Ministry for Primary Industries
Manatū Ahu Matua

Operational Code

Export Germplasm

Official Assurance Programme

22 January 2020

Issued by the Ministry for Primary Industries

New Zealand Government

TITLE

Operational Code: Export Germplasm

COMMENCEMENT

This Operational Code is effective from 22 January 2020.

ISSUING BODY

This Operational Code is issued by the Ministry for Primary Industries.

Dated at Wellington, 17 January 2020

[signed]
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Disclaimer

This guidance does not constitute, and should not be regarded as, legal advice. While every effort has been made to ensure the information in this guidance is accurate, the Ministry for Primary Industries does not accept any responsibility or liability whatsoever for any error of fact, omission, interpretation or opinion that may be present, however it may have occurred.

This operational code replaces the Codes of Practice: Export Germplasm 2013 and the Official Assurance Programme: Definitions 16 November 2011.

Contents

Introduction

This introduction is not part of the Operational Code, but is intended to indicate its general effect.

Purpose

This Operational Code was developed by the germplasm industry and the Ministry for Primary Industries (MPI) to assist germplasm exporters to meet the requirements of the Animal Products Act 1999 (the Act) and in particular the live animal and germplasm Official Assurance Programme.

The live animals and germplasm Official Assurance Programme 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 the following types of documents that set the standards and specifications for export:

- Operational Codes of Practice
- Market and commodity specific Export Requirements (overseas market access requirements)
- General Animal Products Notices.

The Operational Codes of Practice include:

- Operational Code: General Live Animal Export
- Operational Code: Pre-export Quarantine and Isolation
- Operational Code: Export Germplasm (this document)
- Operational Code: Export Poultry Hatcheries

Background

This Operational Code (Code) applies to export approved premises (EAP) that are approved by MPI under the Act for collecting, processing and/or storing germplasm (semen centres or embryo teams) for export with official assurances.

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 Code 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 Technology Society (IETS). The health testing requirements of this Code are based on New Zealand's endemic disease status.

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

This Code includes information about MPI's electronic certification system to allow for the future transition of germplasm exports to this system.

Who should read this Operational Code?

This code applies to premises that are approved by MPI for the export of germplasm and should be read by:

a) germplasm exporters;
b) germplasm export approved premises operators;
c) centre/team veterinarians;
d) recognised persons; and
e) authorised persons.

Why is this important?

This Code is a guidance document on how to meet export requirements of the Act.

Document History

This revised Code reflects the changes made to the Animal Products Notice: Export Approved Premises.

Version Date	Section Changed	Change(s) Description
16 September 2013		
22 January 2020	Whole document	New format and updated content, changes marked in yellow.

Other information

Legal Requirements

Throughout this Code the word "must" is often used to designate a mandatory status under the Act or a Legal Notice. The specific reference to the legal instruments have been included in this document in square brackets after the relevant sentence or clause. For example:

"Exporters of live animals must be registered as an exporter in New Zealand [APA]."

In many cases, the mandatory requirements have been paraphrased for context. Exporters and operators should refer to the legislation for the actual wording of the legal requirement.

Guidance

The information contained within a border throughout this document provides examples, further information and clarifications.

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:

(1) 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/

(2) 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: https://www.oie.int/standard-setting/terrestrial-manual/access-online/

The International Embryo Technology 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: https://www.iets.org/publications.asp

Other Standards

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

(1) Market Specific Export Requirements (OMARs) https://www.mpi.govt.nz/exporting/animals/semen-and-embryos/requirements/

(2) CSS Standards https://www.naab-css.org/uploads/userfiles/files/CSSMinReq-Jan2014201607-ENG.pdf

Legislation, Roles and Responsibilities

(1) The roles and responsibilities of various groups of people involved in the export of live animals and germplasm as shown in Figure 1. A summary of the main legislation that is most applicable to the export of live animals and germplasm as shown in Figure 2.

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

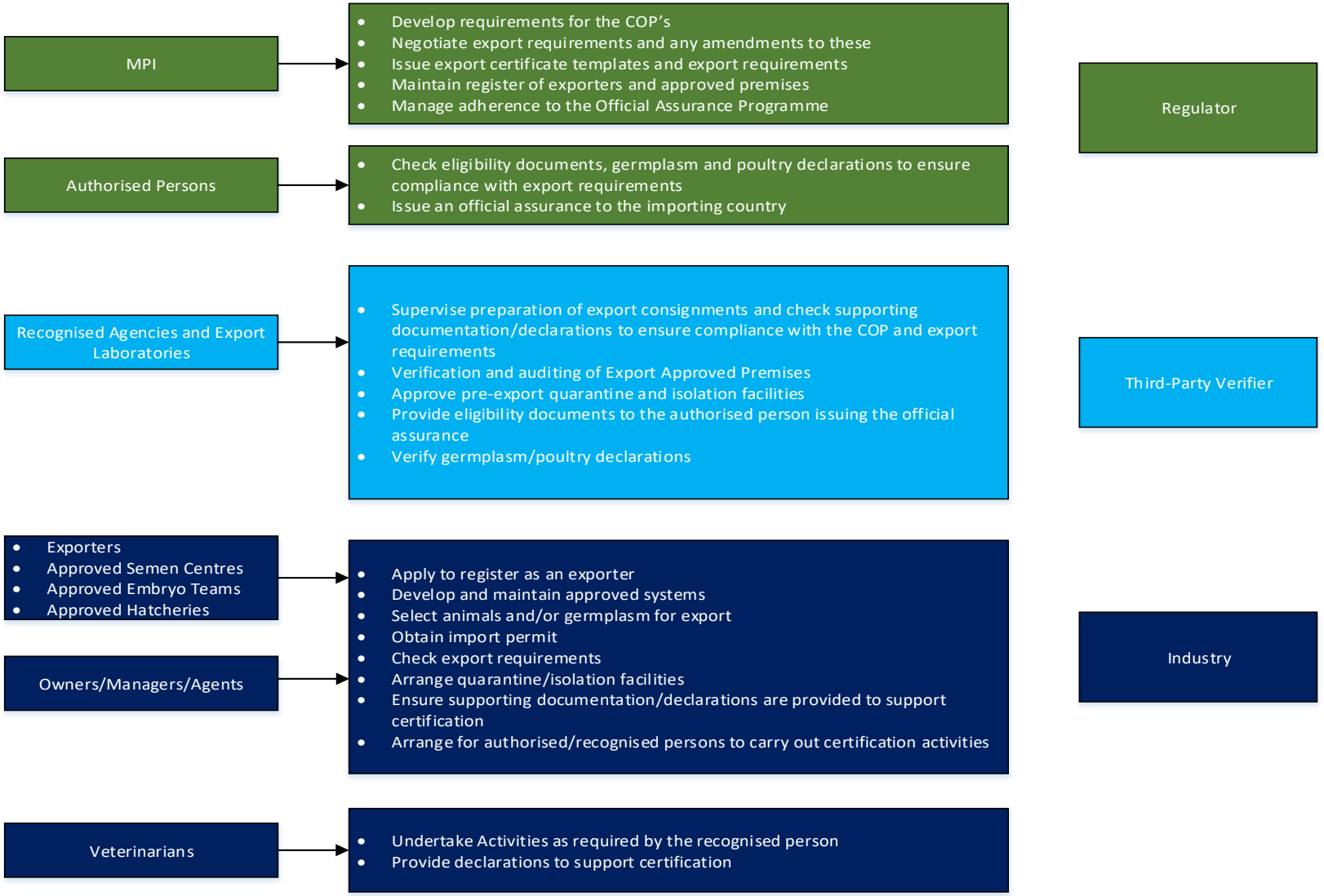
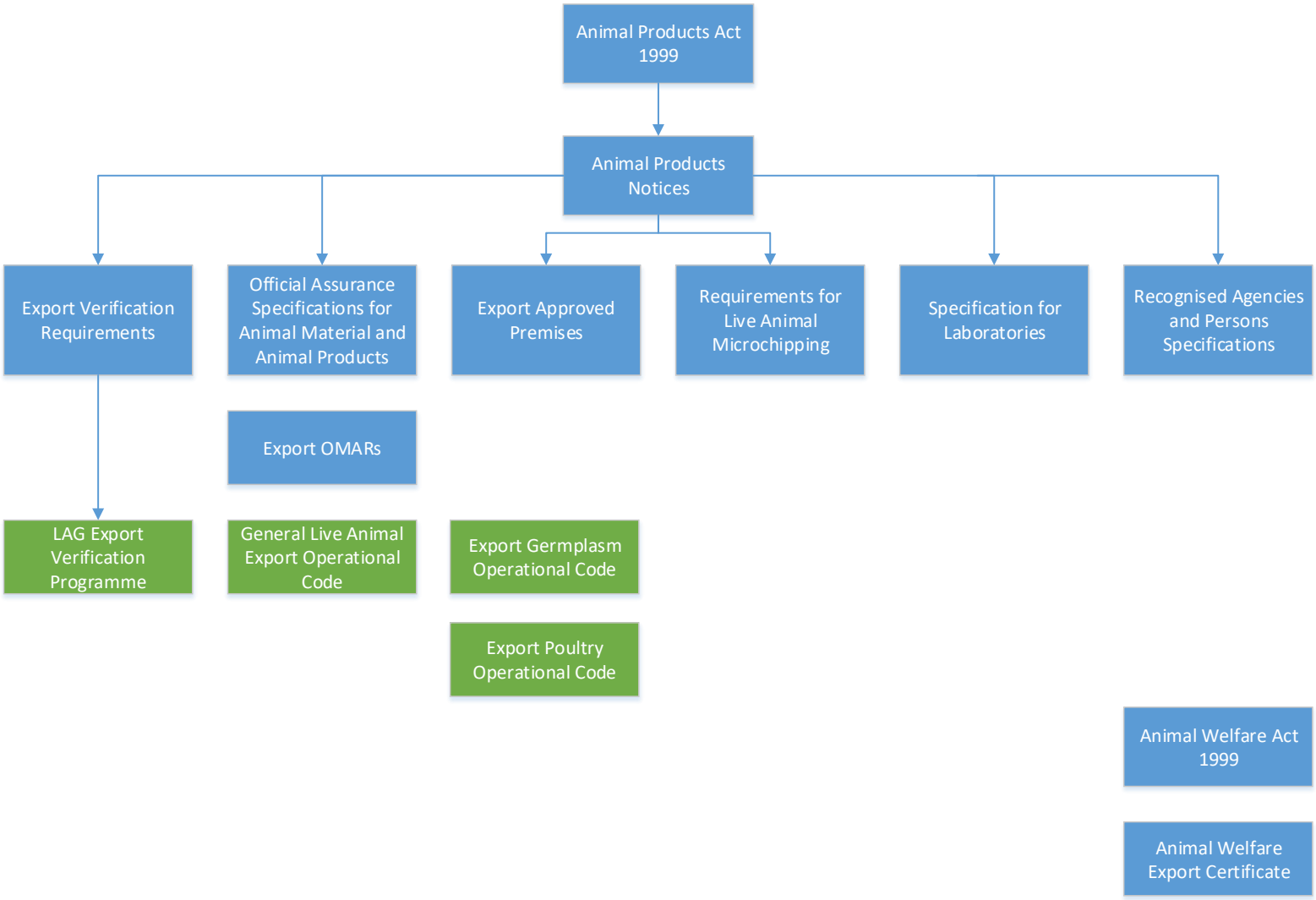


Figure 2. Diagram of main legislation (blue) and associated documents (green) that is most applicable to the export of live animals and germplasm



Part 1: General

1.1 Structure of the Code

(2) This Code is separated into Parts.

(3) Part 1 gives an overview of the content of this Code, definitions and abbreviations.

(4) Parts 2 and 3 summarise the requirements under the Animal Products Act and relevant Animal Products Act Notices.

(5) Parts 4 and 5 provide guidance for what the operators of semen export approved premises need to do in order to become MPI approved and retain this approval. Where the word "must" is used in these sections it is because there is a corresponding legislative requirement, which is referenced.

(6) Parts 6, 7, 8, and 9 are commodity specific testing requirements.

(7) Parts 10, 11, and 12 provide guidance for what the operators of embryo export approved premises need to do in order to become MPI approved and retain this approval. Where the word "must" is used in these sections it is because there is a corresponding legislative requirement, which is referenced.

(8) Export approved premises may use alternative approaches to meet certification requirements, provided all relevant regulatory requirements are met. Those who wish to use an alternative approach should seek guidance from their Recognised Person and MPI.

1.2 Application

(1) This Code is guidance for export approved premises that are approved by MPI for the collection, storage, and export of germplasm.

(2) This Code does not apply to:

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

1.3 Definitions

Any term or expression that is defined in the Animal Products Act 1999, Animal Products (Ancillary and Transitional Provisions) Act 1999, or regulations made under those Acts and used but not defined in this Code, has the same meaning as in those Acts or Regulations.

In this Code, the following definitions, abbreviations and interpretations are used:

The Act means the Animal Products Act 1999 unless otherwise stated.

animal means any member of the animal kingdom, including:

a) any mammal, bird (including hatching eggs), finfish, shellfish, reptile, amphibian, insect, or invertebrate;
b) any other creature or entity that is declared by the Minister by notice in the Gazette to be an animal for the purposes of this Act.

Animal Trade (Exports) means the section within MPI responsible for the development, negotiation and setting of, and adherence to Export Requirements for live animals and germplasm.

authorised person means a person employed by MPI and designated by the Director-General of MPI under section 65 of the Act as an authorised person for the purpose of issuing official assurances under section 61 of the Act, and for withdrawing and reissuing official assurances under section 64 of the Act.

authorised user means an approved veterinarian that has been given authority to access live animal export certificate templates to enable the signing of germplasm or poultry declarations.

centre manager means the person with delegated responsibility covering the following requirements:

a) adequate knowledge of the day-to-day operations of the premises;
b) sound knowledge of applicable export requirements and industry standards;
c) able to be present at the premises at reasonable notice; and
d) able to be present during routine verification.

centre veterinarian means an approved veterinarian who is responsible for the day-to-day compliance of semen collection, processing and/or storage in accordance with this Code and any relevant requirements.

cleaning means the application of procedures that effectively remove surface and built-up dirt, as appropriate to the equipment/facility. These procedures may vary according to the nature of the equipment/facility they are applied to. Examples are:

a) high-pressure hose and/or steam cleaning for concrete, steel, rubber and wooden surfaces associated with an isolation or germplasm collection facility.

b) hot water, detergents and/or abrasive cleaning agents for smooth work/interior surfaces in a laboratory or germplasm storage facility.

closed out means the corrective action for a non-compliance(s) identified in an audit has been verified as successfully completed.

competence means in relation to a person, means a demonstrated ability to apply that person's knowledge and skills.

competent authority means the veterinary authority or other governmental authority of a country having the responsibility and competence for ensuring or supervising the implementation of animal health and welfare measures, international veterinary certification and other standards and guidelines.

conflict of interest means where the duties or responsibilities of a person required by this Code or under the Act could be improperly affected by some other interest or duty the person may have.

consignment means one or a number of live animals, hatching eggs or germplasm, being moved from one country to another and covered, where required, by an official assurance.

consolidated consignment means a consignment consisting of more than one lot of live animals, or germplasm, from different sources being exported under a single official assurance.

custom collection means collection of semen from animals that are not permanently resident on the centre (compared with collection from animals that are permanently resident on the semen collection centre).

defined area means an area within a facility, which is clearly demarcated for a specific purpose.

Director-General this term generally applies to the Director-General of MPI and for the purposes of this document includes his/her authorised delegates namely: the Deputy Director-General; the Director Assurance; the Director Animal Health and Welfare; the Director Performance Oversight and Approvals; or other MPI employees with delegated authority to exercise appropriate powers under the Animal Products Act 1999.

disinfection means the application, after cleaning, of procedures intended to destroy agents of disease.

dispensation means an exemption from a particular Export Requirement which is reflected in the issuing of a one-off official assurance.

dormancy (dormant) means an animal product business temporarily ceases all or some of its functioning under the Act and there is an anticipated re-start date.

eligibility declaration means a document signed by an approved veterinarian that confirms the eligibility for export of any germplasm or day-old poultry or hatching eggs that requires an official assurance.

eligibility document means a copy of an export certificate template with relevant sections completed, which is issued by a recognised person to an authorised person and which confirms information supporting the eligibility for export of any live animal (and germplasm where a germplasm declaration is not used) that requires an official assurance.

embryo means the initial stage of development of a domestic animal, while it is transferable to a recipient dam.

embryo team means a group of technicians, and including facilities related to their operations, under the supervision of an approved team veterinarian, competent to perform the collection/production, processing and storage of embryos/ova.

embryo team veterinarian means an approved veterinarian who is responsible for the day-today compliance of embryo collection, processing and/or storage in accordance with this CODE and any relevant requirements.

entity means an organisation or person that is legally able to enter into a contract and possesses a separate existence for tax purposes. An example of an entity would be a company, corporation, partnership, or trust.

equivalence means the situation where the sanitary measure(s) proposed by the exporting country, is negotiated and accepted by the importing country as an alternative to their requirement.

export approved premises means any premises approved by the Director-General under the Animal Products (Export Approved Premises) Notice 2018 (including semen centres, embryo teams and hatcheries).

export certificate template means the template which is used to raise an official assurance as determined by the Director-General pursuant to section 62 of the Act. Once the export certificate template is completed, printed on security paper, numbered, signed and dated by an authorised person, and stamped with that authorised person's signatory seal, it becomes an official assurance.

Export Requirements means the requirements, issued under section 60 of the Act which are specific to an identified overseas market(s) and related to the export of live animals and germplasm.

exporter means a person or entity that is registered for the purpose of exporting animal products under the Act, unless exempt from registration.

facility means buildings, laboratories, yards, paddocks, etc. associated with the export of live animals.

farm of origin means the farm from which the animals originated immediately prior to entering quarantine or pre-export isolation, or prior to being exported.

first-hand knowledge means knowledge by a person of facts or information which have been directly observed or verified by that person. It does not include knowledge based on what a person has been told by another.

germplasm means semen, embryos, and ova of animals.

germplasm declaration means a copy of an export certificate template with relevant sections completed, issued by an approved centre/team veterinarian to an authorised person and which confirms information supporting the eligibility for export of any germplasm that requires an official assurance.

IETS means International Embryo Technology Society.

IETS Manual means the current edition of The IETS Manual of the International Embryo Technology Society, which includes guidelines for general procedures for bovine embryo transfer. This can be found on the IETS website: https://www.iets.org/publications.asp

internal audit means managerial tool with its primary function being to measure and evaluate the adequacy and effectiveness of internal control systems.

import permit means an official document that is issued by an importing country allowing the importation of live animals or germplasm which may or may not specify the import requirements.

i**nventory** means a system of control whereby an entity is able to satisfactorily demonstrate the identity, traceability and eligibility of live animals or germplasm through their records.

isolation means keeping animals of the same export status separate from other animals of a different or unknown status.

issue means (in relation to an official assurance) refers to the provision of the authorised person's signature and seal on an export certificate template to transform it into an official assurance.

lot means a number of animals, or a collection of containers (e.g. straws, ampoules) containing semen/embryos.

MPI means Ministry for Primary Industries.

MPI website means http://www.mpi.govt.nz.

MPI VS means Ministry for Primary Industries Verification Services Directorate (formerly NZFSA VA).

non-compliances are rated as follows:

a) critical non-compliance.
b) major non-compliance.
c) minor non-compliance.

A **critical** non-compliance compromises the integrity of export certification. Examples include but are not limited to:

a) negligence.
b) non-disclosure of unfavourable test or examination results.
c) substitution of animals or samples.
d) failure to keep essential records.
e) false certification and/or altered signature.
f) failure to declare a conflict of interest.
g) failure to rectify any major non-compliance(s) within the agreed timeframe.

A **major** non-compliance is one that demonstrates a major failure in the operation of a documented procedure or a deficiency in veterinary science application. It may be a specific non-compliance or a system with multiple non-compliances having a cumulative effect. Major non-compliances may be created by escalation of outstanding issues from previous audits. A major non-compliance may compromise the integrity of the official assurance. Examples include but are not limited to:

a) unsatisfactory submission of samples for testing.
b) major omission or inaccuracy in record-keeping.

A **minor** non-compliance is one that does not represent a major failure of an operation or system but that does require correction.

official assurance means a general statement to a foreign government, or an agent of a foreign government, attesting that certain conditions apply with respect to live animals or germplasm export. This includes, but is not limited to, statements regarding New Zealand's animal health status, the residency, isolation, health, testing, treatment and inspection status, and transportation of the commodity to be exported. Only authorised persons may issue an official assurance.

official assurance verifier means a person recognised under section 103 of the Act to undertake official assurance verification relating to the export of live animals and germplasm (refer to recognised person).

official control means the control by a recognised person or authorised person.

official veterinarian means a veterinarian authorised by the Veterinary Authority i.e. competent authority of the country to perform certain designated official tasks associated with animal health and/or public health and inspections of commodities and, when appropriate, to verify in conformity with the provisions of the chapters on "General obligations related to certification" and "Certification procedures" in the current version of the OIE Code (Veterinarians authorised or recognised under the Animal Products Act 1999 can be termed 'official veterinarians').

OIE means World Organisation for Animal Health (the name Office International des Epizooties was abolished in 2003; the acronym has been maintained).

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

OIE Manual means:
The current edition of The OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals (mammals, birds and bees) for diseases listed in the Code. This can be found on the OIE website: https://www.oie.int/standard-setting/terrestrial-manual/access-online/
The current edition of the OIE Manual of Diagnostic Tests for Aquatic Animals, which can be found on the OIE website: https://www.oie.int/standard-setting/aquatic-manual/

operator means the person who has overall responsibility for a quarantine or pre-export isolation facility or export approved premise, its maintenance and operation.

pre-entry isolation means a supervised facility where animals spend a specified period of time in 'isolation' or 'quarantine' immediately prior to entry into a germplasm facility.

premises means the place where a live animal business is operated.

quarantine means keeping animals under a level of biosecurity control that is expected to maintain their export eligibility status.

recognised agency means in relation to any function or activity set out in this notice means a person or body recognised as an agency under section 103 of the Act for the purpose of performing specified functions and/or activities required for export certification of animals and germplasm to which this notice applies.

recognised laboratory means a laboratory recognised by the Director-General under the Export Laboratory Programme https://www.mpi.govt.nz/law-and-policy/approved-organisations-and-people/animal-products-act-recognised-agencies-and-persons/recognised-laboratory-programme/

recognised person means in relation to any function or activity set out in this notice means a person recognised under section 103 of the Act for the purpose of performing specified functions and/or activities relating to the export of live animals and germplasm to which this notice applies.

security seal means an MPI seal, which is a uniquely marked device used for the purpose of detecting whether cages or containers containing live animals or germplasm have been tampered with once the official assurance has been issued.

semen centre means an officially approved and supervised facility(s) where one or more of the following activities occurs: keeping animals, collecting semen, processing semen, and storing semen. A centre may have separate facilities on different sites.

shut down means a shut-down where no level of activity is present and where there is no intended date for restarting processing, and includes an animal product business with a suspended programme.

specifications means any specification issued under section 60 (2) of the Act.

sterilisation means the procedure to free from living micro-organisms.

supporting documentation means a document, provided by a person other than a recognised person, providing information to support the eligibility for export of any live animal or germplasm that requires an official assurance.

team manager means the person with delegated responsibility covering the following requirements:

a) adequate knowledge of the day-to-day operations of the premises;
b) sound knowledge of applicable export requirements and industry standards;
c) able to be present at the premises at reasonable notice; and
d) able to be present during routine verification.

team veterinarian means a veterinarian approved by the Director-General and who is responsible for supervision of the embryo team and the day-to-day compliance of the embryo team with this Code.

unfavourable test result means a test result that causes or could cause a change in the export eligibility of exported animal products/material, or animal products/material intended for export.

veterinarian means a veterinarian registered under the Veterinarians Act 2005.

work manual means the documentation outlining the systems and procedures of a semen centre or embryo team to enable the export approved premises to meet the recommendations of the Code.

1.4 Abbreviations

The abbreviations used for legislation cited in this document are:

APA Animal Products Act 1999

EVR Animal Products Notice: Export Verification Requirements

EAP Animal Products Notice: Export Approved Premises

OAS Animal Products Notice: Official Assurances Specifications for Animal and Animal Products

Part 2: Requirements of the Animal Products Act 1999 and general requirements for export

2.1 Requirements for exporters and operators

(1) The Act is New Zealand's legal framework for the export of animal material (including germplasm) and animal products.

(2) The Act sets out the duties and responsibilities for exporters and operators, while the Animal Products Regulations 2000 and various Notices, detail the specifications of how those duties and responsibilities should be met.

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

a) Animal Products Notice: Export Approved Premises
b) Animal Products Notice: Export Verification Requirements
c) Animal Products (Recognised Agencies and Persons Specifications) Notice 2015
d) Animal Products Notice: Official Assurances Specifications for Animal Material and Animal Products
e) Animal Products Notice: Specifications for Laboratories

(4) These documents can be found on the MPI website: https://www.mpi.govt.nz/law-and-policy/requirements/animal-products-act-notices/

(5) 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.

(6) Exporters of live animals must be registered as an exporter in New Zealand [APA]

(7) The operator of an export approved premises is responsible for [EAP]:

a) applying for listing and approval of a veterinarian that is to be associated with the facility (using the application form AP41 Export Approved Premises Listing);
b) re-applying for listing every two years;
c) providing the relevant verifiers with freedom and access to carry out their functions and activities under the Act;
d) notification to the Director-General if they want to change recognised agencies;
e) notification to the Director-General of any significant change to the export approved premises (e.g. change in ownership, management, or address); and
f) gaining access to MPI's electronic certification system.

(8) For the steps to follow for a new centre or team to become approved as an export approved premises, see Appendix 1.

(9) Note some countries (for example, EU, Chile, Colombia, and China) may have additional requirements that need to be met before a premises is eligible for listing and subsequent export to that country.

(10) The *Live Animal and Germplasm Export Verification Programme* has provision for an export approved premises to undergo dormancy 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

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

(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.

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

(4) Where import permit requirements do not correspond with the Export Requirements, the exporter/operator should inform the Animal Trade (Export) team as soon as practicable.

(5) 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. [OAS]

(6) 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 of a lower health status, with no direct contact.

Further information

- For embryo teams isolation 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 isolation means keeping animals separate from other animals of a different or unknown status in a defined area 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

(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 (see Schedule 1 for interpretation of this term).

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) Where an Export Requirement specifies an examination of an animal by a specific person, such as a centre veterinarian, or a veterinarian (NZ registered), this is taken to mean the examination is carried out by the person specified.

(3) Where an Export Requirement requires an animal to be examined or certified as being free of evidence of clinical signs of disease, but it is not specified who may do this, then the task may be carried out by a person who is trained or assessed as competent to carry out that task.

(4) All laboratory testing specified in the Export Requirements must be carried out by a recognised laboratory unless specifically exempt [APA].

(5) MPI maintains a list of recognised laboratories on the MPI website along with lists of the testing procedures each laboratory is approved to undertake Recognised Laboratory Programme (RLP) Laboratories

2.4 Communications with foreign authorities

(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 Trade (Export) team.

2.5 Equivalence and dispensation

(1) Exporters requesting dispensation or equivalence should contact the Animal Trade (Export) team, and provide them with any relevant information to assist the negotiation process.

(2) MPI reserves the right to reject requests on a case-by-case basis.

Part 3: Requirements for Certification

Further Information - OAS

The Animal Products Notice: Official Assurance Specifications for Animal and Animal Products sets specifications in relation to issue, control, and obtaining official assurances.

3.1 Official assurances and eligibility documents

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

(2) Eligibility documents are copies of export certificate templates with relevant sections completed, issued by a recognised person to an authorised person, these can also take the form of a template in an electronic certification system [OAS].

(3) Germplasm declarations are copies of export certificate templates with relevant sections completed, issued by an approved centre veterinarian or team veterinarian to an authorised person, these can also take the form of a template in an electronic certification system. Germplasm declarations are subject to random verification by a recognised person [OAS].

(4) Germplasm declarations are 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 [OAS].

3.2 Official assurances

(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 [APA]. 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; and
d) sealing the transport container.

(2) Exporters should notify the Animal Trade (Export) team as soon as possible (not later than 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 [APA]:

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 Trade (Export) team can be contacted by email (animalexports@mpi.govt.nz) or phone (0800 00 8333).

(3) Exporters should notify MPI VS Certification team as soon as practical where an official assurance has been lost or misplaced.

(4) Exporters must ensure that [OAS]:

a) information is available allowing for the traceability of the germplasm (this information should include, as appropriate, the premises of origin, transfer documentation, and country of destination);
b) any file copy of supporting documentation is a faithful and legible replica; and
c) all records and supporting documentation for germplasm are kept for a period of at least four years.

(5) Once an official assurance is issued, it remains the property of the Director-General until received by a foreign government [APA].

3.3 Export certificate templates

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

(2) Exporters and centre/team veterinarian can request access to password protected export certificate templates on the MPI website by applying to the Animal Trade (Export) team using the application form Access to Export Certificate Templates for Live Animals and Germplasm.

(3) Templates are able to be accessed through the electronic certification system.

3.4 Electronic certification

Further Information – Electronic certification system

MPI is looking to transition to an electronic certification system, once it is operational then it can be used as the platform for completing certification for live animal and germplasm exports.

Statements regarding the electronic certification system in this document are only relevant after the establishment of this system.

(1) Authorised, recognised persons, exporters, and centre/team veterinarians should have access to the electronic certification system.

(2) Access to the electronic certification system can be gained by contacting the Animal Trade (Exports) team.

3.5 Supporting documentation

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

(2) Any person providing supporting documentation must [OAS]:

a) have the requisite first-hand knowledge of the information he/she is providing; and
b) ensure that the supporting documentation is true and accurate.

(3) The centre/team veterinarian issuing a germplasm declaration must keep copies of any supporting documentation. [OAS]

(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; and
c) declarations from registered veterinarians servicing the property of origin.

(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”; and
b) “I am aware that this declaration is made for the purposes of supporting export certification under the Animal Products Act 1999”.

(6) Where the declaration is for the verification of the identification of the animal(s), the declaration should contain the following statement:

a) "I have checked the identification of the animal(s), for which I am providing this declaration and it is as specified in this declaration".

(7) Similarly, where the declaration is for the verification of the identification of farm/premises/herd/flock, the declaration should contain the following statement:

a) "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".

(8) 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.

(9) 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.

(10) 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.

(11) Supporting documentation may be required to be uploaded to the electronic certification system.

3.6 Germplasm declarations

(1) Any approved centre/team veterinarian issuing germplasm declarations must [OAS]:

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

(2) Germplasm declarations must have a unique identifier which includes the centre/team registration number or premises identifier, plus the unique document number [OAS].

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

(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 [OAS].

If a dispensation or equivalence has been given, then the exact instructions from MPI for amending the document must be followed.

(4) Germplasm declarations must not be issued if the details on the declaration are incomplete, inaccurate or not in accordance with the Export Requirements [OAS].

(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; and
h) the actual date of signing.

(6) Where an attached schedule is used, the schedule must be similar in format to the relevant parts of the export certificate template, and identified with the same shoulder number as the eligibility document [OAS].

(7) Corrections to hardcopy germplasm declarations must be kept to a minimum, and meet the following specifications [OAS]:

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; and
d) each error corrected only once.

(8) If there are too many errors, or where the corrections result in the document becoming unclear, a replacement germplasm declaration must be issued [OAS].

A replacement germplasm declaration requires a new unique identifier and must 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” [OAS].

(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 working days of signing the official assurance [OAS].

(10) In the event of any differences between the electronic version and the signed germplasm declaration, a written explanation should detail the differences.

(11) Communication regarding germplasm declarations should be copied to the relevant recognised person.

(12) At the time of export, the operator must 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 [OAS].

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

In cases of consolidated consignments where multiple separate export approved premises are contributing to a single final germplasm declaration, only the final germplasm declaration should be provided to the recognised person.

(13) Germplasm declarations should only be completed by the veterinarian of the final export approved premises that is in control of the germplasm.

(14) An electronic certification system is being developed and will automate the germplasm declarations and supersede (2) to (13) as these functions will be made automatic or set as a default.

(15) Eligibility documents raised in the electronic certification system should be exhausted once the product has been exported or used in domestic market.

3.7 Verification of germplasm by authorised persons

(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 [APA]. To do so the following should occur:

a) the exporter or a nominated representative should be available during the verification to carry out the handling of the germplasm;
b) due care should be taken to ensure that the quality and viability of the germplasm is not compromised; and
c) appropriate facilities, equipment and protective clothing should be used.

(2) In addition, the authorised person may at any time, where they have reasonable grounds for doing so, audit any supporting documentation [OAS].

3.8 Verification of germplasm declarations by recognised persons

(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.

(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 over the year to ensure that they have been produced correctly. The detail of information requested and scrutinized is subject to the discretion of the recognised person [OAS].

(3) In addition, the recognised person may at any time, where they have reasonable grounds for doing so, audit any supporting documentation [OAS].

(4) An electronic certification system shall automate the process for generating germplasm declarations, and supersede part 3.8 (1), as the recognised person is able to access completed germplasm declaration via the electronic certification system.

Part 4: Guidance for Semen Centre Operators and Veterinarians

4.1 Responsibilities of semen centre operators

(1) The operator can appoint a centre manager that:

a) has adequate knowledge of the day-to-day operations of the premises;
b) has sound knowledge of applicable export requirements and industry standards;
c) is able to be present at the premises at reasonable notice; and
d) is able to be present during routine verification.

(2) An operator is responsible for ensuring that there is a delegated person(s) responsible for:

a) the centre maintains its approval [EAP];
b) the centre employs competent staff;
c) ensuring a centre veterinarian is associated with the centre and is approved by the recognised agency [EAP];
d) Not placing the centre veterinarian in a situation that compromises his/her impartiality and independence in the performance of his/her functions as a centre veterinarian;
e) notifying the recognised person and Animal Trade (Exports) team immediately if there are changes to the status of the centre veterinarian(s) and the centre [EAP];
f) ensuring the recognised person is notified prior to any significant change to the centre's approved facilities or work manual [EAP];
g) ensuring internal audits are undertaken;
h) any corrective actions are closed out within the agreed timeframe [EVR]; and
i) the EAP and the centre veterinarian have access to MPI's electronic certification system.

(3) The operator must apply to MPI every 2 years for renewal of the approval of the centre veterinarian associated with the centre. Applications for approval must be accompanied by a recommendation from the recognised agency that performed the centre's most recent audit. The audit report should be sufficient supporting documentation for approval [EAP].

4.2 Requirements of semen centre veterinarians

(1) The centre veterinarian must meet the following requirements [EAP]:

a) is registered with the Veterinary Council of New Zealand and holds a current practising certificate;
b) has adequate knowledge of the day-to-day operations of the premises;
c) has sound knowledge of applicable export requirements and industry standards;
d) is able to be present at the premises at reasonable notice; and
e) is able to be present during routine verification.

(2) The centre veterinarian should have access to MPI's electronic certification system.

4.3 Responsibilities of semen centre veterinarians

(1) The centre veterinarian should:

a) ensure that only semen that meets the relevant parts of this Code, the Export Requirements, and the import permit (if required) will be presented for export [OAS];
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 [EAP].
c) have a detailed understanding of the relevant requirements within and made under the Act;

d) be present at every approval audit (or at least annually) [EAP];
e) ensure internal audits are undertaken; and
f) ensure that any corrective actions identified are closed out within the agreed timeframe [EVR].

(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*.

4.4 Competencies

(1) The following staff should be identified (either by position, designation or name) in the EAP manual:

a) the day-to-day manager or person responsible for the day-to-day running of the EAP;
b) the centre vet(s) who authorises all or parts of the EAP procedures; and
c) key personnel involved in quality control, process control, monitoring, corrective action, and record keeping, animal management, collection, processing, and storage of germplasm.

(2) The operator should document the skills or competencies needed by the persons or positions identified in 4.4 (1) above to enable the effective operation of the premises.

(3) These competencies may be documented in job descriptions.

(4) The day-to-day manager and centre vet should be familiar with the documented procedures and have the following competencies:

a) knowledge in regulatory requirements, including responsibilities, related to the effective development and implementation of the EAP work manual procedures;
b) technical knowledge and experience in the ongoing processes of the premises; and
c) ability to liaise and communicate effectively with personnel and the regulator.

(5) Personnel involved in key tasks e.g. 4.4 (1) above, should have the following competencies:

a) an appropriate level of knowledge and skill in implementing their assigned task;
b) a good understanding of, and be able to consistently comply with the EAP manuals; and
c) a good understanding of Recognised Agency audits and verification.

4.5 Training

(1) The operator should ensure that the skills of those persons involved in key tasks, are maintained on an ongoing basis.

(2) Any training provided should be appropriate to the nature of the person's assigned task or activity and level of responsibility. This may include induction training, regular in-house meetings, on-the-job training and external training courses.

(3) The developed training programme should include:

a) the identification of skills and competencies required for key roles;
b) training schedules (including refresher training); and
c) training records of personnel.

Training can include attendance at MPI germplasm exporter meetings and MPI ATAC meetings, regular review of relevant MPI notices, OMARS and signed export certificates, internal review of EAP procedures, internal audits, peer review of other centre veterinarian's germplasm declarations, auditing qualifications, certification training, etc.

(4) Personnel should also be trained against written instructions or procedures for their specific tasks, including equipment operation, and monitoring of product and process parameters. Training on specific areas, such as monitoring procedures, and internal auditing, should also be identified by the operator and undertaken as appropriate.

(5) The training programme should be reviewed annually to:

a) ensure the training of personnel remains up-to-date and effective; and
b) identify requirements for new training or refresher training, e.g. new product/equipment/process.

(6) Where appropriate, ensure there are clear instructions on biosecurity practices and operational tasks posted in the premises to re-enforce the procedures.

(7) Staff should ensure visitors and contractors report to the responsible person on arrival at the premises. Ensure they are supervised by appropriately assigned staff while within the premises. Ensure it is the responsibility of the assigned staff that biosecurity practices and procedures are followed by the visitor or contractor.

Part 5: Guidance for Semen Centres

5.1 Purpose

(1) The purpose of official sanitary control of semen collection, processing and storage are to:

a) 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; and
b) ensure that semen is collected, processed and stored in a manner that maintains its export status, so allowing the issuing of official assurances [EVR].

5.2 Requirements for approval and registration of semen centres

(1) Centres must be approved and registered by the Director-General for the collection and/or processing and/or storage of semen of specified species for export [EAP], and for the isolation of donor animals where this is required by Export Requirements. For the steps to follow for a centre to become approved as an export approved premises, see Appendix 1.

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

The list of approved centres is available on the MPI website:
https://www.foodsafety.govt.nz/registers-lists/export-approved-premises/

(3) Any change of any approved team veterinarians should be reported to the Animal Trade (Export) team so that the email distribution list can be kept up to date. The Approvals team should also be contacted to keep their current list of approved team veterinarians up to date.

5.3 Supervision of semen centres

(1) A centre should 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 should include:

a) having adequate knowledge of what is happening on the centre on a day-to-day basis [EAP];
b) being able to be present on centre at reasonable notice [EAP];
c) oversight of the export health status of the resident animals;
d) responsibility for the health and welfare of the resident animals;
e) being responsible for ensuring that all staff are trained and supervised; and
f) responsibility for the standard of hygiene during production, processing, storage and dispatch of semen.

(2) The semen centre veterinarian should be able to demonstrate a sufficient level of control and supervision to enable the official assurance verifier to have confidence that the semen centre is able to meet the outcomes described in section 5.1 (1).

5.4 Facility requirements for semen centres

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

(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; and
e) a storage facility.

These facilities may be at different locations.

(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.

(4) Facilities should be designed in such a way that animals can 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

(1) The centre must establish, document and maintain systems and procedures to ensure that only semen that meets the relevant Parts of this Code, the Export Requirements, and the import permit (if required) will be presented for export [EVR].

(2) The systems and procedures should be fully described in the centre's work manual [EAP]:

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 is eligible to exports to; and
e) clear descriptions of how the centre meets export requirements for the countries listed in the work manual.

(3) Procedures should include:

a) a document control system;
b) conditions for the presence of other domestic animals;
c) control of visitors and vehicles;
d) managing shared facilities;
e) pre-entry isolation;
f) cleaning and disinfection;
g) sterilisation of equipment;
h) the preparation of animals prior to collection;
i) collection of semen;
j) processing semen, including details of diluents, additives and extenders;
k) sexing of semen;
l) labelling, packaging and storing semen;
m) maintaining an inventory of stored semen;
n) transport of semen;
o) receiving semen from other centres;
p) submission of laboratory samples;
q) actions to be taken in the event of an unfavourable test result;
r) internal audits; and
s) record keeping.

(4) The work manual should specify in detail how the relevant outcomes will be achieved for the countries listed in the work manual [EAP].

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

(5) The centre must ensure that the centre's work manual is approved every three years by a recognised person [EAP].

(6) 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 [EAP].

Significant changes can include, but are not limited to, a major change in procedures, animals of different health status, or list of countries that are exported to.

(7) The centre must keep records for all matters that demonstrate the export eligibility of the semen [EAP]. 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; and
h) details of any examination, testing, treatment(s) and/or vaccination(s) in accordance with the Export Requirements.

(8) Records, including those of animals that have left the centre (if applicable), should be retained for future reference for a minimum of four years following export [EAP]. Any germplasm intended for export stored at a semen centre should have fit for purpose documents supporting export eligibility.

5.6 Management of the semen collection facility

(1) Staff should be technically competent and observe high standards of hygiene.

(2) The entry of visitors to the semen collection facility should be strictly controlled.

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

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

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

(6) Only animals that are tested to the required standard should enter the semen collection facility.

(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.

(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.

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

(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.

(11) The semen collection area should be cleaned daily after collection.

(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

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

(2) The semen processing laboratory should be managed so that semen is processed hygienically.

(3) Entry to the laboratory should be prohibited to unauthorised personnel.

(4) Visitors to the laboratory should be kept to a minimum.

(5) The laboratory personnel should be technically competent, and observe high standards of personal hygiene.

(6) The laboratory should be constructed with materials that permit effective cleaning and disinfection.

(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.

(8) The laboratory should be kept clean and tidy, and be protected against rodents and insects.

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

(10) Antibiotics added to the semen should be in accordance with international recommendations.

(11) Only semen from donors that meet at least the requirements of this part of the Operational Code should be processed at the same time.

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

(13) Each individual dose of semen should be indelibly marked in accordance with international recommendations.

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

(15) The semen storage areas and individual semen containers should be easy to clean and disinfect.

5.8 Additional considerations for germplasm sexing laboratories

(1) If a separate germplasm sexing laboratory is included under the registration of an export approved premises, the centre vet should have functional knowledge of all day to day activities related to the export eligibility status of germplasm [EAP].

5.9 Germplasm storage and transport

(1) Germplasm storage facilities should be constructed so that the interior can be cleaned and disinfected.

(2) Germplasm should be transported and/or stored under conditions that maintain its health status and export eligibility [OAS].

(3) Where non-export germplasm is stored at the same facility, there should be a robust system in place that distinguishes germplasm that is not eligible for export from germplasm that is. Such a system should be based on physical separation, product identification and labelling and traceability to ensure there is adequate control.

(4) Non-export germplasm is germplasm that is unable to meet export requirements; some examples can include: not processed in accordance with OMAR requirements, not being under the control of an export approved premises, etc.

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

(6) Fit for purpose transfer documents should accompany any export eligible germplasm that is being transferred between export approved premises, or separate processing laboratories.

(7) When an electronic certification system is available, it can be used in place of transfer documents to log the transfer of any germplasm between sites.

5.10 Unfavourable test results

(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, including notifying the recognised person.

In this context, an unfavourable test result is a test result that causes or could cause a change in the export eligibility of any germplasm exported, or intended to be exported.

(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 should immediately notify the recognised person. An investigation should be undertaken to establish the true health status of the sampled animal.

(3) The Director-General may carry out an investigation to ascertain the actual export status of the export approved premises [APA]. This investigation should be carried out in consultation with the recognised agency involved and any technical experts involved.

(4) Any unfavourable test result that relates to an export approved premises listed OMARs should be documented in a company register. Any follow-up action, if required, should be recorded, and this information should be available to the recognised person at approval audits.

This does not apply to: Bovine viral diarrhoea virus (BVDV) ELISA-Ab and Infectious bovine rhinotracheitis (IBR) ELISA-Ab.

5.11 Calibration and maintenance of critical equipment

(1) General requirements.

a) The operator should document and implement a calibration and maintenance programme for measuring devices that are used to provide critical measurements (such as thermometers), and critical equipment to ensure OMARs are met (such as autoclaves and fridges). This ensures that the premises, facilities and equipment are maintained in good working condition.

(2) Critical equipment and measuring equipment that is used to provide critical measurements should:

a) be appropriate to the task performed;
b) be regularly maintained as per the manufactures' recommendations or (if no such recommendation exists) be maintained on a basis that is documented in procedures;
c) have the accuracy, precision and conditions of use appropriate to the task performed;
d) be calibrated against a reference standard (shows traceability of calibration to a national or international standard of measurement) or (if no such standard exists) be calibrated on a basis that is documented in procedures; and
e) be uniquely identified (e.g. by using serial numbers, indelible tags or other permanent means of identification) to enable traceability of the calibrations and to identify the calibration status.

(3) The calibration/maintenance programme should include the following information:

a) scope of the calibration and/or maintenance programme that includes a description of each piece of equipment (e.g. type of equipment, model);

b) a means of identifying each equipment (e.g. serial numbers, indelible tags or other permanent means of identification);
c) procedures for routine or programmed calibration and/or maintenance (i.e. preventive maintenance);
d) calibration schedule (i.e. when the equipment was last calibrated and when the next calibration is due);
e) corrective actions;
f) procedures for inspection of any completed repairs or maintenance work; and
g) records to be kept.

(4) The operator should keep records demonstrating compliance with documented procedures. Records should include:

a) identification, location and calibration status of equipment;
b) calibration records e.g. calibration method and frequencies;
c) maintenance records e.g. maintenance schedule, maintenance forms, repairs and maintenance register;
d) calibration schedules;
e) calibration certificates showing traceability to appropriate standard measurement;
f) any equipment diagrams and specifications; and
g) monitoring and corrective action records.

5.12 Verification audits

(1) Prior to an audit, the centre's work manual should be assessed for completeness in relevance to the scope of operation, including countries being exported to and country listings.

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

(2) Each export approved premises must be audited by a recognised person:

a) before recommendation for listing as an export approved premises is given [EAP];
b) before recommendation for approval of veterinarians associated with the centre is given [EAP];
c) at scheduled verification audits or at least annually thereafter [EVR];
d) with at least one unscheduled audit in addition to every five scheduled audits undertaken;
e) within twenty working days of the approval being surrendered; and
f) within twenty working days from when a new centre veterinarian commences sole supervision of a centre.

Clarification

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 months.
Unscheduled audits can be undertaken to audit significant changes to the export approved premises eg. new centre veterinarian

(3) Routine verification audits should include:

a) auditing against the relevant parts of the centre's work manual;
b) the centre's inventory control;
c) the centre facilities;
d) an annual observation of collection and/or processing as applicable to the scope;
e) the health status of the resident animals;
f) each centre veterinarian is meeting the requirements and responsibilities of this code;
g) the training records for each centre veterinarian;

h) at least two 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; and
i) management of issues and non-compliances.

Further information

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

(4) At the completion of any audit, the recognised person must 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 [EVR]. The report should be completed within twenty working days of the audit, and made available to the centre veterinarian and operator. Non-compliances may be identified during audits, or may occur due to issues identified between audit visits.

(5) The actions to be taken 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 Trade (Export) team within twenty four 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; and
d) the Director-General may decide to refer the issue to the Veterinary Council of New Zealand.

(6) The actions to be taken 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.

(7) 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

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

a) bovine tuberculosis (*Mycobacterium bovis*);
b) bovine viral diarrhoea/mucosal disease (BVD/MD) using an antigen test;
c) bovine genital campylobacteriosis (*Campylobacter fetus* subsp. *venerealis*); and
d) trichomonosis (*Trichomonas foetus*).

(2) Any additional tests should be carried out in accordance with the Export Requirements.

(3) If there is conflict between the testing requirements specified in the Export Requirements and this Code, the Export Requirements prevail.

6.2 Testing of animals on the semen centre

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

a) bovine tuberculosis (*Mycobacterium bovis*);
b) bovine viral diarrhoea/mucosal disease (BVD/MD); and
c) for donor bulls only - bovine genital campylobacteriosis (*Campylobacter fetus* subsp. *venerealis*) and trichomonosis (*Trichomonas foetus*).

(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

(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.*

(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.

(3) Any additional tests should be carried out in accordance with the Export Requirements.

(4) If there is conflict between the testing requirements specified in the Export Requirements and this Code, the Export Requirements prevail.

Part 8: Cervine testing requirements

8.1 Movement of animals onto the semen centre

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

(2) Any additional tests should be carried out in accordance with the Export Requirements.

(3) If there is conflict between the testing requirements specified in the Export Requirements and this Code, the Export Requirements prevail.

Part 9: Equine testing requirements

9.1 Movement of animals onto the semen centre

(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.

(2) Any isolation or testing should be carried out in accordance with the Export Requirements.

Part 10: Guidance for Embryo Team Operators and Team Veterinarians

10.1 Responsibilities of embryo team operators

(1) The operator can appoint a team manager who:

a) has adequate knowledge of the day-to-day operations of the premises;
b) has sound knowledge of applicable export requirements and industry standards;
c) is able to be present at the premises at reasonable notice; and
d) is able to be present during routine verification.

(2) The operator is responsible for ensuring that there is a delegated person(s) responsible for:

a) the team maintaining its approval [EAP];
b) the team employs competent staff;
c) ensuring a team veterinarian is associated with the team and is approved by the recognised agency [EAP];
d) the team veterinarian is not placed in a situation that compromises his/her impartiality and independence in the performance of his/her functions as a team veterinarian;
e) notifying the recognised person and Animal Trade (Exports) team immediately if there are changes to the status of the team veterinarian(s) and the team [EAP];
f) ensuring the recognised person is notified prior to any significant change to the centre's approved facilities or work manual [EAP];
g) ensuring internal audits are undertaken;
h) any corrective actions are closed out within the agreed timeframe [EVR]; and
i) the EAP and the and the team veterinarian having access to MPI's electronic certification system.

(3) The team manager should apply to MPI every 2 years for renewal of the approval of the team veterinarian associated with the team. Applications for approval should be accompanied by a recommendation from the recognised agency that performed the team's most recent audit. The audit report should be sufficient supporting documentation for approval [EAP].

10.2 Requirements for embryo team veterinarians

(1) The team veterinarian must meet the following requirements [EAP]:

a) is registered with the Veterinary Council of New Zealand and holds a current practising certificate;
b) has adequate knowledge of the day-to-day operations of the premises;
c) has sound knowledge of applicable export requirements and industry standards;
d) is able to be present at the premises at reasonable notice; and
e) is able to be present during routine verification.

(2) The team veterinarian should have access to MPI's electronic certification system.

10.3 Responsibilities of embryo team veterinarians

(1) The team veterinarian should:

a) ensure that only embryos that meets the relevant parts of this Code, the Export Requirements, and the import permit (if required) will be presented for export [OAS];
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 [EAP].
c) have a detailed understanding of the relevant requirements within and made under the Act;

d) be present at every approval audit (or at least annually) [EAP];
e) ensure internal audits are undertaken; and
f) ensure that any corrective actions identified are closed out within the agreed timeframe [EVR].

(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.*

10.4 Competencies

(1) The following staff should be identified (either by position, designation or name) in the EAP manual:

a) the day-to-day manager or person responsible for the day-to-day running of the EAP;
b) the team vet(s) who authorises all or parts of the EAP procedures; and
c) key personnel involved in quality control, process control, monitoring, corrective action, and record keeping, animal management, collection, processing, and storage of germplasm.

(2) The operator should document the skills or competencies needed by the persons or positions identified in 10.4 (1) above to enable the effective operation of the EAP.

(3) These competencies may be documented in job descriptions.

(4) The day-to-day manager and team vet should be familiar with the documented EAP procedures and have the following competencies:

a) knowledge in regulatory requirements, including responsibilities, related to the effective development and implementation of the EAP work manual procedures;
b) technical knowledge and experience in the ongoing processes of the EAP; and
c) ability to liaise and communicate effectively with personnel and the regulator.

(5) Personnel involved in key tasks e.g. 10.4 (1) above, should have the following competencies:

a) have appropriate level of knowledge and skill in implementing their assigned task;
b) have a good understanding of, and be able to consistently comply with the EAP manuals; and
c) a good understanding of Recognised Agency audits and verification.

10.5 Training

(1) The operator should ensure that the skills of those persons involved in key tasks, are maintained on an ongoing basis.

(2) Any training provided should be appropriate to the nature of the person's assigned task or activity and level of responsibility. This may include induction training, regular in-house meetings, on-the-job training and external training courses.

(3) The developed training programme should include:

a) the identification of skills and competencies required for key roles;
b) training schedules (including refresher training); and
c) training records of personnel.

Further information

Training can include attendance at MPI germplasm exporter meetings and MPI ATAC meetings, regular review of relevant MPI notices and OMARS, signed export certificates, internal review of EAP procedures, internal audits, peer review of other team veterinarian's declarations, auditing qualifications, certification training etc

(4) Personnel should also be trained against written instructions or procedures for their specific tasks, including equipment operation, and monitoring of product and process parameters. Training on specific

areas, such as monitoring procedures, and internal auditing, should also be identified by the operator and undertaken as appropriate.

(5) The training programme should be reviewed annually to:

a) ensure the training of personnel remains up-to-date and effective; and
b) identify requirements for new training or refresher training, e.g. new product/equipment/process.

(6) Where appropriate, ensure there are clear instructions on biosecurity practices and operational tasks posted in the premises to re-enforce the procedures.

(7) Staff should ensure visitors and contractors report to the responsible person on arrival at the premises. Ensure they are supervised by appropriately assigned staff while within the premises. Ensure it is the responsibility of the assigned staff that biosecurity practices and procedures are followed by the visitor or contractor.

Part 11: Guidance for Embryo Teams

11.1 Purpose

(1) The purpose of official sanitary control of embryo production and storage are to:

a) 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; and
b) 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 [EVR].

11.2 Requirements for approval and registration of embryo teams

(1) Embryo teams can be approved and registered by the Director-General for the collection, processing, and/or storage of *in-vivo* and *in-vitro* embryos of specified species for export [EAP], 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.

For the steps to follow for a premise to become approved as an export approved premises, see Appendix 1.

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

The list of approved embryo teams is available on the MPI website: https://www.foodsafety.govt.nz/registers-lists/export-approved-premises/

(3) Any change of any approved team veterinarians should be reported to the Animal Trade (Export) team so that the email distribution list can be kept up to date. The Approvals team should also be contacted to keep their current list of approved team veterinarians up to date.

11.3 Supervision of an embryo team

(1) An embryo team should 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 should include:

a) having adequate knowledge of what is happening at the facilities on a day-to-day basis [EAP];
b) being able to be present at reasonable notice [EAP];
c) oversight of the export health status of the donor animals;
d) responsibility for the health and welfare of the donor animals when under the management of the embryo team;
e) being responsible for ensuring that all staff are trained and supervised; and
f) responsibility for the standard of hygiene during production, processing, storage and dispatch of embryos.

(2) The embryo team veterinarian should be able to demonstrate a sufficient level of control and supervision to enable the official assurance verifier to have confidence that the embryo team is able to meet the outcomes described in section 11.1.(1).

11.4 Facility requirements for embryo teams

(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;
c) a laboratory for processing embryos, which should be physically separated from the embryo collection area; and
d) a storage facility.

These facilities may be at different locations.

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

(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.

11.5 System requirements for embryo teams

(1) The team must establish, document and maintain systems and procedures to ensure that only embryos that meet the relevant Parts of this Code, the Export Requirements, and the import permit (if required) will be presented for export [EVR].

(2) The systems and procedures must be fully described in the embryo team's work manual [EAP]:

a) the name and contact details of the approved 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 are eligible to exports to; and
e) clear descriptions of how the embryo team meets export requirements for the countries listed in the work manual.

(3) Procedures should include:

a) a document control system;
b) conditions for the presence of other domestic animals;
c) control of visitors and vehicles;
d) managing shared facilities;
e) pre-collection isolation;
f) cleaning and disinfection;
g) sterilisation of equipment;
h) the preparation of animals prior to collection;
i) management of semen used for embryo production;
j) collection of embryos;
k) details of any on-farm collection;
l) production and processing of embryos, including details of media and solutions;
m) labelling, packaging and storing embryos;
n) maintaining an inventory of germplasm;
o) transport of germplasm;
p) receiving germplasm from other export premises;
q) submission of laboratory samples;
r) actions taken in the event of an unfavourable test result;
s) internal audits; and
t) record keeping.

(4) The work manual should specify in detail how the relevant outcomes will be achieved for the countries listed in the work manual [EAP].

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

(5) The team manager must ensure that the work manual is approved every 3 years by a recognised person [EAP].

(6) 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 [EAP].

Significant changes can include, but are not limited to, a major change in procedures, on-farm collection, or list of countries that are exported to.

(7) The team should keep records for all matters that demonstrate the export eligibility of the embryos [EAP]. This could include:

a) supporting declarations regarding the farm of origin or herd of origin;
b) supporting declarations regarding the semen used for insemination or fertilisation;
c) date of insemination or fertilisation;
d) date on which pre-collection isolation began;
e) dates of embryos collection and production;
f) health records of all embryo donors; and
g) details of any examination, testing, treatment(s) and/or vaccination(s) in accordance with the Export Requirements.

(8) Records, including those of animals that have left the EAP (if applicable), should be retained for future reference for a minimum of four years following export [EAP].

Any germplasm intended for export stored at the EAP should have fit for purpose documents supporting export eligibility.

11.6 Management of embryo collection

(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.

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

(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.

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

(4) Staff should be technically competent and observe high standards of hygiene.

(5) The entry of visitors to the collection facility should be strictly controlled.

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

(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.

(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.

(9) Donors should be prepared for collection so that the collection hygiene can be managed effectively.

(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

(1) The embryo processing laboratory should be physically separated from the embryo collection facilities.

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

(3) Entry to the laboratory should be prohibited to unauthorised personnel.

(4) Visitors to the laboratory should be kept to a minimum.

(5) The laboratory personnel should be technically competent, and observe high standards of personal hygiene.

(6) The laboratory should be constructed with materials that permit effective cleaning and disinfection.

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

(8) The laboratory should be kept clean and tidy, and be protected against rodents and insects.

(9) The germplasm storage areas and individual storage containers should be easy to clean and disinfect.

(10) The washing and examination of embryos should be carried out in accordance with the IETS *Manual.*

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

(12) Antibiotics used in any media should be in accordance with international recommendations.

(13) Each individual straw should be indelibly marked in accordance with international recommendations.

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

(15) Only embryos from donors of the same export status should be processed at the same time.

11.8 Germplasm storage and transport

(1) Storage facilities should be constructed so that the interior can be cleaned and disinfected.

(2) Germplasm should be transported and/or stored under conditions that maintain its health status and export eligibility [OAS].

(3) Where non-export germplasm is stored at the same facility, there should be a robust system in place that distinguishes germplasm that is not eligible for export from germplasm that is. Such a system should be based on physical separation, product identification and labelling and traceability to ensure there is adequate control.

Non-export germplasm is germplasm that is unable to meet export requirements; some examples can include: not processed in accordance with OMAR requirements, not being under the control of an export approved premises, etc.

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

(5) Fit for purpose transfer documents should accompany any export eligible germplasm that is being transferred between export approved premises or separate processing laboratories.

(6) When an electronic certification system is available, it can be used in place of transfer documents to log the transfer of any germplasm between sites.

11.9 Unfavourable test results

(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, including notifying the recognised person.

In this context, an unfavourable test result is a test result that causes or could cause a change in the export eligibility of any germplasm exported, or intended to be exported.

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

(3) The Director-General may carry out an investigation to ascertain the actual export status of the export approved premises [APA]. This investigation should be carried out in consultation with the recognised agency and any technical experts involved.

(4) Any unfavourable test result that relates to an export approved premises listed OMARs should be documented in a company register. Any follow-up action, if required, should be recorded, and this information should be available to the recognised person at approval audits.

11.10 Calibration and maintenance of critical equipment

(1) General requirements.

a) The operator should document and implement a calibration and maintenance programme for measuring devices that are used to provide critical measurements (such as thermometers), and critical equipment to ensure OMARs are met (such as autoclaves and fridges). This ensures that the premises, facilities and equipment are maintained in good working condition.

(2) Critical equipment and measuring equipment that is used to provide critical measurements should:

a) be appropriate to the task performed;
b) be regularly maintained as per the manufactures' recommendations or (if no such recommendation exists) be maintained on a basis that is documented in procedures;
c) have the accuracy, precision and conditions of use appropriate to the task performed;
d) be calibrated against a reference standard (shows traceability of calibration to a national or international standard of measurement) or (if no such standard exists) be calibrated on a basis that is documented in procedures; and
e) be uniquely identified (e.g. by using serial numbers, indelible tags or other permanent means of identification) to enable traceability of the calibrations and to identify the calibration status.

(3) The calibration/maintenance programme should include the following information:

a) scope of the calibration and/or maintenance programme that includes a description of each piece of equipment (e.g. type of equipment, model);
b) a means of identifying each equipment (e.g. serial numbers, indelible tags or other permanent means of identification);
c) procedures for routine or programmed calibration and/or maintenance (i.e. preventive maintenance);
d) calibration schedule (i.e. when the equipment was last calibrated and when the next calibration is due);
e) corrective actions;
f) procedures for inspection of any completed repairs or maintenance work; and
g) records to be kept.

(4) The operator should keep records demonstrating compliance with documented procedures. Records should include:

a) identification, location and calibration status of equipment;

b) calibration records e.g. calibration method and frequencies;
c) maintenance records e.g. maintenance schedule, maintenance forms, repairs and maintenance register;
d) calibration schedules;
e) calibration certificates showing traceability to appropriate standard measurement;
f) any equipment diagrams and specifications; and
g) monitoring and corrective action records.

11.11 Verification Audits

(1) Prior to an audit, the team's work manual should be assessed for completeness in relevance to the scope of operation, countries being exported to and country listings.

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

(2) Each export approved premises must be audited by a recognised person:

a) before recommendation for listing as an export approved premises is given [EAP];
b) before recommendation for approval of veterinarians associated with the team is given [EAP];
c) at scheduled verification audits or at least annually thereafter [EVR];
d) with at least one unscheduled audit for every five scheduled audits undertaken;
e) within twenty working days of the approval being surrendered; and
f) within twenty working days from when a new team veterinarian commences sole supervision of a team.

Clarification

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 months.

Unscheduled audits can be undertaken to audit significant changes to the export approved premises eg. new embryo team veterinarian

(3) Routine verification audits should include:

a) auditing against the relevant parts of the team's work manual;
b) the facilities;
c) inventory control;
d) an annual observation of collection and/or processing as applicable to the scope;
e) health records of the donor animals;
f) each team veterinarian is meeting the requirements and responsibilities of this code;
g) the training records for each team veterinarian;
h) at least two 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; and
i) management of issues and non-compliances.

Further information

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

(4) At the completion of any audit, the recognised person must prepare an audit report in which he/she lists any non-compliance, draws conclusions and makes a recommendation about the audit frequency of the team [EVR]. The report should be completed within twenty (20) working days of the audit, and

made available to the team veterinarian and the operator. Non-compliances may be identified during audits, or may occur due to issues identified between audit visits.

(5) The actions to be taken 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 Trade (Export) team 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; and
d) the Director-General may decide to refer the issue to the Veterinary Council of New Zealand.

(6) The actions to be taken 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; and
c) the corrective action should be checked by the recognised person for compliance within the agreed timeframe.

(7) All non-compliances should be closed out. Documentation which attests to this should be viewed by the recognised person.

Part 12: Dormancy and Shutdown for Export Approved Premises

12.1 Premises Dormancy

(1) An export approved premises intending to enter dormancy must apply to the Recognised Agency Technical Manager prior to the next audit due date [EVR].

(2) An export approved premises that is in dormancy must meet the minimum verification requirements for any activities that continue to function (e.g. ongoing storage and export of germplasm at a premises) [EVR].

(3) An operator of a premises in dormancy should have an audit report from their previous verification visit which would have occurred no more than 12 months prior to the application for dormancy is submitted to the recognised person [EVR].

(4) Dormancy must not be extended for more than one year, so it is a temporary seasonal ceasing of operations, with an intended restart date [EVR].

(5) The verifier, in consultation with the Recognised Agency Technical Manager, may reassess the verification needs, and apply a suitable interval during the period of dormancy [EVR].

After an extended dormancy period, the verifier may conduct a pre-start verification, these parameters are determined at the discretion of the Recognised Agency Technical Manager.

(6) Export approved premises with country listings: The operator should maintain the business in a manner that permits processing to start at short notice for these countries [EVR].

12.2 Shutdown

(1) An export approved premises entering Shutdown should do so under the conditions that they are to cease all business functions, and discontinue their MPI registration. The premises should be in communication with their verifier to discuss the shutdown process [EAP].

(2) The verifier in consultation with the Recognised Agency Technical Manager, may determine there is a need to conduct a closeout audit of the premises prior to shutdown [EAP].

12.3 Coming out of Dormancy

(1) EAP's coming out of dormancy should communicate with their verifier to discuss if there is a need to conduct a pre-start up verification visit which can include a review of the operator work manual and systems, facility inspection, centre veterinarian interview, (and storage if applicable) [EVR].

Schedule 1: Interpretation of Export Requirements

Terms occurring in some export certificate templates and their interpretations are presented below. Where terms are defined otherwise in the supplementary notes to an export certificate template that definition takes precedence over the interpretation listed here.

after due enquiry / to the best of my knowledge and belief
Where declarations are taken to support 'due enquiry', a number of declarations may be required to satisfy an Export Requirement, depending on the depth of knowledge of the person providing the declaration. Declarations should be taken from appropriate persons and should relate to their first-hand knowledge of a situation, not their knowledge of another person's integrity.

area / premises / herd / individual animal disease status
Disease status may be required to be certified for area / premises / herd / individual animal. For further information, see 'clinically diagnosed', 'disease', 'disease-free region', 'evidence of contagious or infectious disease', 'free from veterinary/quarantine restrictions', 'freedom from disease', 'not been known to occur' and 'premises of origin'.

case
Means an individual animal infected by a pathogenic agent, with or without clinical signs. (OIE definition)

cleaning and disinfection
See definitions for 'cleaning' and 'disinfection' in section 1.1 Definitions. For pre-export isolation/quarantine, poultry and germplasm collection facilities, MPI accepts the following surfaces as able to be cleaned and disinfected:

a) wood and concrete surfaces, as long as they are in good condition (e.g. rotten wood and broken concrete surfaces are not able to be cleaned and disinfected)
b) surfaces where aggregate (e.g. sand or bedding) is used and can be removed and replaced
c) other surfaces (e.g. carpet), although not able to be effectively cleaned and disinfected, may be used if they can be easily removed.

clinically diagnosed
For a disease to be clinically diagnosed, it is based on clinical evidence that includes one or more of the following: visual and physical veterinary examination of the animal, testing, post mortem, and health records. This means the same as "clinical case".

Examples:

A sheep that is emaciated and has chronic scours has clinical evidence of Johne's disease but not a clinical diagnosis/case of Johne's disease. The clinical evidence of Johne's disease can be ruled out with a negative test for Johne's disease. A sheep that is emaciated and has chronic scours and has a positive ELISA for Johne's disease has a clinical diagnosis/case of Johne's disease.

A bull that has signs of a respiratory infection and nasal discharge, has clinical evidence of IBR but not a clinical diagnosis/case of IBR. The clinical evidence of IBR can be ruled out with a negative test for IBR antigen.

A clinically health cow from a herd that has a clinical record of a positive bovine viral diarrhoea (BVD) bulk milk test does not have any clinical evidence of BVD, is not clinically diagnosed and is not a clinical case of BVD.

clinical evidence
Evidence of clinical disease, which includes one or more of the following: visual examination, physical examination, post mortem, health records.

Further information

For cases of exotic diseases, e.g. Brucella abortus, it is presumed that even though an animal may have clinical signs of Brucella abortus like orchitis, it is not clinical evidence of Brucella abortus as this is not found in New Zealand. This is not applicable to endemic diseases.

clinically free
Free of clinical evidence of disease

disease
'Disease' may be mentioned in the context of the following broad categories:

OIE diseases
These can be found in the Terrestrial Animal Health Code (Mammals, Birds and Bees). Export Requirements usually refer to specific diseases. The Animal Imports and Exports Group may be consulted for further information regarding these diseases.

specific diseases
These are specified in the Export Requirements. Their status should be established using the information under 'freedom from disease'.

notifiable diseases
These may be notifiable in New Zealand or in the importing country. They should be specified in the Export Requirements. Notifiable diseases in New Zealand are published under the current Biosecurity (Notifiable Organisms) Order on the MPI website.

general disease
This is often used in terms of assessing the fitness of an animal to travel (see 'fit to travel'). Where specific examinations are required, these will be stated in the Export Requirements.

disease-free region
The term 'region' is not definitive. It should either be defined in the supplementary notes to the Export Requirements or be part of an official disease control or eradication programme. Investigations for this type of claim should include the relevant enquiries from those listed under 'freedom from disease'.

equivalent health status
Any in-contact animals should be of the same certifiable disease status as those being certified; therefore, treatment and testing of the in-contact animals may be necessary. If the disease status of an animal or group of animals is unclear, they should not be mixed with another group until the disease status is clarified.

evidence of contagious or infectious disease
The diagnostic criteria may be specified in the Export Requirements. For some diseases, this may be solely laboratory confirmation of the disease. For others, a clinical veterinary examination may be required.

herd of origin
A group of animals, living and feeding together as an epidemiological unit, from which animals to be exported have been derived or had their primary source. The importing country may qualify the term of 'herd of origin' for a specified amount of time in the immediate past. Some farming units may be able to have more than one herd of origin on the one property, however, shared facility(s) may be used only where the following are unequivocal:

a) sharing does not compromise the export status of the animals
b) the facility(s) is constructed such that it can be cleaned and disinfected between usage by animals of a different export status.

Any changes to the make-up of the herd of origin should not affect the ability to certify with regard to disease freedom. Therefore the following should be considered:

a) the health status of the animals entering the herd
b) the health status of the property from which they originate
c) specific Export Requirements.

freedom from disease
The Export Requirements should state:

a) the disease in question
b) the period of time for which freedom is required
c) the area to which the term "freedom from disease" applies.

Declarations to support this type of statement should be based on information from:

a) registered veterinarians who service the premises/animal(s) in question
b) industry control or eradication databases
c) animal health laboratory databases
d) National Notifiable Diseases databases
e) National Disease Surveillance reports
f) MPI Verification Services
g) animal product businesses
h) export test reports
i) premises staff or owners of animals.

A number of declarations may be required to satisfy an Export Requirement clause, depending on the depth of knowledge of the person providing the declaration. For example, the farmer may state that to the best of his or her knowledge no cases of a disease have been diagnosed and give the names of the veterinary practices that have serviced the farm over the period required. The veterinarian(s) servicing the farm, in a separate declaration, may state that the practice has visited the farm a certain number of times in the period in question and that no cases of the disease have been diagnosed by their veterinary practice. The official veterinarian has the discretion to decide where a declaration is insufficient.

free from veterinary/quarantine restrictions
The owner of the premises in question should be asked whether the property is under movement control or other restrictions. The Animal Health Board database shows properties under 'movement control' for bovine tuberculosis.

fully vaccinated
This means vaccinated according to the recommendations of the manufacturer. Other terms such as 'correctly', 'properly' and 'appropriately' will be taken to mean the same as 'fully' unless otherwise stated.

not been known to occur
This refers to the absence of clinical disease (see 'clinically diagnosed'). Enquiries should be made such as those set out in 'freedom from disease'.

premises of origin
Premises are considered to be the unit of land, including buildings, from which the animal(s) for export are derived. Clarification of this term may be required in the supplementary notes of the Export Requirements to give a time period over which all the premises on which the animal(s) has resided should be considered to be premises of origin for disease freedom purposes, particularly where the animal(s) is not required to stay on a single property during the time stated.

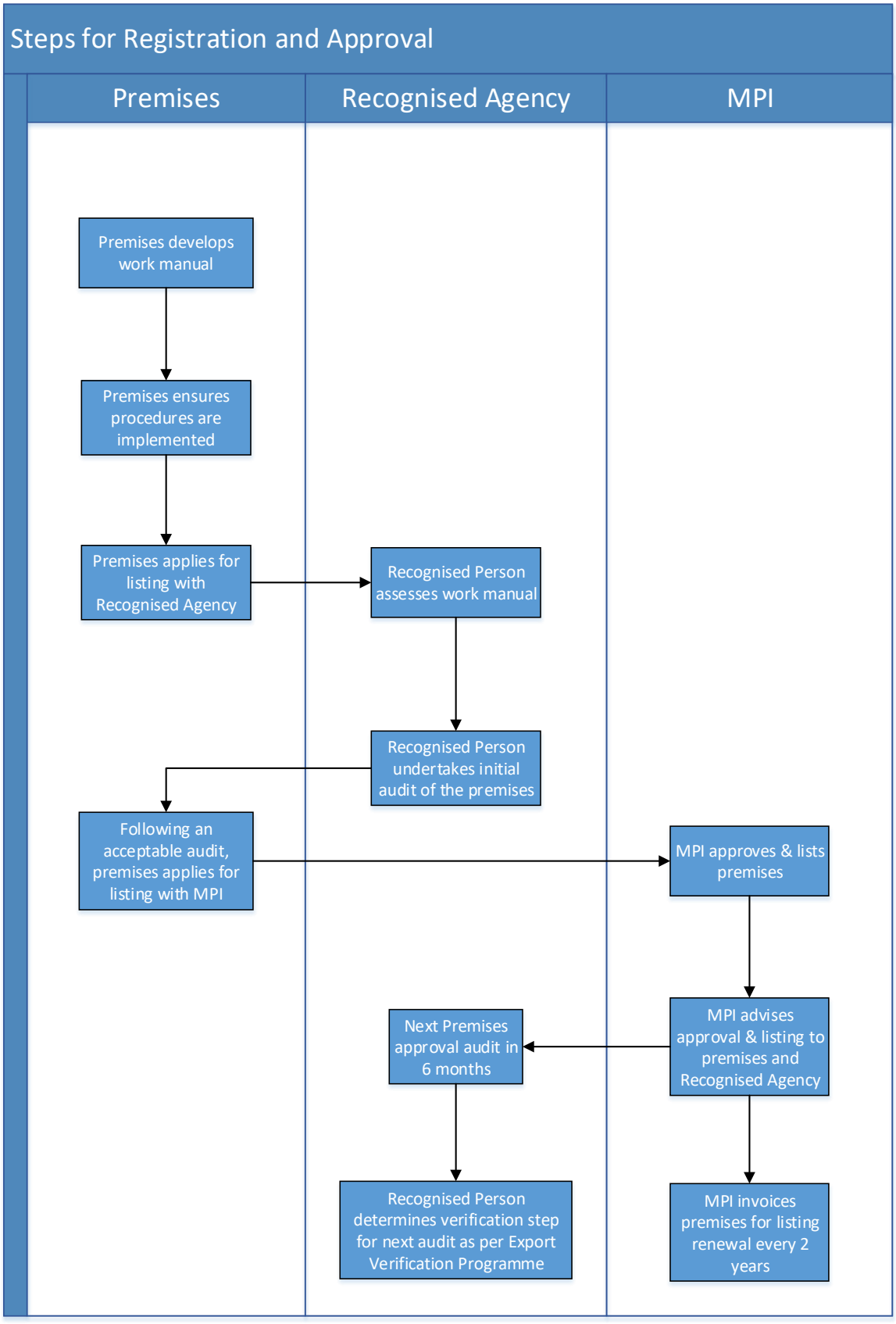
salmonellosis
clinical disease caused by any *Salmonella* spp

supervision
Supervision may be direct or indirect.

a) 'Direct supervision' means that the specified person is present throughout the task.
b) 'Indirect supervision' means that the specified supervisor is in a position to respond to a request for assistance. In both cases, the person undertaking the activity should be properly informed of the expectations placed on them. Some Export Requirements state that persons of a certain status should perform activities in the export process. In those cases, the specified person should perform the task.

vaccinated
The successful immunisation of susceptible animals through the administration, according to the manufacturer's instructions and the OIE Terrestrial Manual, where relevant, of a vaccine comprising antigens appropriate to the disease to be controlled

Appendix 1: Approval of a new Export Approved Premises



AP41 Export Approved Premises Listing application form

(1) Prior to submitting an AP41application to MPI to be listed as an export approved premises, the premises must be audited by a recognised person.

(2) For a listing audit, the premises must be able to demonstrate the scope of the activities for which they want to be approved.

(3) The operator is responsible for submitting the application to MPI for listing, which must include the listing audit report.

(4) Once the listing is approved, MPI will notify the operator that the premises is listed as an export approved premises, after which the collection of germplasm for export can begin. Note that the germplasm is not eligible for export until after the export approved premises is officially listed and the operator is notified.

(5) Normal processing time for the MPI Approvals Operations team, to which the application is submitted, is approximately twenty (20) working days.

(6) 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.

Appendix 2: Premises Entering Shutdown or Dormancy