



Australian Government

**Department of Agriculture
and Water Resources**



**Canadian Food
Inspection Agency**

**Agence canadienne
d'inspection des aliments**

Ministry for Primary Industries
Manatū Ahu Matua



**Assessment of Systems Recognition of Quads
Bovine Semen Collection Centres and Embryo Collection
Teams**

15 February 2016



Assessment of Systems Recognition of Quads Bovine Semen Collection Centres and Embryo Collection Teams

This assessment builds on the draft *Report of the Desktop Evaluation of Systems Recognition of Quads Bovine Semen Centres*, a similar working document for bovine embryos, and the comparisons made between the OIE Terrestrial Animal Health Code (OIE Code) and the systems in Australia, Canada, New Zealand and the United States for the export of bovine semen and embryos.

The in-country visits were conducted during May 2014 in Australia and New Zealand, followed by Canada and the United States in September 2014. The visits covered an overall introduction to the systems in the various countries, a visit to a laboratory that carried out diagnostic testing required to meet export requirements, and at least two bovine semen collection centres and two bovine embryo collection teams. The centres and teams were not representative of the entire industry in the respective country, with a preference given to the larger operators as well as those centres/teams that were geographically convenient.

The goals of the visits were:

- to enable in-country familiarisation of the bovine germplasm export sector in the Quads countries as part of the ongoing work of the Quads Germplasm Comparison Project;
- to facilitate the systems recognition process by sharing information about the regulatory oversight of the competent authority, as well as carrying out site visits;
- to improve familiarity with the differences in country contexts, including identifying opportunities for equivalence while noting points of difference; and
- to facilitate the development of harmonised and/or simplified certification for trade in germplasm between the Quads countries as far as possible.

It was agreed that the in-country familiarisation visits were to enable an objective comparison of the host country's processes for certification of bovine germplasm exports against the OIE Code and the import conditions of the other Quads countries. Where there was a variation in interpretation, the issues were to be noted and discussed prior to the completion of the exit meeting.

Any issues identified with production of germplasm for domestic use were, by mutual agreement, considered out of the scope of the project.

It should also be noted that the germplasm industries are dynamic, and rapidly evolving new technologies such as in-vitro fertilisation (IVF), sex-sorting of semen, and genomics impose regulatory challenges. The OIE Code and individual importing country requirements are not always updated in step with technological advances. Therefore, the Quads Germplasm Project team needs to continue to monitor these rapidly evolving industries.

1: Regulatory Foundation

This section relates to the legislation, regulations, rules, ordinances, policies, or other regulatory requirements that govern the operation of bovine semen collection centres and bovine embryo collection teams for export. This includes inspection, approval, and supervision of the centres and teams by a veterinarian approved for this purpose by the competent authority. In order to ensure compliance with importing country requirements, the competent authority must demonstrate that they have the legal authority framework in place to regulate bovine semen collection centres and embryo collection teams.

Initial assessment

The Australian Government Department of Agriculture, the Canadian Food Inspection Agency (CFIA), the New Zealand Ministry for Primary Industries (MPI) and the United States Department of Agriculture, Animal and Plant Health Inspection Service (USDA-APHIS) all have legislation that governs the operation of bovine semen collection centres and embryo collection teams for export. The four countries' systems are different but there are also many similarities. There is variation in the systems and processes used; however, all four systems enable collection of bovine germplasm at a centre or by a veterinarian accredited for that purpose; product being collected to the required hygienic standard; and an official veterinarian attesting to this by endorsement of the export certificate that accompanies the product to its country of destination.

The OIE Code (2014) states "Veterinary legislation should, at a minimum, provide a basis for Competent Authorities to meet their obligations as defined in the Terrestrial Code" and "The Veterinary Services should develop and document appropriate procedures and standards for all providers of relevant activities and associated facilities."

The Quads Germplasm Project team concluded that, overall, the regulatory foundations are equivalent across the Quads countries and the OIE Code recommendations are being met.

In-country assessment Australia:

Export of bovine germplasm is regulated under the *Export Control Act 1982* which requires an official veterinarian to issue and endorse official health certificates. The Export Control Act 1982 also requires compliance with the importing country requirements – product cannot be legally exported from Australia unless it meets the destination country's requirements and this has been attested to by an official veterinarian.

For a centre/team to be approved for export of product to the Quads countries (and the majority of other markets), the centre/team must be assessed against, and be deemed compliant with, the relevant standards of the OIE Code (Chapters 4.5 and 4.6 for bovine semen, Chapters 4.7, 4.8 and/or 4.9 for bovine embryos).

There is no specific Australian program for approval of bovine semen collection centres. However, embryo collection team veterinarians must comply with the *Program for the AQIS Accreditation for ET Veterinarians (May 1999)*. This program should be reviewed and updated to take into account changes in embryo transfer technology in the 16 years since it was established.

In-country assessment New Zealand:

New Zealand utilises a unique third party verification program under the *Animal Products Act 1999* and relevant legal notices. This Act requires that official MPI veterinarians sign the official health certificate. The bovine semen collection centres and bovine embryo collection teams are Export Approved Premises and are approved under the *Animal Products (Export Approved Premises) Notice 2011*. The third party verifiers audit the compliance of the Export Approved Premises and are recognised under the *Animal Products (Recognised Agencies and Persons Specifications) Notice 2011*. They are required to be ISO 17020 compliant.

Assessment of Systems Recognition of Quads Bovine Semen Collection Centres and Embryo Collection Teams

The individual export requirements for countries are legally issued under the Animal Products Act 1999.

Codes of Practice have been developed with industry for live animal and germplasm exports. Although these are not legally enforceable, they provide outcome-based guidelines for industry, and semen collection centres and embryo collection teams are required to meet these Codes of Practice prior to approval by the third party verifiers.

In-country assessment Canada:

The *Health of Animals Act* and Regulations provide the legislative authority for bovine semen production for both domestic trade and export and for embryo production for export. All domestic and export bovine semen collection centres require a permit issued by CFIA, as do all export embryo team veterinarians. CFIA has hands-on regulatory control over the day-to-day operations of bovine semen collection centres and embryo collection teams. It should be noted that CFIA is considering altering the artificial insemination program.

CFIA differs from the other Quads members in that it has established mandatory standards for all domestic production of bovine semen; however, the embryo program is only for export.

CFIA's Embryo Export Approval Program is more prescriptive than its semen program. The Embryo Export Approval Program was originally developed in 1990 but has been periodically updated (last updated in April 2013). It has extensive linked documents and training aids.

There is a process of accrediting veterinarians to do certain certification and testing functions. For example, on-farm testing of bulls entering the centre is verified by the certifying CFIA veterinarian.

The Quads Germplasm Project team noted that there has been a reduction in CFIA headquarters staff overseeing the programs for both semen and embryos over the years. Genetic exports are, by nature, challenging because of the complexity of protocols and the dynamic nature of the industry. Therefore, it is important to ensure that there are adequate resources and expertise to develop and maintain the programs.

In-country assessment United States:

There is legal backing for the export of bovine semen and embryos under the *Animal Health Protection Act (AHPA)* of 2002, the Code of Federal Regulations (CFR) title 9, part 91, and various memoranda and guidance documents.

APHIS approves accredited veterinarians to perform certain functions on behalf of the competent authority, including conducting all diagnostic testing and health examinations for export. The accredited veterinarian issues the health certificate, which is then reviewed and endorsed by APHIS. Some states have additional State regulations that pertain to oversight of accredited veterinarians.

Certified Semen Services (CSS) has a significant role in oversight of the bovine semen industry (domestic and export) in the United States. CSS is an industry group that was set up as a for-profit organisation in 1976 and is wholly owned by National Association of Artificial Breeders (NAAB). Most semen collection centres that export semen are CSS participants, although participation is not

Assessment of Systems Recognition of Quads Bovine Semen Collection Centres and Embryo Collection Teams

mandatory for domestic or international trade. Amongst its various functions, it produces position statements on diseases of interest (e.g. bovine viral diarrhoea virus), audit checklists and several other documents, one of which is the “CSS Minimum Requirements for Disease Control of Semen produced for AI” (updated January 2014). All CSS-participating collection centres must apply the Minimum Requirements in order to market their semen as complying with CSS standards. Through a Memorandum of Understanding (MOU) between APHIS and CSS, depending on the individual importing country requirements, CSS may inspect and approve certain CSS-participating semen collection centres for export.

The United States does not currently have an official embryo export program. The embryo transfer industry group in the United States is the American Embryo Transfer Association (AETA), a private organisation that adheres to the International Embryo Transfer Society standards. Requiring an embryo collection team veterinarian to be a member of AETA is variable, depending on the importing country’s requirements. APHIS has an MOU with AETA that mandates that team veterinarians must be AETA-approved in order to export bovine embryos to the EU. AETA approval is also required for export to Canada.

Final assessment

There are sound regulatory frameworks in place in each of the Quads countries, which give the governments the ability to regulate bovine semen collection centres and embryo collection teams. The Quads countries meet the OIE Code requirements for veterinary legislation but there is variability in the level of documented procedures and standards.

2: Inspection Program

This section relates to an effective inspection/auditing program for bovine semen collection centres and embryo collection teams. In order to meet the basic requirements of this standard, the competent authority must have an inspection/auditing program in place that ensures compliance with standards by maintaining regular surveillance of the premises. This allows for regulation of the centres and teams by the competent authority and ensures that certification of product is based on a sound system.

Initial assessment

All four competent authorities audit bovine semen collection centres and embryo collection teams. This is carried out either directly by the competent authority or by third party verifiers with delegated responsibility to carry out these audits.

The OIE Code states that Veterinary Services should undertake periodical self-evaluation and should recognise the right of importing countries to undertake an evaluation of its Veterinary Services. Veterinary Authorities of exporting countries should have procedures for authorisation of certifying veterinarians, defining their functions and duties as well as conditions of oversight and accountability, including possible suspension and termination of the authorisation; ensure that the relevant instructions and training are provided to certifying veterinarians; and monitor the activities of the certifying veterinarians to verify their integrity and impartiality.

Assessment of Systems Recognition of Quads Bovine Semen Collection Centres and Embryo Collection Teams

The bovine semen collection centres and bovine embryo collection teams in all Quads countries are under the supervision of official veterinarians or private veterinarians approved by the competent authority for that purpose. In addition, competent authorities audit their own systems to ensure that all exported germplasm meets the requirements of the importing country.

The OIE Code is increasingly being used by importing and exporting countries as the basis for the international trade in bovine genetics. The Quads Germplasm Comparison project uses the OIE Code as a basis for comparison of the Quads countries systems. The OIE Code requirements are specifically incorporated into or provide the foundation for many importing countries' conditions, including the EU, China, many South American countries and countries in Asia. The Food and Veterinary Office (FVO) of the European Commission has carried out audits of all Quads countries to assess their systems for the export of bovine germplasm to the European Union (Australia: 2012, 2007; Canada: 2007; New Zealand: 2012, 2007; United States: 2006). All Quads countries maintained EU approval for the export of bovine germplasm following these audits. The Quads countries are regularly audited by Chinese officials to approve centres for export of bovine genetics to China. Quads countries have all received approval for their centres to export to China. Various Quads countries have been audited by officials from other competent authorities including Chile and Thailand. Although the results of these competent authority audits are not all publically available, the continuation of trade with each of these assessing authorities indicates that each of the Quads countries systems have been found to be fulfilling the requirements of the individual importing country and, by implication the OIE Code, which underpins the individual countries' requirements.

The definition of "supervision" is not clear in the OIE Code with respect to semen collection. The Quads Germplasm Project team found it was difficult to compare the interpretation of this term between Quads members using the desktop comparison only. Despite the confusion caused by the words "direct" and "indirect", Quads countries were in general agreement that supervision in this context requires that the veterinarian is involved in the day-to-day veterinary decisions of the bovine semen collection centres and embryo collection teams; has comprehensive knowledge of the disease status of animals, test and isolation and disease management procedures; has responsibility for training staff in biosecurity measures; can reach the centres within a reasonable time frame and commits to attending audits by the competent authority and overseas importing countries.

In-country assessment Australia:

The certifying official veterinarians have first-hand knowledge of the collection centres and teams. There is rigorous assessment of eligibility of product for export at the time of certification.

The Australian system requires regular audits of centres/teams by an official veterinarian to ensure compliance with the standard of their approval (at least annual audits for centres approved to OIE Code, at least semi-annually for centres approved to the requirements of the EU). There is no mandatory requirement that the official veterinarian hold formal audit qualifications, although this is preferred. The system could be strengthened by improvements in the auditing process, particularly in regards to ensuring a consistent application of the relevant standards.

Operations manuals (or other similar formalised documents) are required as a first step when applying to the department for approval of a new collection centre or team. Operations manuals must demonstrate compliance with the relevant export standard before the department conducts physical

Assessment of Systems Recognition of Quads Bovine Semen Collection Centres and Embryo Collection Teams

audits. In addition, centres/teams are encouraged to have their own internal verification processes to verify compliance against their documented procedures.

The Australian Government Department of Agriculture (the department) carries out audits of all centres/teams a minimum of once every 12 months. Centres/teams approved for export to the EU are audited at least twice each year. The audits are carried out by an official veterinarian from the closest departmental office. While there is no formal program for training the official veterinarians in the germplasm programs, on-the-job training occurs.

There is a comprehensive system of internal and external audits to ensure that the department complies with all of its legislative requirements, including for the export of bovine germplasm, which mandate compliance with the importing countries' requirements. The department has its own annual internal verification procedures to ensure that the regional offices that deliver export certification are meeting their legislative requirements. In addition, the Australian Government has an Audit Office that carries out periodic audits of all Government departments.

In-country assessment New Zealand:

Certification of bovine germplasm is undertaken by Authorised Persons (veterinarians) employed by MPI. They sign on the basis of certification by centre/team veterinarians that the importing country requirements have been met. The system that supports certification is four-fold:

1. The Authorised Persons have the ability to scrutinise any documentation to support the information on the centre or team veterinarian's certification. However, certification is usually undertaken on the basis of the auditing described below.
2. Centres/teams are required to have their own internal documented procedures and verification processes.
3. Third party verifiers audit the centres and teams at least every 12 months. (Centres/teams accredited for export to the EU are audited at least twice each year.) Included in those audits is verification of records, including health records, underpinning the centre/team veterinarian's certification, and the centre/team's internal verification processes. Audits are performance-based, with any poor performers being subject to increased verification. In addition, copies of all certification by centre/team veterinarians must be provided to the third party verifier at the time of certification. The verifier has the authority to seek verification of any certificate provided.

The third party verification agency is required to have a formal program for training the auditors of germplasm centres and teams, including a formal auditor qualification. In addition, the agency is accredited to, and audited annually under, ISO/IEC 17020. These accreditation audits specifically include germplasm functions.

4. The MPI Systems Audit team, comprising formally qualified auditors, including four veterinarians, carries out audits of systems administered by MPI. The scope of the annual audit in any one year might not encompass any of the germplasm programs but, in 2013 and 2014, it included bovine germplasm centres/teams. Any issues identified in these audits are

Assessment of Systems Recognition of Quads Bovine Semen Collection Centres and Embryo Collection Teams

passed to the MPI Animal Exports Team, who work closely with the third party verifiers to resolve them.

Maintaining the integrity and rigor of the multi-tiered audit process is a key component of New Zealand's unique regulatory system and important to trading partner confidence in the system.

In-country assessment Canada:

Under the CFIA's Artificial Insemination Program and the Embryo Export Approval Program (EEAP), centres/teams are required to have Standard Operating Procedures and are encouraged to have their own internal verification processes. Official CFIA veterinarians carry out audits of all centres/teams semi-annually.

The CFIA certifying veterinarian has extensive first-hand knowledge of the centres/teams because of his or her high level of oversight and direct supervision. All sampling of animals at a semen collection centre is done by CFIA veterinarians and all certification responsibilities lie with the CFIA veterinarian. Official veterinarians are also responsible for conducting internal audits through the Quality Management System (QMS) (ISO 9000 standard).

The updated EEAP has a training module for its auditors. Although there are currently no mandatory requirements in the Artificial Insemination Program that the official veterinarian holds formal audit qualifications, it is encouraged where possible. On-the-job training is the most common form of training for auditors of this program. In the past, the National Program Manager visited semen collection centres during regular travel within Canada. This has not been possible recently. If the CFIA Artificial Insemination Program is amended in the future and shifts more responsibility to centre and accredited veterinarians, it would be imperative to incorporate attention to oversight procedures through a strong audit framework.

Currently, accredited veterinarians can conduct pre-entry and entry testing for semen collection centres, and bovine embryo practitioners must be certified by the Canadian Embryo Transfer Association and meet certain competency requirements to be certified under the EEAP. There is a well-documented and detailed system for both bovine semen collection centres and bovine embryo collection teams. Due to its recent re-write, the embryo program is more prescribed than the semen program, and as mentioned above, also contains training of CFIA official veterinarians. Planned re-writes of the AI program would follow this same path.

In-country assessment United States:

The National Import and Export Services (NIES) unit is responsible for all APHIS import and export activities. Centres/teams are approved by APHIS for export of bovine germplasm to particular countries. The process for this approval depends on the importing countries' requirements. All centres/teams visited had documented standard operating procedures (SOP) but it was noted that other centres/teams may not have documented procedures. At this time, APHIS encourages, but does not mandate, that centres/teams maintain SOPs. APHIS is working on providing all centres/teams with an SOP template and intends to require an SOP Manual in the future.

If required by the importing country, APHIS audits centres/teams at least every 12 months (centres/teams approved for export of semen and embryos to the EU are audited semi-annually).

Assessment of Systems Recognition of Quads Bovine Semen Collection Centres and Embryo Collection Teams

Depending on the requirements of the importing country, audits of semen collection centres may be carried out either by an APHIS veterinarian from the closest APHIS office or by CSS (for CSS participating centres).

APHIS recently updated its MOU (July 17, 2014) with CSS that authorises CSS, under certain circumstances, to inspect and approve CSS-participating semen collection centres for export to some countries. At present, the CSS Service Director conducts inspections/audits of all CSS participating semen collection centres annually. According to the MOU, an APHIS veterinarian must accompany the CSS Service Director on at least three audits annually. This arrangement could benefit from greater clarity concerning the scope of APHIS's oversight of CSS for export approval and the role of the APHIS veterinarian particularly if issues are identified that could affect the export certification of bovine germplasm.

There were some concerns about the scope and rigor of CSS annual audits in relation to importing country requirements. The primary purpose of CSS appears to be focused on semen quality control. Use of CSS to inspect semen collection centres for export may also present a conflict of interest as the CSS Board consists of CSS-participating centre veterinarians. In addition, CSS income is derived directly from the CSS centres. It was also observed that the CSS Service Director, who conducts all the audits, is not a veterinarian.

Where required, APHIS veterinarians carry out audit of centres/teams in accordance with the importing countries' requirements. There is no mandatory requirement that the official veterinarian holds formal audit qualifications; however, APHIS provides periodic, formal training on inspection and approval of centres/teams. Unless the importing country provides specific standards for inspection and approval of a centre, the default standard for audits to countries other than the EU is either the checklist developed by APHIS for approval of CSS-participating centres or the EU checklist.

Diagnostic sampling of animals for export is done by APHIS accredited veterinarians. APHIS veterinarians have access to all the laboratory results directly from the laboratory. The accredited veterinarian issues the health certificate, and forwards the certificate along with all supporting documentation to APHIS for review. The APHIS veterinarian reviews the certificate and all supporting documentation and then endorses the certificate.

There is a well-documented system for accreditation of the centre and team veterinarians.

Final assessment

All Quads countries have inspection/audit programs in place for bovine semen collection centres and bovine embryo collection teams that meet current Quad partner importing country requirements.

All Quads countries have the capability for periodical self-evaluation, as recommended by the OIE. All Quads countries recognise the right of the competent authority of the importing country to undertake an evaluation of the exporting country's Veterinary Services. All Quads countries have procedures for authorisation, monitoring, and verifying the integrity and impartiality of certifying veterinarians, therefore meeting the OIE Code requirements.

3: General Hygiene

This section relates to the essential requirement of bovine semen collection centres and embryo collection teams to collect, process and store product hygienically. In order to meet the general hygiene requirements, the competent authority must have standards and processes that are equivalent to the OIE Code.

Initial assessment

The OIE Code has requirements for the general hygiene for semen collection and processing centres, and for collection and processing of embryos. These requirements also cover the storage of embryos and semen.

All Quads countries have standards and processes for hygienically collecting and processing of bovine semen and embryos. However, standards for semen collection centre management of visitors, vehicles, sick animals and fodder need to be further clarified. Standards for storage of semen and embryos should also be clarified and compared.

We conclude that the general hygiene standards are broadly equivalent across the Quads countries but that some aspects of semen collection centre management and semen storage need to be clarified.

In-country assessment all:

Bovine semen and embryo collection demonstrations occurred during site visits. This provided an opportunity to observe hygiene practices, competency, and differences in technique among the Quads countries.

There is an overall high level of biosecurity maintained by all centres and teams visited. There is good hygienic practice in all countries ensuring that the product produced meets the requirements of the importing country for which it has been collected.

In general, there needs to be a clearer delineation of the semen collection centre boundaries in order to make decisions about the movement of people/vehicles/animals.

During the in-country assessment, arrangements were in place for the management of sick animals and biosecurity arrangements were in place for fodder.

Final assessment

Quads countries ensure that bovine semen and embryos are collected, processed and stored in a manner that is equivalent to the hygienic practices required by OIE Code and/or the individual importing country's requirements.

4: Sanitary Requirements

This section relates to the risk mitigation measures in place for diseases related to bovine semen and embryos. These include the seven diseases specified in the OIE Code Chapter 4.6 (tuberculosis, brucellosis, bovine viral diarrhoea (BVD), infectious bovine rhinotracheitis (IBR), bluetongue,

Assessment of Systems Recognition of Quads Bovine Semen Collection Centres and Embryo Collection Teams

campylobacter and trichomonas), but also other diseases required by some Quads members; for example, leptospirosis, Johne's disease, Q fever, enzootic bovine leukosis (EBL) and epizootic haemorrhagic disease of deer.

Although the OIE Code does not have any explicit risk mitigation measures for embryos (it refers to the International Embryo Transfer Society), Quads countries may require measures related to specific diseases for import.

Initial assessment

All Quads countries have measures in place for the seven diseases covered in Chapter 4.6 of the OIE Code in relation to collection of bovine semen for export. While all Quads countries' systems provide health guarantees for these diseases that are considered at least equivalent to those in the OIE Code, some differences with the specific requirements of the OIE Code have been noted (see Table 1 below). Further evaluation is required to establish equivalence with some of these diseases, particularly BVD and IBR. A common understanding amongst Quads partners of OIE Code BVDV requirements and interpretation would enable comparison with individual country standards and country animal health status with respect to BVD virus (BVDV) types.

Sanitary measures in place for bovine embryos were not evaluated prior to the in-country visit.

In-country assessment Australia:

Australia applies the OIE Code as its export standard for approval of semen collection centres and embryo collection teams. The testing requirements for semen centres are those stipulated in the OIE Code.

Comments were made about the inconsistency of the OIE Code bluetongue requirements (Chapters 4.6 and 8.3.) and about the BVDV testing inconsistencies across the Quads.

In-country assessment New Zealand:

MPI requires pre-entry testing for bovine tuberculosis, BVD, campylobacter and trichomonas. In addition, annual testing is also required for these diseases. The New Zealand Code of Practice does not prescribe test methods for these diseases or specific test timings. The Code of Practice does not require IBR testing, but measures have been voluntarily put in place at the two bovine semen collection centres visited. The Quads Germplasm Project team noted that importing countries need to be aware of this. Testing for other diseases ensure that the importing country's requirements are met.

The New Zealand Export Laboratory Program allows for tests to be used that may not be in alignment with the OIE Manual. It was noted that the ELP was issued in 2010 and contained outdated references.

Although New Zealand's bovine tuberculosis program is not in accordance with OIE Code, it meets the principles of the OIE Code.

In-country assessment Canada:

CFIA's domestic/export standard requires Johne's and leptospirosis testing. This is not required by the OIE Code.

Assessment of Systems Recognition of Quads Bovine Semen Collection Centres and Embryo Collection Teams

The BVDV requirements of the CFIA program are also in excess of the OIE Code.

In-country assessment United States:

Although APHIS does not mandate any export testing, they ensure that the importing countries' requirements are met.

The CSS testing standards are not in alignment with the OIE Code but APHIS ensures OIE alignment if required by the importing country.

The bluetongue issues are similarly applicable to the United States as there is no bluetongue zoning in the United States.

Table 1: Quads measures in place for 7 OIE listed diseases for bovine semen

	Australia	USA	New Zealand	Canada
Bovine brucellosis				
Bovine tuberculosis			3	
Bovine viral diarrhoea		2	3	
Infectious bovine rhinotracheitis		2	3	
Bluetongue	1	2		
Campylobacter			3	
Trichomonas			3	

Key:

- Freedom from disease
- OIE Code equivalent or alignment
- Not OIE Code equivalent

- 1** In the BTV free zone this is OIE aligned but in the BTV affected zone there are issues with complying with the inconsistency of the OIE Code (not applicable to Canada as this zone has no semen centres)
- 2** As noted, the CSS Minimum Health Requirements testing protocol is not completely aligned with the OIE Code, but APHIS ensures OIE alignment if required by the importing country
- 3** The NZ Code of Practice is not in alignment with the OIE Code as the test methods are not specified, IBR testing is not mandatory and timing of tests not specified. MPI ensures OIE alignment if required by the importing country

Final assessment

While risk management measures for OIE listed diseases seem effective within each Quads country, there are some differences in implementation of the sanitary measures between Quads countries. This suggests the possibility for further discussions or review of such differences, with the aim of seeking simplification or equivalence in certification across Quads whilst maintaining appropriate biosecurity protection. However, as some requirements are embedded in domestic and/or export standards or regulations, there are likely to be some logistical challenges ahead. The Quads Germplasm Project team recognises this as a longer term aim of the project which may be only addressed through incremental changes as opportunities arise. Such activity is likely to be subject to considerable interest from industry, governments and other external parties.

5: Laboratory Support

This section relates to whether laboratories carrying out diagnostic tests for sanitary requirements at bovine germplasm centres/teams meet international standards. In order to meet the basic laboratory support requirements the competent authority must have a program in place that ensures that laboratory support is effective and routinely monitored.

Initial assessment

Although laboratory support was not specifically evaluated at this stage of the project, the Quads countries all have laboratories that are accredited to ISO/IEC 17025.

All bodies that accredit the laboratories fall under the International Laboratory Accreditation Cooperation (ILAC).

In-country assessment Australia:

Australian laboratories that carry out export testing are all accredited to ISO/IEC 17025: *General requirements for the competence of testing and calibration laboratories*. The National Association of Testing Authorities (NATA) is the authority responsible for the accreditation of laboratories to this standard. NATA provides independent assurance of technical competence and maintains a public database of accredited facilities.

There is a Memorandum of Understanding (MOU) between the Commonwealth of Australia and NATA. This MOU specifically addresses laboratories conducting veterinary testing of animals and animal products. It includes advice on information NATA will make available to the department and enables departmental staff to observe NATA assessment activities.

Comments were made that traditional diagnostic methods are still in use and PCR use was very limited. This comment is applicable to all the Quads countries. Other comments were made about the possible issues with pooling of samples.

Assessment of Systems Recognition of Quads Bovine Semen Collection Centres and Embryo Collection Teams

In-country assessment New Zealand:

In New Zealand, both government and private laboratories are used for export testing. Exotic diseases are tested for at the government laboratory (Animal Health Laboratory); private laboratories can offer tests for whichever endemic diseases they desire. However, they must be approved and accredited for those tests. Approval is under the Export Laboratory Program. Accreditation is by the accreditation body, International Accreditation New Zealand (IANZ). If requested by MPI internal teams, the laboratories can be audited by the MPI Systems Audit team.

Currently, private laboratories offer mostly kit tests but one offers trichomonas and campylobacter testing.

A conflict of interest was raised at a recent audit of a private laboratory because the same company owns an export semen centre. This conflict has been managed to the satisfaction of MPI.

In-country assessment Canada:

CFIA's Animal Health Laboratory Services are delivered by a network of Centres of Expertise, each of which is the national centre for its area of specialisation.

All testing is currently conducted at CFIA or CFIA-approved laboratories. All laboratories are ISO/IEC 17025 accredited. An observation at the one laboratory visited is that there may be resourcing concerns, affecting not just this laboratory and these are expected to continue into the future.

Standards Council of Canada accredits testing and calibration laboratories to ISO/IEC 17025. The management system requirements contained in ISO/IEC 17025 meet the principles of, and are aligned with, the internationally recognised quality management system standard, ISO 9001:2008 - Quality management systems - Requirements.

In-country assessment United States:

Export testing may be conducted at either (1) the USDA National Veterinary Services Laboratories (NVSL); (2) a laboratory approved by NVSL to conduct certain diagnostic tests (including bluetongue, brucellosis, EBL, Johne's disease, bovine tuberculosis gamma interferon, and vesicular stomatitis); or (3) or a laboratory accredited by the American Association of Veterinary Laboratory Diagnosticians (AAVLD) and/or the American Association for Laboratory Accreditation (A2LA).

AAVLD labs are accredited to the OIE Quality Standard which has been recognised by the OIE and NVSL to be equivalent to the ISO/IEC 17025 standard from which it was derived. The AAVLD accreditation process is based on the Requirements for an Accredited Veterinary Medical Diagnostic Laboratory, Version 4.3, which incorporates by reference the current OIE Quality Standard and Guidelines for Veterinary Laboratories: infectious diseases (2008). Both of these documents are based on the ISO/IEC 17025 and parts of the ISO 9000 series that are relevant to the scope of testing. A2LA accredits veterinary laboratories to the ISO/IEC 17025 standard.

The majority of export testing for semen collection centres and embryo collection teams is done at State or university-based laboratories which are accredited by the AAVLD.

Final assessment

The Quads countries have a program in place that ensures that the laboratory support is effective and routinely monitored.

6: International Communication and Harmonisation

This section relates to the interaction between the competent authority and the international community. The competent authority must have mechanisms in place to interact with the international community regarding international standards as well as communication mechanisms to enact during animal disease events of international concern.

Initial assessment

Although international communication and harmonisation was not specifically evaluated in this project, the Quads countries participate regularly in the OIE, with one another through the Animal Health Quadrilateral Group, and the World Trade Organisation (WTO) Sanitary and Phytosanitary (SPS) and Technical Barriers to Trade (TBT) committees. In theory, the Quads countries also notify changes of import measures to the WTO. In practice, notification of changes to import requirements or of export standards does not always occur before implementation.

The Quads Germplasm Project team concludes that international communication and harmonisation across the Quads countries could be improved.

In-country assessment Australia:

The department has not always been informed of changes to the export standards of Quad countries in advance, or at the time of implementation, of those changes. For example, Australia was not notified of a change to the U.S. CSS standards for BVD diagnostic testing.

Australia considered that confidence in systems for the export of bovine semen and embryos would be enhanced by an agreement amongst Quads members to notify of any changes to a standard or third party arrangement (for Quad countries not using the Code as their standard).

In-country assessment New Zealand:

Changes to MPI's Code of Practice need to be notified wider to overseas countries (similar to issue of changes to CSS standards and CFIA standards).

In-country assessment Canada:

It would be helpful if CFIA's external website could contain more information regarding the germplasm programs to help with transparency. Similar to Australia and New Zealand, there needs to be notification of changes to a standard before implementation.

In-country assessment United States:

Assessment of Systems Recognition of Quads Bovine Semen Collection Centres and Embryo Collection Teams

It would be helpful if changes to the CSS program could be communicated externally as it may have an impact on import requirements.

Final assessment

In general, the international communication and harmonisation is good but there is opportunity for improvement.

7: Summary

Based on the in-country assessment and the desktop review, the Quads countries have generally equivalent systems in place for the export of bovine semen and embryos. This determination addresses the current situation in each Quads country and is based upon evaluation of supporting documentation provided prior to the in-country visit, and the knowledge gained from the site visits. The systems in place differ but that is to be expected. The Quads in-country visits, in particular, served to clarify many aspects of the desktop assessments and instilled confidence in systems currently in place in each Quads country.

Taking into account the high health status and systems equivalence amongst the Quads, there is an opportunity for harmonisation of import conditions and simplified export certification, although it is recognised that there may be associated logistical challenges. Therefore, this is a longer-term aim.

General Recommendations from the In-Country Assessment:

1. There should be a permanent working group established to continue this work which would provide increased communication amongst the Quads in regards to germplasm imports and exports.

There should be at least semi-annual technical teleconferences to discuss any changes or issues related to the germplasm sector.

The in-country assessment should be repeated at least every five years to continue with the familiarisation process (for these visits, there should be no fewer than two people per country, one from the imports side and one from the exports side). Other centres/teams should be visited at the next round of in-country visits to get a better picture within the Quads countries.

Notification of changes to the germplasm programs should be communicated more effectively among the Quads members, noting that this is likely to require more discussion within Quads to agree how this is achieved.

2. Import conditions for germplasm for each Quads country should be reviewed in context of the in-country visit with a view to harmonisation amongst the Quads to the extent possible. This will take into account this in-country assessment with a potential for simplified certification amongst the Quads.
3. If it is possible to harmonise the import conditions, then a Quads standard for exports should be explored. This standard could also be extended to exports to other countries such as MERCOSUR and the European Union. Collectively promoting a Quads standard during negotiations could facilitate its broad international acceptance. However, the Quads Germplasm Project team also recognises that this recommendation may be difficult to achieve in practice.
4. Resourcing in the germplasm regulatory sector should possibly be reviewed by individual Quads members for their own country. It was observed that this may be an issue in some countries with regards to laboratory, operational, and head-office personnel.
5. Ideally, all government auditors of germplasm centres/teams should have audit training or a formal audit qualification.
6. Given that bluetongue requirements in the Code are relevant to all countries where BTV is present, and the substantial attention given to bluetongue virus risk management for international trade in relevant commodities (including ruminant germplasm), the Quads Germplasm Project team recommends a unified Quads group approach to the Code Commission to amend the bluetongue requirements in OIE Chapter (4.6) about collection and processing of semen. The group may determine that making Chapter 4.6 requirements consistent with OIE Chapter 4.8 on bluetongue is the best way forward, considering that the disease specific chapter (Chapter 4.8) specifies preferred risk management for exported bovine semen in Article 8.3.11 relative to that specified in Chapter 4.6.

Country Specific Recommendations from the In-Country Assessment:

Australia: That the department updates their embryo transfer program and consider developing a program for bovine semen. Australia uses the current OIE Code (Chapters 4.5 and 4.6) as its export standard for bovine semen. An Australian Semen program could outline the framework for implementation of the OIE Code chapters and include a 'basis of certification' to clarify elements of the Code that require interpretation.

New Zealand: That there is increased validation of the health certificate by the MPI certifying veterinarian to provide a higher level of confidence to importing countries; that the Codes of Practice have more alignment with the OIE Code; that there is more prescription about testing in the Code of Practice; and that the Export Laboratory Program is updated.

Canada: That any future changes in CFIA's semen and embryo programs to devolve oversight responsibilities to the centre and team veterinarians should be communicated with Quads members as this may impact on the current assessment; and that CFIA might update its semen program similar to the periodically updated Embryo Export Approval Program.

United States: That APHIS should review the APHIS-CSS relationship; and that APHIS should consider developing a specific program to strengthen its oversight of the approval process for bovine semen collection centres and bovine embryo collection teams for export.

For further information please contact your relevant government officials

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