) can be taken even the day after semen collection which makes it irrelevant!

35. The time the animal has spent at the SCC does not influence the reliability of the tests mentioned under 34. Should be excluded!

Bovine herpes virus abortifacient strains (IBR/IPV)

We kindly request same initial text as under BVDV 33 as option “At the time of collection of semen to New Zealand, the exporting country was free from IBR/IPV, i.e. there have been no cases of IBR/IPV for at least 3 years”

42. The OIE requirements should be sufficient since it is applied to all animals at the SCC. This ensures that there is no virus circulation at the SCC. It is interesting that the post collection antibody test (bullet point 4) can be taken even the day after semen collection which makes it irrelevant!

Bovine embryos

Embryo collection team and facility requirements

13. Exclude on farm embryo collection with a mobile laboratory

Donor and facility health standards

17. Will any semen fulfilling EU Directive 88/407 be possible to use?

Embryo collection, processing, storage and transport

20. Would a biopsied embryo be eligible for NZ provided the biopsy is taken after proper washing according to IETS and examination of the zona pelucida?

35. To ensure that the embryo donor is not infected during embryo collection either virus detection at the time of flushing or antibody testing ≥ 21 days after should be sufficient.

36. Since very few, if any, animals would spend their entire lives at an embryo collection facility this would be applicable to all donors. The time an animal has spent at the facility does not influence the reliability of the tests mentioned under 35 nor regarding the suggested alternative. Should be deleted!

58 and 62. Tests for Mycoplasma bovis and Q fever 21 - 120 days after flushing are possible but the provision that the samples should be taken at the ET facility is irrelevant (item 15.). Are these diseases a threat provided the embryos have been washed and trypsin treated?

Please do not hesitate to contact DVFA should you have any questions or comments to the above.

Best regards

Annette Junker Karpinski

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16. Australia – Biosecurity Australia – Semen & Embryo – 02/09/2010

Dear Mark

We have a few comments on the draft IHS for bovine semen and embryos dated 21 June 2010. We've been waiting on our ruminant genetics industry to comment but no response to date, so I hope we've caught issues of particular note. Apologies for being late.

A) Bovine semen

Some comments on bluetongue, FMD, IBR, sexed semen, and a query concerning scope as follows:

PART C. Specific requirements for identified risk organisms Bluetongue

25. BTV (not just BT)

26. Recommend amendment to include bolded, underlined words :

Semen donors were kept in a BT virus free zone, as defined by the OIE Code or recognised by NZ MAF, for at least the 60 days immediately prior.....New Zealand"

- 100 days was a transitory OIE code aberration. It reverted back to 60 days a few years ago taking into account the evidence regarding duration of BT viraemia.

- We've observed the recent changes to the OIE code BTV code chapter with dismay. The bluetongue Code chapter is now no longer supported by Australia as it is unscientific and disregards the epidemiology of this viral infection in parts of the world outside Europe. The long-established and credible Australian BTV free zone that met OIE Code requirements for many years is now not able to meet the updated BTV code chapter, yet it is still as credible as it ever was, perhaps even more so with accumulating data and constant refinement.

In particular, Article 8.3.3.3 in the 2010 Code chapter is of concern.
Article 8.3.3.3 :

"A BTV free country or zone in which surveillance has found evidence that Culicoides are present will not lose its free status through the importation of vaccinated or seropositive animals from infected countries or infected zones, provided: ...

b) the animals are not vaccinated and, at least 60 days prior to dispatch, are demonstrated to have specific antibodies against the bluetongue virus serotypes whose presence has been demonstrated in the exporting country or zone."

This change is also reflected in Article 8.3.8.5.

BA interprets this to mean that BTV susceptible animals moving from our zone of possible BTV transmission into the free zone must be tested to confirm they have antibodies to all BTV serotypes in the "exporting zone" before they are moved into the free zone. This implies that movement restrictions should be in place between the transmission and free zones. We continue to argue strongly that movement restrictions relating to BTV are unnecessary in this country because there are insufficient populations of competent culicoides vectors in the free zone to transmit BTV. Note that the OIE Code chapter no longer makes the important distinction between competent Culicoides vectors and Culicoides which are irrelevant as it simply refers to Culicoides (8.3.3.1b).

As NZ MAF would be aware from past discussions with us, non-competent species of Culicoides (e.g. C. victoriae) are present in Victoria, SA,

Tasmania and the southwest of WA. Very small numbers of vectors, blown over long distances from populations within the zone of possible virus transmission, are occasionally trapped in the free and surveillance zones in the absence of any evidence that cattle are seroconverting to bluetongue. We've pointed this out to many trading partners (most of whom accept BTV zoning in Australia), to the EC (who has not yet accepted our free zone for reasons which we can speculate about) and to the OIE Commission. It is also documented in our BTV zoning submission (p8) which we regularly update Latest version attached for information.

<<Blu Zoning_Aug10.doc>>

We request that NZ MAF amends the proposed BTV requirement, which currently exclusively requires compliance with the OIE Code, to permit recognition of Australia's BTV free zone.

27. 60 days as above

28. We no longer allow AGID for BTV for imports. (See p60 of BTV review - http://www.daff.gov.au/__data/assets/pdf_file/0007/1656493/2010_16_BTV_Policy_Review.pdf

<http://www.daff.gov.au/__data/assets/pdf_file/0007/1656493/2010_16_BTV_Policy_Review.pdf>

<http://www.daff.gov.au/__data/assets/pdf_file/0007/1656493/2010_16_BTV_Policy_Review.pdf>

<http://www.daff.gov.au/__data/assets/pdf_file/0007/1656493/2010_16_BTV_Policy_Review.pdf> >

29. What would constitute a MAF approved PCR test for BTV? See p61 of

http://www.daff.gov.au/__data/assets/pdf_file/0007/1656493/2010_16_BTV_Policy_Review.pdf

<http://www.daff.gov.au/__data/assets/pdf_file/0007/1656493/2010_16_BTV_Policy_Review.pdf>

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<http://www.daff.gov.au/__data/assets/pdf_file/0007/1656493/2010_16_BTV_Policy_Review.pdf> >

FMD

For information, in Australia's case imports of FMD susceptible animals and their products are not permitted from countries which have not been approved by BSG as FMD free countries where import requirements stipulate FMD country or zone freedom.

(BSG is Biosecurity Services Group - includes AQIS and BA).

MAF NZ's current proposal does not appear to have a similar exclusion with regard to FMD and import of bovine genetic material, though in practice we may not have a significantly different approach (noting clause 41 requiring verification activities). NZ's current IHS for bovine semen from EU - clause 1.2.2 under Sanitary information - has been of some interest to us in this respect.

IBR

Your proposal interests us as we recently updated our IBR import requirements for bovine semen from EU and North America. For context, NZ and Australia have similar health status with regard to BHV1 i.e. only the relatively benign subtype BHV1.2b, whereas most other countries have all 3 subtypes - BHV1.1, 1.2a and 1.2b. (BHV1.1 and 1.2a being more virulent and abortigenic).

Canada raised issues with us concerning our proposed adoption of the current Code requirements regarding herd IBR/IPV freedom (this amended a previous similar requirement). The revised proposal is attached fyi but

please do not distribute as I have not yet written the formal letter to CFIA (they are aware it is coming and support it)

In attached you will see we have been very particular about isolation and the type of test permitted.

Regarding NZ MAF's proposal, the final antibody test after collection seems excessive, providing your prior requirements have sufficient rigour with regard to isolation and tests. It is also not in line with current OIE recs and adds to the cost of the trade - it could be deleted. I suspect you will be getting similar comment from CFIA.

<<Draft proposed modification of IBR_IPV reqs for bovine semen from Canada_final version for formal letter_30.08.2010.pdf>>

Sexed semen

We made a number of recommendations to the OIE code concerning use of sexed semen about a year ago. The OIE Code adopted the following (Chapter 4.6):

Sperm sorting

Equipment used for sex-sorting sperm should be clean and disinfected between animals <file:///en_glossaire.htm> according to the recommendations of the licencer of the system.

Where seminal plasma, or components thereof, is added to sorted semen prior to cryopreservation and storage, it should be derived from animals <file:///en_glossaire.htm> of same or better health status.

In addition, we have:

Where reproductive material was removed from containers for further processing or aggregation with other reproductive material at an approved centre or laboratory, the dates of transfer, reason for transfer (e.g. for sex sorting), name of the approved centre of laboratory and the Approved Veterinarian must be listed against the containers. The unique serial number of each shipping container must be included in this documentation. (extracted from ICON - bovine semen from EU).

Scope

On page 3 of IHS - "... bovine semen being semen derived from any member of the sub-family Bovinae".

This subfamily is quite broad. We're interested in why you elected to nominate the scope as "any member of the sub-family Bovinae" as we've been pondering this issue ourselves (informally) .

For example, would you import bison semen from North America under the same conditions as (domestic) cattle semen from North America?

As an example, Australia's conditions for import of bovine embryos from NZ currently state: These conditions allow the import of embryos derived from domestic cattle (*Bos taurus* and *Bos indicus*), and breeds derived from these species only.

B) Bovine embryos

A comment on:

17. The semen used to produce the embryos in this consignment either:

* Met the minimum health standards for semen imported into the exporting country.

Our general policy regarding use of semen imported from a third country for fertilising embryos for export to Australia is that the health conditions

under which the semen was imported must be demonstrably equivalent to conditions for import of that semen directly into Australia. However, In NZ's case, for bovine embryos to Australia, we have (for the time being) accepted a slightly different approach taking into account a number of relevant factors (refer email Louise Kench to Karen Nicoll dated 31 August 2010). As would be the case in NZ and any other importing country, import conditions can come under review if circumstances change and the situation warrants a review.

23 The embryos for export were stored in the frozen state for at least 28 days before shipment to New Zealand...

We assume this requirement would not apply for embryos from Australia.

As a general enquiry, it's not entirely clear to me how this generic IHS will be incorporated into a bilaterally agreed health certificate. As indicated above, some requirements would be excessive to needs (and current practice), eg storage of embryos from Australia for 28 days before export, or if not amended will be likely to cause problems eg BTV free zone as per current OIE code.

Regards
Louise

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**17.Canadian Food Inspection Agency (CFIA); Dr. Alain Moreau – Embryo
– 08/09/2010**

Dr Mirkin,

I am back to work and in the process to finalize the review.

The purpose of this reply is simply to mention that obligation to identify the straw itself instead of using gummed labels and plugs would contravene to the IETS recommendations, mentioned in Chapter 9, Certification and identification of embryos, 4th edition 2010, page 89, subsection "Labelling straws". first paragraph.

Less and less ET teams write by hand on the straws as manipulation very often causes disappearance of information.

Only ET teams linked to a semen production centre or having a contract to print straws in advance use laser printed straws such as used for semen.

Extension plugs are now extensively used internationally and also gummed labels.

It would be unfortunate that NZ restricts methods internationally approved by IETS and OIE to label embryos straws.

Alain Moreau
TAHD, CFIA