Ministry for Primary Industries
Manatū Ahu Matua

Official Assurance Programme

Code of Practice:
Export Germplasm

16 September 2013

New Zealand Government

Growing and Protecting New Zealand

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Disclaimer

While every effort has been taken to ensure that the guidance material and internet references in this document is accurate and complete, the Ministry for Primary Industries (including its employees and agents) does not accept liability or responsibility to any person for any loss caused by reliance on this material.

Review of Code of Practice

This code of practice will be reviewed, as necessary, by the Ministry for Primary Industries Animal Exports Team and the industry.

Suggestions for alterations, deletions or additions to this code of practice should be sent with the reasons for the suggested change, including any relevant data and contact details for the person making the suggestion, to:

Animal Exports Team
Animal and Animal Products Directorate
Ministry for Primary Industries
PO Box 2526
Wellington 6140
New Zealand

Phone: 0800 00 83 33
Fax: + 64 4 894 0733

A copy of this document can be found at: http://www.mpi.govt.nz/regs/exports/animals/CoP

Queries can be made to: animalexports@mpi.govt.nz

Amendment Record

It is important that this publication is kept up-to-date by the prompt incorporation of amendments.

To update this publication when you receive an amendment, remove the appropriate outdated pages, destroy them, and replace them with the pages from the new issue.

Complete instructions will be given in the covering letter accompanying the amendment, including a summary of what has changed and the reason for the changes. File the covering letter at the back of the publication, and sign off and date this page.

If you have any queries, please contact the Animal Exports Team.

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Part 1 Introduction

1.1 Purpose

MPI policy and the Animal Products Act 1999 aim to facilitate the entry of animal material and products into overseas markets by providing the standards and mechanisms needed to give and to safeguard official assurances for entry into those markets. Most importing governments require official assurances for the live animals and germplasm being exported, to provide confidence that their import requirements have been met.

The claims made on official assurances must be substantiated in order to maintain the integrity of New Zealand as a trading partner and MPI's reputation as a competent authority.

This is achieved through providing guidance material on the recommended standards to be used by the industry in the form of Codes of Practice (CoP), and by putting in place systems allowing the information relating to the assurances to be independently verified.

Each export approved premises is responsible for developing and maintain a manual of procedures outlining how the outcomes required by the Code of Practice will be met.

The Official Assurance Programme (OAP) for live animals and germplasm is an export programme specifically related to the export of live animals, and to the germplasm of some species. The programme is supported by legal notices and is published as two types of documents that set the requirements for export:

- Codes of Practice
- Export Requirements (overseas market access requirements)

The Codes of Practice consolidate the recommendations that are agreed with industry for the minimum export standards supporting the issue of official assurances under Part 5 of the Animal Products Act 1999.

The Codes of Practice include:

- Code of Practice: General Live Animal Export
- Code of Practice: Pre-export Quarantine and Isolation
- Code of Practice: Export Germplasm
- Code of Practice: Export Poultry.

1.2 Scope

This Code of Practice (CoP) applies to export approved premises that are approved by MPI for collecting, processing and/or storing germplasm (semen centres or embryo teams) for export.

It describes the agreed standards that should be followed in order for the export approved premises to receive an official assurance to accompany exported germplasm.

This CoP has been developed based on the general requirements of international standards as recommended by the World Organisation for Animal Health (OIE) and the International Embryo Transfer Society (IETS). The health testing requirements of this CoP are based on New Zealand's endemic disease status.

Additional market access requirements as outlined in the Export Requirements may also be required.

The requirements of this CoP allow exporters to have different procedures for meeting the requirements, where practicable.

1.3 Exclusions

This CoP does not apply to:

- exporters of germplasm who are not required to be export approved premises (e.g. canine and feline semen)
- germplasm that is able to be exported without requiring an official assurance
- germplasm for the domestic market.

1.4 International Standards

The World Organisation for Animal Health (OIE) is designated by the World Trade Organisation as the international animal health standard-setting organisation. The OIE produces a number of documents, including:

a. the OIE Code
The current edition of the *Terrestrial Animal Health Code*, which can be found on the OIE website:
http://www.oie.int/international-standard-setting/terrestrial-code/access-online/

b. the OIE Manual
The current edition of the OIE *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals* for diseases listed in the *Code,* which can be found on the OIE website:
http://www.oie.int/international-standard-setting/terrestrial-manual/access-online/

The International Embryo Transfer Society (IETS) recommends the standards associated with embryos, and produces the IETS *Manual*. The current edition of the IETS *Manual* can be found on the IETS website:
http://www.iets.org/manual.htm

There are a number of additional standards which may be necessary for certain exports:

- specific Export Requirements (OMARs)
- CSS Standards
http://www.naab-css.org/about_css/CSSMinReqJan2011rev0312.htm

Part 2 Requirements for Exporters and Operators

2.1 Requirements of the Animal Products Act 1999

The Animal Products Act 1999 is New Zealand's legal framework for the export of animal material and animal products.

The legal notices (as may be amended from time to time or any notice that replaces that notice) relevant to the export of germplasm include:

- Animal Products (Export Approved Premises) Notice 2011
- Animal Products (Export Verification Requirements) Notice 2011
- Animal Products (Recognised Agencies and Persons Specifications) Notice 2011
- Animal Products (Official Assurances Specifications) Notice 2013.

Further information on the verification (audit) programme can be found in the policy document *Live Animal and Germplasm Export Verification Programme* on the MPI website.

These documents can be found on the MPI website:
http://www.mpi.govt.nz/regs/exports/animals/oap

The operator of an export approved premises is responsible for:

a. re-applying for listing every two (2) years

b. providing the relevant verifiers with freedom and access to carry out their functions and activities under the APA

c. notification to the Director-General if they want to change recognised agencies

d. notification to the Director-General of any significant change to the export approved premises (e.g. change in operator, change to a premise).

For the steps to follow for a new centre or team to become approved as an export approved premises, see Appendix 2.

Note that for some countries, a listing to be able to export to a particular country may have additional requirements to be met before that premises is eligible to export to that country. *Examples include the EU and Chile where the approval involves MPI, or Colombia where the premise is responsible for ensuring their own country listing.*

The *Live Animal and Germplasm Export Verification Programme* has provision for an export approved premises to undergo shut down if they are non-operational for a season. This allows seasonal operators to elect not to operate for a season if they have insufficient export orders, with an amended verification frequency negotiated.

2.2 General requirements for export

2.2.1 Prior to undertaking collections of germplasm for export, operators should check the importing country's latest requirements.

2.2.2 Export Requirements (OMARs) published by MPI are the latest requirements as understood by MPI. These are not necessarily up-to-date, as importing countries often do not automatically advise any changes to MPI.

Import permits issued by the importing country often contain their latest import requirements, but these have not necessarily been agreed with MPI.

2.2.3 Where import permit requirements do not correspond with the Export Requirements, the exporter/operator should inform the Animal Imports and Exports Group as soon as practicable.

2.2.4 Exporters intending to export germplasm for which an official assurance is required should give reasonable notice to any recognised or authorised persons involved with the consignment so that any verification activities can be carried out in a timely manner.

2.2.5 Export approved premises should ensure that suitable pre-entry isolation facilities are used where isolation prior to entry to the collection facility is specified in the Export Requirements.

Where the Export Requirements state that animals must be isolated, this is taken to mean that the animals undergoing preparation for collection for export must be kept physically separate from other animals, with no direct contact.

For embryo teams this can be achieved by keeping animals separated by a minimum distance appropriate to the species, and by separating by time and distance when using common facilities such as yards and races.

For semen centres this means keeping animals separate from other animals of a different or unknown status in a defined area that is physically separate from the main centre facilities.

For new semen centres and semen centres dealing with seasonal breeding species or managing animals on an all-in/all-out basis, the status of parts of the centre may change to accommodate the change in status of the animals, provided this is adequately managed by the centre veterinarian.

2.3 Supervision, examination and testing

2.3.1 Where an Export Requirement specifies a level of supervision required by a centre or team veterinarian, unless clarified otherwise this is taken to mean that the supervision is indirect supervision.

Where there is no level of supervision specified, the level of supervision to be applied should be consistent with the recommendations of the OIE *Code*.

2.3.2 All laboratory testing specified in the Export Requirements should be carried out by a recognised laboratory.

The Animal Imports and Exports Group maintains a list of recognised laboratories on the MPI website along with lists of the testing procedures each laboratory is approved to undertake (http://www.mpi.govt.nz/regs/exports/animals/oap/elp).

2.4 Official assurances

2.4.1 For preparation of an export consignment the export approved premises must ensure that the germplasm is export eligible and meets the relevant Export Requirements.

This usually includes:

a. checking the identification and export eligibility of the germplasm

b. checking dates, any testing and treatment requirements, declarations, and supporting documentation

c. correctly entering any information on the germplasm declaration

d. sealing the transport container.

2.4.2 Exporters should notify the Animal Imports and Exports Group as soon as possible (not later than twenty four (24) hours after the event or first knowledge of the event) where an official assurance has been signed and the germplasm exported or to be exported:

a. do not meet or may no longer meet the conditions of the official assurance under which they have been, or will be, exported; or

b. are refused entry by the importing country.

The Animal Imports and Exports Group can be contacted by email (animalexports@mpi.govt.nz) or phone (0800 00 8333).

2.4.3 Exporters should notify MPI VS as soon as practical where an official assurance has been lost or misplaced.

2.4.4 Exporters must ensure that:

a. information is available allowing for the traceability of the germplasm

This information should include, as appropriate, the premises of origin and country of destination.

b. any file copy of supporting documentation is a faithful and legible replica

c. all records and supporting documentation for germplasm are kept for a period of at least four (4) years.

2.4.5 Once an official assurance is issued, it remains the property of the Director-General until received by a foreign government.

2.5 Communications with foreign authorities

2.5.1 On matters relating to official assurances, persons should not communicate with foreign governments or agencies on behalf of MPI or represent that they are communicating on MPI's behalf or with MPI's authority, unless they have the prior written approval of the Animal Imports and Exports Group.

2.6 Equivalence and dispensation

2.6.1 Exporters requesting an equivalence or dispensation should provide the following information, as applicable, to the Animal Imports and Exports Group:

a. the exporter's name

b. the importing country

c. the intended date of shipment

d. details of the germplasm

e. details of the issue or requirement for which equivalence or dispensation is proposed

f. the technical justification for equivalence.

A proposed draft germplasm declaration may be the easiest way to supply the information.

2.6.2 Exporters requesting dispensation or equivalence should contact the Animal Imports and Exports Group, and provide them with any relevant information to assist the negotiation process.

2.6.3 MPI reserves the right to reject requests on a case-by-case basis.

Part 3 Requirements for Certification

3.1 Introduction

3.1.1 Official assurances (signed export certificates) are issued based on eligibility documents / germplasm declarations and/or supporting documentation.

3.1.2 Eligibility documents are copies of export certificate templates with relevant sections completed, issued by a recognised person to an authorised person.

3.1.3 Germplasm (eligibility) declarations are copies of export certificate templates with relevant sections completed, issued by an approved centre veterinarian or team veterinarian to an authorised person. Germplasm declarations are subject to random verification by a recognised person.

3.1.4 Germplasm declarations will be the norm for approved centre/team veterinarians. The pathway of a recognised person issuing eligibility documents can also be used, for example where the centre/team veterinarian has a conflict of interest, or when they are away on holiday or overseas.

3.2 Export certificate templates

3.2.1 Authorised and recognised persons are automatically provided with a password to access the restricted export certificate templates on the MPI website.

3.2.2 Exporters and centre/team veterinarian can request access to password protected export certificate templates on the MPI website by applying to the Animal Imports and Exports Group using the application form "Approval for Access to Export Certificate Templates" located on the website page:
http://www.biosecurity.govt.nz/regs/exports/animals/oap/forms

3.3 Supporting documentation

3.3.1 Supporting documentation refers to documents that provide information to support the eligibility for export of any germplasm which requires an official assurance.

3.3.2 Any person providing supporting documentation should:

a. have the requisite first-hand knowledge of the information he/she is providing

b. ensure that the supporting documentation is true and accurate

3.3.3 The centre/team veterinarian issuing a germplasm declaration should keep copies of any supporting documentation.

3.3.4 Supporting documents include (but are not limited to):

a. laboratory reports

b. declarations from owners/managers regarding animal residency, health status, and property of origin disease status

c. declarations from registered veterinarians servicing the property of origin.

3.3.5 All declarations (excluding laboratory reports and veterinary certificates) used as supporting documentation should contain the following statements:

a. the information that I have provided is true, correct and complete in every particular

b. I am aware that this declaration is made for the purposes of supporting export certification under the Animal Products Act 1999.

3.3.6 For declarations in which the verification of the identification of the animal(s) is required, the declaration should also contain the following statement: "I have checked the identification of the animal(s), for which I am providing this declaration and it is as specified in this declaration".

Similarly, where the declaration is for the verification of the identification of farm/premises/herd/flock, the declaration should contain the following statement: "I have checked the identification of the farm/premises/herd/flock for which I am providing this declaration and it is as specified in this declaration".

3.3.7 Veterinary declarations are applicable where an Export Requirement clause relates to property freedom from disease, and the use of an owner declaration as a supporting document should be additionally supported by a corresponding veterinary declaration from the veterinary practice servicing the property.

While an owner declaration relates to the identity of specific animals, a veterinary declaration relates to a herd or property, but does not usually include animal identification unless that is relevant first-hand knowledge.

3.3.8 Signing and dating of the declaration should be done underneath all the information and statements in the declaration, to signify that the declarer attests to all the information in the declaration.

3.4 Germplasm declarations

3.4.1 Germplasm declarations should have a unique identifier which includes the centre/team registration number or premises identifier, plus the unique document number.

An example of a unique identifier is NZS56/213, where 213 is the 213rd eligibility declaration issued by the semen centre NZS56.

3.4.2 Any approved centre/team veterinarian issuing germplasm declarations should:

a. have first-hand knowledge of the information they are providing and/or be assured that any supporting documentation is true and accurate

b. be assured that the person signing the supporting documentation has the requisite first-hand knowledge of the information they are providing and is in a position to provide the supporting documentation accurately.

3.4.3 Any alteration to the wording of an export certificate template being used for a germplasm declaration is prohibited unless prior approval of the Director-General has been obtained.

The wording of the document should not be altered or deleted unless a dispensation or equivalence has been given, in which case the exact instructions from MPI for amending the document must be followed.

3.4.4 Germplasm declarations should not be issued if the details on the declaration are incomplete, inaccurate or not in accordance with the Export Requirements.

3.4.5 A germplasm declaration should include:

a. the exporter's registration identification

b. the centre/team approval number

c. adequate traceability where multiple centres/teams have been involved in the collection or processing,

d. deletion of all uncompleted tasks (by striking through the relevant clauses) and notify the authorised person accordingly in writing

e. voiding of any spaces in the germplasm declaration into which unauthorised information could be added, i.e. ruled off using a diagonal line, insert the words "not applicable", etc.

f. dates that are in the correct format of dd/mmm/yyyy, e.g. 17 Dec 2008. For the month the abbreviated or full word may be used

g. a signature, with name and designation (e.g. John Smith, Centre Veterinarian) below the signature

h. the actual date of signing.

3.4.6 Where an attached schedule is used, the schedule should be similar in format to the relevant parts of the export certificate template, and identified with the same shoulder number as the eligibility document.

3.4.7 Corrections to hardcopy germplasm declarations should be kept to a minimum:

a. wording struck out so that the original wording remains still legible

b. a full signature and date

c. no more than four corrections per document

d. each error corrected only once.

3.4.8 If there are too many errors, or where the corrections result in the document becoming unclear, a replacement germplasm declaration should be issued.

A replacement germplasm declaration that replaces one already issued for use requires a new unique identifier and should refer to the original germplasm declaration by containing the following statement at the top of the first page: "Replacement of <<insert original unique identifier>>, which is cancelled".

3.4.9 A draft electronic version of the germplasm declaration may be sent to the authorised person to aid in the preparation of the official assurance. Prior to issuing the official assurance, the original, signed germplasm declaration should be available to the authorised person. Where the original signed germplasm declaration cannot be made available, and a faithful and legible copy has been provided instead, the original signed germplasm declaration must be sent to the authorised person within five (5) working days of signing the official assurance.

3.4.10 In the event of any differences between the electronic version and the signed germplasm declaration, an explanation should detail the differences.

3.4.11 Communication regarding germplasm declarations should be copied to the relevant recognised person.

3.5 Verification of germplasm identification

3.5.1 An authorised person may, at any time, require an inventory check of a representative sample of germplasm in tanks to verify conformity with the information on the eligibility document / germplasm declaration.

To do so the following should be met:

a. the exporter or a nominated representative should be available during the verification to carry out the handling of the germplasm

b. due care is taken to ensure that the quality and viability of the germplasm is not compromised

c. appropriate facilities, equipment and protective clothing are used.

3.6 Verification of germplasm declarations by recognised persons

3.6.1 At the time of export, the semen centre/embryo team veterinarian should ensure that a copy of the original signed germplasm declaration is provided to the recognised person responsible for the verification of the export approved premise.

This can be achieved by emailing the recognised person a scanned copy of the signed document.

3.6.2 The recognised person responsible for the centre/team where germplasm declarations are completed must, on an ongoing basis, check at least 5% of germplasm declarations to ensure that they have been produced correctly.

In addition, the recognised person may at any time, where they have reasonable grounds for doing so, audit any supporting documentation.

Part 4 Requirements for Semen Centre Managers and Veterinarians

4.1 Responsibilities of semen centre managers

4.1.1 A centre manager is responsible for ensuring that:

a. the centre maintains its approval

b. the centre employs competent staff

c. a centre veterinarian is associated with the centre

d. the centre veterinarian is not placed in a situation that compromises his/her impartiality and independence in the performance of his/her functions as a centre veterinarian

e. changes to the status of the centre veterinarian(s) and the centre are notified to the recognised person immediately

f. the recognised person is notified prior to any significant change to the centre's approved facilities or work manual

g. internal audits are undertaken

h. any corrective actions are closed out within the agreed timeframe.

4.2 Requirements of semen centre veterinarians

4.2.1 A centre veterinarian should be a registered veterinarian and hold a current annual practising certificate.

4.2.2 The centre veterinarian should follow the guidelines and requirements in the following documents:

i. the relevant Parts of this CoP

ii. the centre's own work manual

iii. any relevant Export Requirements

iv. the *Code of Professional Conduct for Veterinarians*

v. the relevant parts of the OIE *Code.*

4.3 Responsibilities of semen centre veterinarians

4.3.1 The centre veterinarian should:

a. ensure that only semen that meets the relevant Parts of this CoP, the Export Requirements, and the import permit (if required) will be presented for export

b. ensure that he/she has adequate knowledge of what is happening on the centre on a day-to-day basis, and is able to be present at reasonable notice

c. be present at every approval audit

d. ensure that any corrective actions identified are closed out within the agreed timeframe.

4.3.2 The centre veterinarian should ensure that any conflicts of interest are identified, disclosed and managed as per the conflict of interest policy in the *Code of Professional Conduct for Veterinarians*.

Part 5 Requirements for Semen Centres

5.1 Introduction

5.1.1 The purposes of official sanitary control of semen collection, processing and storage are to:

- Maintain the health of animals on a semen collection centre at a level that permits the international distribution of semen having negligible risk of infecting inseminated animals with specific pathogenic organisms that can be transmitted by semen
- ensure that semen is collected, processed and stored in a manner that maintains its export status, so allowing the issuing of official assurances.

5.2 Requirements for approval and listing of semen centres

5.2.1 Centres can be approved and listed by the Director-General for the collection and/or processing and/or storage of semen of specified species for export, and for the isolation of donor animals where this is required by Export Requirements.

For the steps to follow for a premise to become approved as an export approved premises, see Appendix 2.

5.2.2 An approval is valid for a maximum of two (2) years, or until the approval is surrendered, or withdrawn by the Director-General.

5.2.3 The list of approved centres is a public document and is available on the MPI website: http://www.mpi.govt.nz/exports/animals/agencies/semen-embryo-reg-info.

5.3 Supervision of semen centres

5.3.1 A centre must be under the supervision of an approved centre veterinarian who is responsible for ensuring that the health status of the animals associated with the semen centre and the export eligibility of the semen is maintained.

This would usually include:

a. having adequate knowledge of what is happening on the centre on a day-to-day basis

b. being able to be present on centre at reasonable notice

c. responsibility for the health and welfare of the resident animals

d. being responsible for ensuring that all staff are trained and supervised

e. responsibility for the standard of hygiene during production, processing, storage and dispatch of semen.

5.4 Facility requirements for semen centres

5.4.1 The centre should be designed and managed to ensure that any resident animals are able to maintain their export eligible status.

This would normally include:

a. the centre being physically separated from neighbouring properties

b. restricted access

c. animal handling and collection facilities that are able to be adequately cleaned and disinfected.

5.4.2 The centre should have the following facilities, as appropriate to the approval sought:

a. animal accommodation areas

b. an area for separation of sick animals

c. a semen collection room, or area

d. a semen processing facility (laboratory), which should be physically separated from the semen collection area

e. a storage facility.

These facilities may be at different locations.

5.4.3 Where a pre-entry isolation facility is associated with the centre, it should be physically separated from the centre such that the health status of the animals on the centre is maintained.

These facilities may be at different locations.

5.4.4 Animals should be kept isolated from other animals not of the same health status so that their export health status is maintained.

5.5 System requirements for semen centres

5.5.1 The centre should establish, document and maintain systems and procedures to ensure that only semen that meets the relevant Parts of this CoP, the Export Requirements, and the import permit (if required) will be presented for export.

5.5.2 The systems and procedures should be fully described in the centre's work manual:

a. the name and contact details of the centre veterinarian(s)

b. a comprehensive site plan showing the layout of the site, the facilities and all defined areas

c. documented procedures, appropriate to the approval sought

d. the list of countries the semen centre exports to.

Procedures could include:

i. a document control system

ii. conditions for the presence of other domestic animals

iii. control of visitors and vehicles

iv. managing shared facilities

v. pre-entry isolation

vi. cleaning and disinfection

vii. sterilisation of equipment

viii. the preparation of animals prior to collection
ix. collection of semen
x. processing semen, including details of diluents, additives and extenders
xi. sexing of semen
xii. labelling, packaging and storing semen
xiii. maintaining an inventory of stored semen
xiv. transport of semen
xv. receiving semen from other centres
xvi. submission of laboratory samples
xvii. actions to be taken in the event of an unfavourable test result
xviii. internal audits
xix. record keeping.

5.5.3 The work manual should specify in detail how the relevant outcomes will be achieved.

Procedures could detail what, who, how, when and where, including what records are kept.

5.5.4 The centre should ensure that the centre's work manual is approved by a recognised person. Any significant changes to the work manual should be authorised by the centre veterinarian and approved by the recognised person prior to the change being implemented.

Significant changes include a major change in procedures, animals of different health status, or list of countries that are exported to.

5.5.5 The centre should keep records for all matters that demonstrate the export eligibility of the semen.

This would normally include:

a. supporting declarations regarding the farm of origin or herd of origin
b. date of last natural service
c. date on which pre-entry isolation began
d. written permission from the centre veterinarian for entry onto the centre
e. date of entry onto, and departure from, the centre
f. dates of semen collection and processing
g. health records of all semen donors and any teasers.

5.5.6 Records, including those of animals that have left the centre, should be retained for future reference for a minimum of four (4) years following export.

5.6 Management of the semen collection facility

5.6.1 Staff should be technically competent and observe high standards of hygiene.

5.6.2 The entry of visitors to the semen collection facility should be strictly controlled.

5.6.3 Staff and visitors entering the semen collection area should wear appropriate clothing and footwear, so as not to compromise the level of hygiene.

5.6.4 General equipment for use with the livestock should be dedicated to the semen collection facility or be disinfected prior to entry.

5.6.5 The centre should contain only animals associated with semen collection. Other domestic animals may be used, where necessary, for managing donor animals.

5.6.6 Only animals that are tested to the required standard should enter the semen collection facility.

5.6.7 The collection area should be managed to facilitate the hygienic collection of semen while managing the welfare of the donors and any teasers. This includes providing safe footing in the mounting area.

5.6.8 On the day of collection, the animal being collected from should not show any evidence of infectious disease that would compromise the export eligibility of the semen.

5.6.9 Semen donors and any teasers should be prepared for collection so that the semen collection hygiene can be managed effectively.

5.6.10 Equipment used for the collection of the semen should be new, or cleaned and disinfected prior to use. Storage of artificial vaginas should be managed to minimise contamination. When lubricant is used, its use should be managed to minimise any risk of contamination of the artificial vagina.

5.6.11 The semen collection area should be cleaned daily after collection.

5.6.12 Measures should be in place to manage pests that may be a source of disease for the semen donors.

5.7 Management of the semen processing laboratory

5.7.1 The semen laboratory should be physically separated from the semen collection facilities, and include separate areas for semen evaluation, processing, and semen storage.

5.7.2 The semen processing laboratory should be managed so that semen is processed hygienically.

5.7.3 Entry to the laboratory should be prohibited to unauthorised personnel.

5.7.4 Visitors to the laboratory should be kept to a minimum.

5.7.5 The laboratory personnel should be technically competent and observe high standards of personal hygiene.

5.7.6 The laboratory should be constructed with materials that permit effective cleaning and disinfection.

5.7.7 The laboratory should be regularly cleaned. Work surfaces for semen evaluation and processing should be cleaned and disinfected at the end of each workday.

5.7.8 The laboratory should be kept clean and tidy, and be protected against rodents and insects

5.7.9 Any products of animal origin used in the processing of semen should be obtained from sources that minimise any animal health risk.

5.7.10 Antibiotics added to the semen should be in accordance with international recommendations.

5.7.11 Only semen from donors that meet at least the requirements of this part of the Code of Practice should be processed at the same time.

5.7.12 For sex-sorted semen, seminal plasma added to the sorted semen should be derived from animals of the same or higher health status.

5.7.13 Each individual dose of semen should be indelibly marked in accordance with international recommendations.

5.7.14 Any receptacle (including straws, shippers and tanks) used for the packaging, storage and transport of semen should be new, or cleaned and disinfected.

5.7.15 The semen storage areas and individual semen containers should be easy to clean and disinfect.

5.8 Germplasm storage and transport

5.8.1 Germplasm storage facilities should be constructed so that the interior can be cleaned and disinfected.

5.8.2 Germplasm should be transported and/or stored under conditions that maintain its health status and export eligibility.

5.8.3 Where non-export germplasm is stored at the same facility, there should be a system in place for the identification and separation of germplasm that is not export eligible.

5.8.4 Inventory control should record all germplasm movements, inwards and outwards, including origin and destination, as appropriate.

5.9 Unfavourable test results

5.9.1 Where an unfavourable test result occurs (i.e. a result that is not negative, whether it be a suspicious positive or a weak positive), appropriate action should be taken pending confirmation of the test result.

5.9.2 In the event of a confirmed unfavourable routine test result for a disease listed in Parts 6, 7, 8 or 9 (as relevant to the species on the centre) the centre veterinarian must immediately notify the recognised person. An investigation should be undertaken to establish the true health status of the sampled animal.

5.9.3 The Director-General may carry out an investigation to ascertain the actual export status of the facility. This investigation should be carried out in consultation with the recognised agency involved.

5.10 Verification audits

5.10.1 Prior to an audit, the centre's work manual should be assessed for completeness and relevance to the scope of the operation before it is approved for use.

For situations where a work manual includes procedures that are outside the scope of a Code of Practice, a legal notice, or any Export Requirements, the approval should clearly state what procedures are included or excluded from the approval.

5.10.2 Each centre should be audited by a recognised person:

a. before recommendation for listing as an export approved premises is given

b. at least annually thereafter

c. within twenty (20) working days of the approval being surrendered

d. within twenty (20) working days from when a new centre veterinarian commences sole supervision of a centre.

In this context, a new centre veterinarian means a veterinarian who has not participated in an audit of the centre concerned within the previous twelve (12) months.

5.10.3 Audits for continuous approval should include:

a. auditing against the relevant parts of the centre's work manual

b. the centre facilities

c. an annual observation of collection and/or processing as applicable to the scope

d. the health status of the resident animals

e. each centre veterinarian at least once every twelve (12) months

f. at least two (2) export consignments, including all the supporting documents. This check must ensure that supporting documentation has traceability via the inventory control system, including (where relevant) traceability to any documentation for inwards movement of germplasm.

g. management of issues and non-compliances.

Where eligibility documents for the export consignments have been raised by the recognised person, these are not subject to additional audit.

5.10.4 At the completion of any audit, the recognised person should prepare an audit report in which he/she lists any non-compliance, draws conclusions and makes a recommendation about the audit frequency of the centre. The report should be completed within twenty (20) working days of the audit, and made available to the centre veterinarian.

Any change in status of any centre veterinarians should be reported to the Animal Imports and Exports Group so that the register on the website can be kept up to date.

5.10.5 Non-compliances may be identified during audits, or may occur due to issues identified between audit visits.

5.10.6 The corrective actions for a critical non-compliance are:

a. the recognised person should discuss the non-compliance with the centre veterinarian and document the issue

b. a non-compliance report should be sent to the Animal Imports and Exports Group within twenty four (24) hours of completion of the audit. This could lead to the suspension of the approval of the centre veterinarian and the centre

c. a full investigation may be carried out by MPI, who may make recommendations regarding the re-instatement or cancellation of approval of the centre veterinarian and/or the centre

d. the Director-General may decide to refer the issue to the Veterinary Council of New Zealand.

5.10.7 The corrective actions for major and minor non-compliances are:

a. the recognised person should discuss the non-compliance with the centre veterinarian and document the corrective actions agreed upon between the recognised person and centre veterinarian

b. a deadline for rectification should be set and agreed

c. the corrective action should be checked by the recognised person for compliance within the agreed timeframe

d. all non-compliances should be closed out. Documentation which attests to this should be viewed by the recognised person.

Part 6 Bovine testing requirements

6.1 Movement of animals onto the semen centre

6.1.1 Prior to entering the centre the animals should be tested, with negative results, for the following diseases:

a. bovine tuberculosis

b. bovine viral diarrhoea/mucosal disease (BVD/MD) using an antigen test

c. bovine genital campylobacteriosis (*Campylobacter fetus* subsp. *venerealis*)

d. trichomonosis (*Trichomonas foetus*)

6.1.2 Any additional tests should be carried out in accordance with the Export Requirements.

6.1.3 If there is conflict between the testing requirements specified in the Export Requirements and this CoP, the Export Requirements prevail.

6.2 Testing of animals on the semen centre

6.2.1 Once on the centre, resident animals should be tested at least once every twelve (12) months for the following diseases, with negative results:

a. bovine tuberculosis

b. bovine viral diarrhoea/mucosal disease (BVD/MD)

c. for donor bulls only - bovine genital campylobacteriosis (*Campylobacter fetus* subsp. *venerealis*) and trichomonosis (*Trichomonas foetus*).

6.2.2 Any additional tests should be carried out in accordance with the Export Requirements.

Part 7 Ovine and caprine testing requirements

7.1 Movement of animals onto the semen centre

7.1.1 Prior to entering the semen centre (i.e. test on the farm of origin or during pre-entry isolation) ovine animals should be tested, with negative results, for *Brucella ovis.*

7.1.2 Prior to entering the semen centre, (i.e. test on the farm of origin or during pre-entry isolation) caprine animals should be tested, with negative results, for Caprine Arthritis-Encephalitis.

7.1.3 Any additional tests should be carried out in accordance with the Export Requirements.

7.1.4 If there is conflict between the testing requirements specified in the Export Requirements and this CoP, the Export Requirements prevail.

Part 8 Cervine testing requirements

8.1 Movement of animals onto the semen centre

8.1.1 Prior to entering the pre-entry isolation facility of the centre the animals should be tested, with negative results, for bovine tuberculosis.

8.1.2 Any additional tests should be carried out in accordance with the Export Requirements.

8.1.3 If there is conflict between the testing requirements specified in the Export Requirements and this CoP, the Export Requirements prevail.

Part 9 Equine testing requirements

9.1 Movement of animals onto the semen centre

9.1.1 Depending on the country that the semen will be exported to, a stallion may be either resident on the centre, or visit the centre for custom collections.

9.1.2 Any isolation or testing should be carried out in accordance with the Export Requirements.

Part 10 Requirements for Embryo Team Veterinarians

10.1 Requirements for embryo team veterinarians

10.1.1 A team veterinarian should be a registered veterinarian and hold a current annual practising certificate.

10.1.2 The team veterinarian should follow the guidelines and requirements in the following documents:

i. the relevant Parts of this CoP

ii. the centre's own work manual

iii. any relevant Export Requirements

iv. the latest version of the *IETS Manual*

v. the *Code of Professional Conduct for Veterinarians*

vi. the relevant parts of the OIE *Code.*

10.2 Responsibilities of embryo team veterinarians

10.2.1 The centre veterinarian should:

a. ensure that only embryos that meet the relevant Parts of this CoP, the Export Requirements, and the import permit (if required) will be presented for export

b. ensure that he/she has adequate knowledge of what is happening on the facilities on a day-to-day basis, and is able to be present at reasonable notice

c. be present at every approval audit

d. ensure that internal audits are undertaken

e. ensure that any corrective actions identified are closed out within the agreed timeframe.

10.2.2 The team veterinarian should ensure that any conflicts of interest are identified, disclosed and managed as per the conflict of interest policy in the *Code of Professional Conduct for Veterinarians.*

Part 11 Requirements for Embryo Teams

11.1 Introduction

11.1.1 The purposes of official sanitary control of embryo production and storage are to:

- Maintain the health of animals at a level that permits the international distribution of ova and embryos having negligible risk of infecting recipient animals and progeny with specific pathogenic organisms that can be transmitted by embryos
- ensure that ova and embryos are collected, processed and stored in a manner that maintains their export status, so allowing the issuing of official assurances.

11.2 Requirements for approval and listing

11.2.1 Embryo teams can be approved and listed by the Director-General for the collection, processing and/or storage of *in-vivo* and *in-vitro* embryos of specified species for export, and for the isolation of donor animals where this is required by Export Requirements.

An approved embryo team may carry out embryo collection at a permanent facility and/or on-farm.

11.2.2 An approval is valid for a maximum of two (2) years, or until the approval is surrendered, or withdrawn by the Director-General.

11.2.3 The list of approved embryo teams is a public document and is available on the MPI website. (http://www.mpi.govt.nz/exports/animals/agencies/semen-embryo-reg-info).

11.3 Team veterinarian and other staff

11.3.1 An embryo team must be under the supervision of an approved team veterinarian who is responsible for the oversight of the health status of the donor animals and the export eligibility of the embryos.

This would usually include:

a. having adequate knowledge of what is happening at the facilities on a day-to-day basis

b. being able to be present at reasonable notice

c. responsibility for the health and welfare of the donor animals when under the management of the embryo team

d. being responsible for ensuring that all staff are trained and supervised

e. responsibility for the standard of hygiene during production, processing, storage and dispatch of embryos.

11.4 Facility requirements for embryo teams

11.4.1 The embryo team should have adequate facilities and equipment as appropriate to the approval sought:

a. animal holding or accommodation areas

b. a collection facility

Examples of collection facilities for cattle are a crush, head bail, and a bail on a rotary platform.

c. a laboratory for processing embryos, which should be physically separated from the embryo collection area

d. a storage facility.

These facilities may be at different locations.

11.4.2 Where pre-entry isolation is associated with the facility, it should be physically separated from the facility such that the health status of any donor animals resident on the facility is maintained.

These facilities may be at different locations.

11.5 System requirements for embryo teams

11.5.1 The team should establish, document and maintain systems and procedures to ensure that only embryos that meet the relevant Parts of this CoP, the Export Requirements, and the import permit (if required) will be presented for export.

11.5.2 The systems and procedures should be fully described in the embryo team's work manual:

a. the name and contact details of the team veterinarian

b. a comprehensive site plan showing the layout of the site, the facilities and all defined areas

c. documented procedures, appropriate to the approval sought

d. the list of countries the embryo team exports to.

Procedures could include:

i. a document control system

ii. conditions for the presence of other domestic animals

iii. control of visitors and vehicles

iv. managing shared facilities

v. pre-collection isolation

vi. cleaning and disinfection

vii. sterilisation of equipment

viii. the preparation of animals prior to collection

ix. collection of embryos

x. details of any on-farm collection

xi. production and processing of embryos, including details of media and solutions

xii. labelling, packaging and storing embryos

xiii. maintaining an inventory of germplasm

xiv. transport of germplasm

xv. receiving germplasm from other export premises

xvi. submission of laboratory samples

xvii. actions taken in the event of an unfavourable test result

xviii. internal audits

xix. record keeping.

11.5.3 The work manual should specify in detail how the relevant outcomes will be achieved.

Procedures could detail what, who, how, when and where, including what records are kept.

11.5.4 The team veterinarian should ensure that the team's work manual is approved by a recognised person. Any significant changes to the work manual should be authorised by the team veterinarian and approved by the recognised person prior to the change being implemented.

Significant changes include a major change in procedures, on-farm collection, or list of countries that are exported to.

11.5.5 The team should keep records for all matters that demonstrate the export eligibility of the embryos.

This could include:

a. supporting declarations regarding the farm of origin or herd of origin

b. date of insemination or fertilisation

c. date on which pre-collection isolation began

d. dates of embryos collection and production

e. health records of all embryo donors.

11.5.6 Records, including those of animals that have left the centre, should be retained for future reference for a minimum of four (4) years following export.

11.6 Management of embryo collection

11.6.1 Frozen semen used to inseminate donor females should be compliant with the Export Requirements. Where natural service or fresh semen is used, donor males should have the same export status as donor females.

When imported semen is used, supporting documentation may be required to support the export eligibility of the embryos produced.

11.6.2 Any pre-collection testing and/or treatment requirements should be in accordance with the Export Requirements. Where pre-collection testing/treatment is required, the animals should be kept isolated from animals of a lesser health status from the time of sampling/treatment.

11.6.3 The team veterinarian should ensure that all pre-collection requirements have been completed prior to the start of embryo collection (flushing).

11.6.4 Staff should be technically competent and observe high standards of hygiene.

11.6.5 The entry of visitors to the collection facility should be strictly controlled.

11.6.6 Staff and visitors entering the collection area should wear appropriate clothing and footwear, so as not to compromise the level of hygiene.

11.6.7 The collection processes should be managed to facilitate the hygienic collection of embryos while managing the welfare of the donors. This includes using appropriate anaesthesia.

11.6.8 On the day of collection, the animal being collected from should not show any evidence of infectious disease that would compromise the export eligibility of the embryos.

11.6.9 Donors should be prepared for collection so that the collection hygiene can be managed effectively.

11.6.10 Equipment used for the collection of the embryos should be new, or cleaned and disinfected prior to use.

11.7 Management of the embryo processing laboratory

11.7.1 The embryo processing laboratory should be physically separated from the embryo collection facilities

The processing laboratory used by the embryo team may be permanent or mobile.

11.7.2 Entry to the laboratory should be prohibited to unauthorised personnel.

11.7.3 The laboratory personnel should be technically competent and observe high standards of personal hygiene.

11.7.4 Visitors to the laboratory should be kept to a minimum.

11.7.5 The laboratory should be constructed with materials that permit effective cleaning and disinfection.

11.7.6 The laboratory should be regularly cleaned. Work surfaces for evaluation and processing should be cleaned and disinfected before and after embryo processing.

11.7.7 The laboratory should be kept clean and tidy, and be protected against rodents and insects

11.7.8 The germplasm storage areas and individual storage containers should be easy to clean and disinfect.

11.7.9 The washing and examination of embryos should be carried out in accordance with the IETS *Manual*

11.7.10 Any products of animal origin used in the processing of embryos should be obtained from sources that minimise any animal health risk.

11.7.11 Antibiotics used in any media should be in accordance with international recommendations.

11.7.12 Each individual straw should be indelibly marked in accordance with international recommendations.

11.7.13 Any receptacle (including straws, shippers and tanks) used for the packaging, storage and transport of embryos should be new, or cleaned and disinfected.

11.7.14 Only embryos from donors of the same export status should be processed at the same time.

11.8 Germplasm storage and transport

11.8.1 Storage facilities should be constructed so that the interior can be cleaned and disinfected.

11.8.2 Germplasm should be transported and/or stored under conditions that maintain its health status and export eligibility, as applicable.

11.8.3 Where non-export germplasm is stored at the same facility, there should be a system in place for the identification and separation of germplasm that is not export eligible.

11.8.4 Inventory control should record all germplasm movements, inwards and outwards, including origin and destination, as appropriate.

11.9 Unfavourable test results

11.9.1 Where an unfavourable test result occurs (i.e. a result that is not negative, whether it be a suspicious positive or a weak positive), appropriate action should be taken pending confirmation of the test result.

11.9.2 In the event of a confirmed unfavourable test result the team veterinarian should immediately notify the recognised person in writing. An investigation should be undertaken to establish the true health status of the sampled animal.

11.9.3 The Director-General may carry out an investigation to ascertain the actual export status of the facility. This investigation should be carried out in consultation with the recognised agency involved.

11.10 Verification Audits

11.10.1 Prior to an audit, the team's work manual should be assessed for completeness and relevance to the scope of the operation before it is approved for use.

For situations where a work manual includes procedures that are outside the scope of a Code of Practice, a legal notice, or any Export Requirements, the approval should clearly state what procedures are included or excluded from the approval.

11.10.2 Each embryo team should be audited by a recognised person:

a. before recommendation for listing as an export approved premises is given

b. at least annually thereafter

c. within twenty (20) working days of the approval being surrendered

d. within twenty (20) working days from when a new team veterinarian commences sole supervision of the team.

In this context, a new team veterinarian means a veterinarian who has not participated in an audit of the team concerned within the previous twelve (12) months.

11.10.3 Audits for continuous approval should include:

a. auditing against the relevant parts of the team's work manual

b. the facilities

c. include an annual observation of collection and/or processing as applicable to the scope

d. health records of the donor animals

e. each team veterinarian at least once every twelve (12) months

f. at least two (2) export consignments, including all the supporting documents. This check must ensure that supporting documentation has traceability via the inventory control system, including (where relevant) traceability to any documentation for inwards movement of germplasm

g. management of issues and non-compliances.

Where eligibility documents for the export consignments have been raised by the recognised person, these are not subject to additional audit.

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11.10.5 Non-compliances may be identified during audits, or may occur due to issues identified between audit visits.

11.10.6 The corrective actions for a critical non-compliance are:

a. the recognised person should discuss the non-compliance with the team veterinarian and document the issue

b. a non-compliance report should be sent to the Animal Imports and Exports Group within twenty four (24) hours of completion of the audit. This could lead to the suspension of the approval of the embryo team

c. a full investigation may be carried out by MPI, who may make recommendations regarding the re-instatement or cancellation of approval of the embryo team

d. the Director-General may decide to refer the issue to the Veterinary Council of New Zealand.

11.10.7 The corrective actions for major and minor non-compliances are:

a. the recognised person should discuss the non-compliance with the team veterinarian and document the corrective actions agreed upon between the recognised person and team veterinarian

b. a deadline for rectification should be set and agreed

c. the corrective action should be checked by the recognised person for compliance within the agreed timeframe

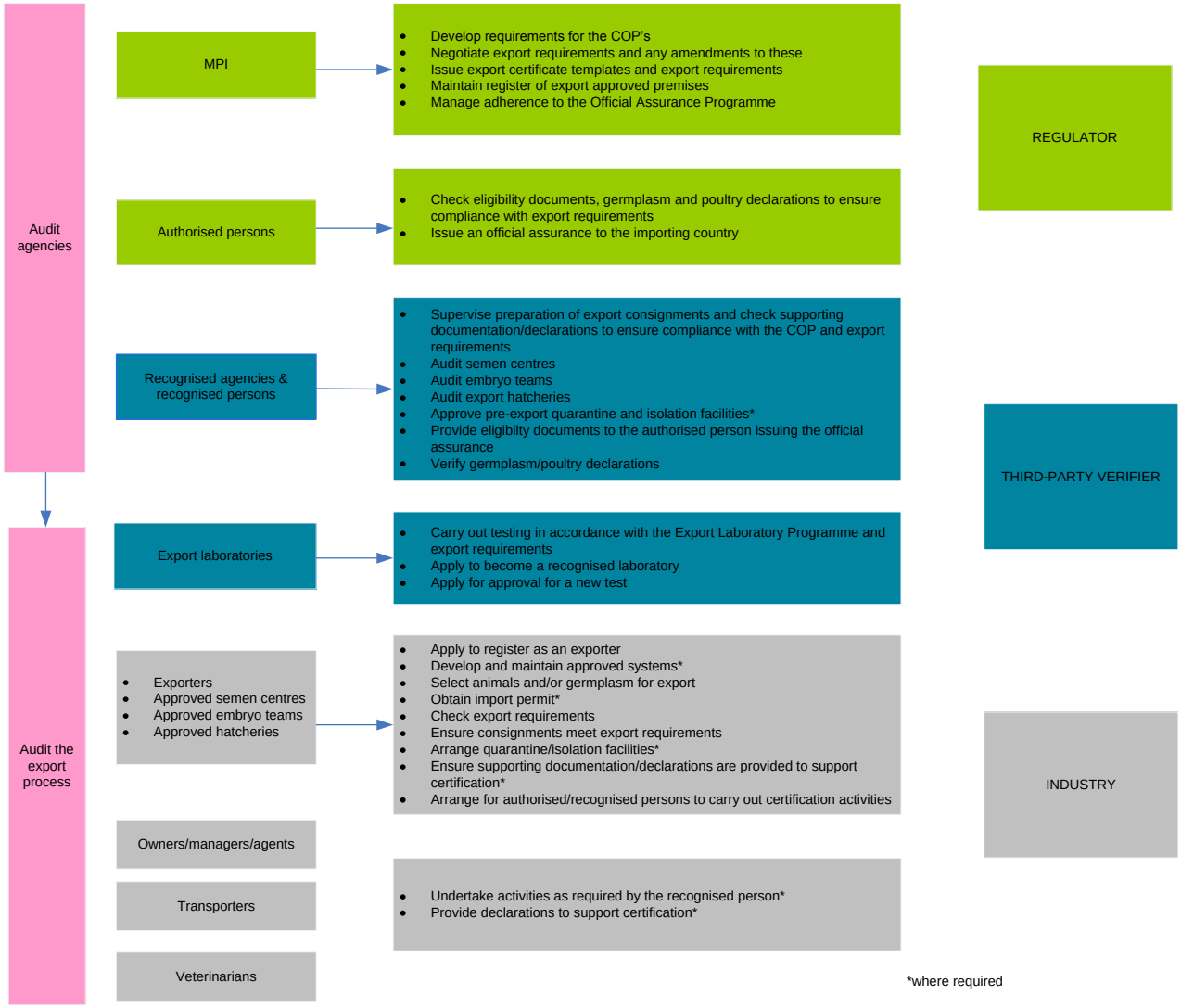
d. all non-compliances should be closed out. Documentation which attests to this should be viewed by the recognised person.

Part 12 Appendix 1

Roles and Responsibilities

The roles and responsibilities of various groups of people involved in the export of live animals and germplasm as shown in figure 1.

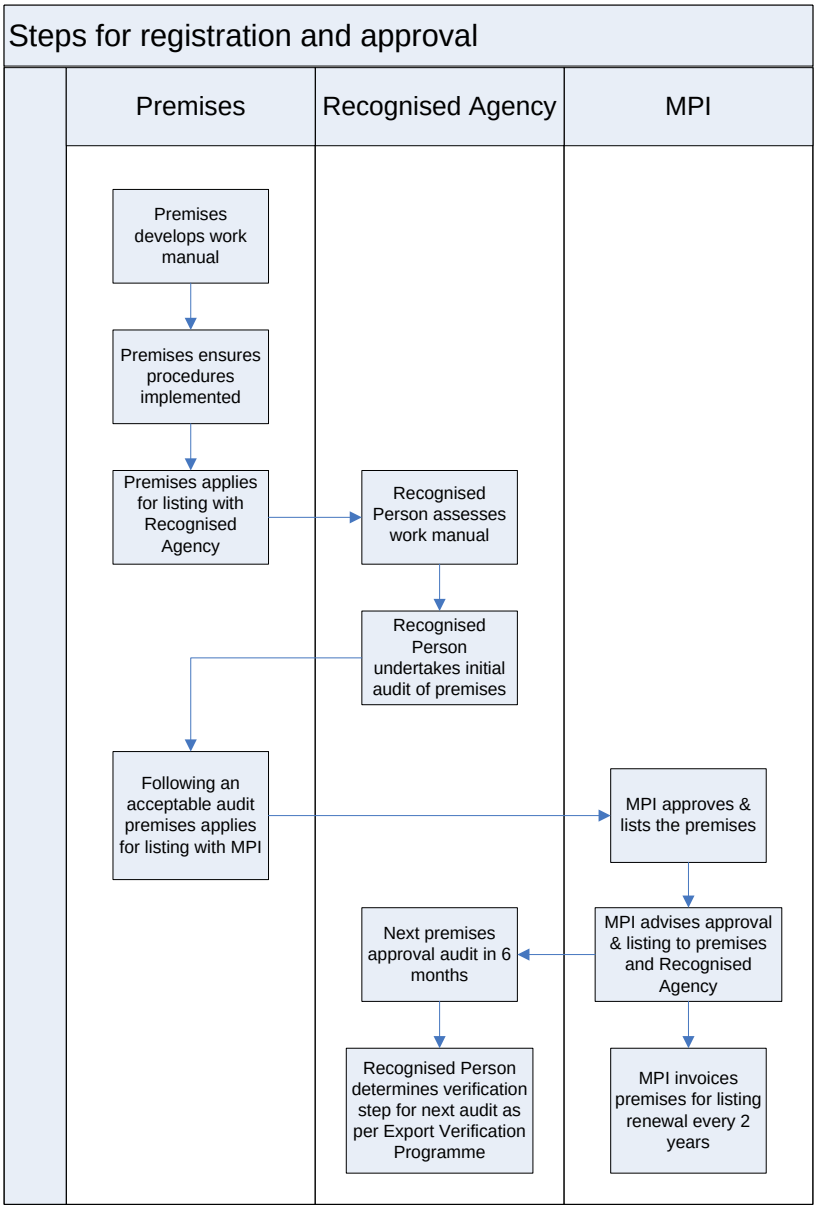
Figure 1. The roles and responsibilities in the export of live animals and germplasm



Part 12 Appendix 2

Approval of a new export approved premises:

Figure 2: Steps for a premises to become approved



Prior to submitting an AP41 application to MPI to be listed as an export approved premises, the premises must be audited by a recognised person. For a listing audit, the premises must be able to demonstrate the scope of the activities for which they want to be approved.

The operator is responsible for submitting the application to MPI for listing, which must include the listing audit report. The AP41 application form for listing is on the MPI website.

Link: http://www.biosecurity.govt.nz/regs/exports/animals/oap/forms

Once the listing is approved, MPI will notify the operator that the premises is listed as an export approved premises, after which the collection/processing/storage for export can begin. Note that germplasm is **not** eligible for export until after the export approved premises is officially listed and the operator is notified.

Normal processing time for the MPI Approvals and Appointments Group, to which the application is submitted, is approximately twenty (20) working days.

Operators wanting to be listed as an export approved premises should notify the recognised agency in advance of any intention to apply for a listing, so that there is time for the listing to occur prior to the proposed export.