



Treatment Requirement

Treatment Programme

Overview and General Requirements for the Supply of Official Treatments

15 November 2018

TITLE

Treatment Requirement: Treatment Programme

COMMENCEMENT

This Treatment Requirement is effective from 15 November 2018

ISSUING BODY

This Treatment Requirement is issued by the Ministry for Primary Industries.

Dated at Wellington, 15 November 2018

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Introduction

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

Purpose

This document sets out how the MPI Treatment Supplier Programme operates, the roles and interactions of the three primary participants (i.e. MPI, IVA's and treatment suppliers), the requirements of the treatment supplier supervision programme and describes how treatment suppliers are approved.

One or more Import Health Standards incorporate this Treatment Requirement by reference

Background

The Ministry for Primary Industries (MPI) has responsibility to ensure that official treatments¹ being applied to imported risk goods provide the best practicable level of control, and that official treatments being applied to export goods comply with importing country requirements.

MPI has designed and operates a system of control over official treatment activities to ensure that only competent organisations and individuals are involved with the delivery of official treatment activities.

The treatment supplier programme provides an integrated MPI system for the:

- a) Formal recognition of competent, professional and effective external independent verification agencies (IVAs) who work as MPI Agents for the supply of verification services to treatment suppliers.
- b) Provision of official treatments to imported and exported goods by an approved treatment supplier.

Official treatments may be provided by treatment suppliers who operate either:

- a) Under direct IVA supervision, where each and every treatment is directly supervised by an IVA. This is known as the "**Supervision Programme**"; or
- b) Under the "**Approved Treatment Supplier Programme**", where a treatment supplier establishes and complies with a documented quality management programme, is audited by an IVA, and approved to provide treatments by MPI.

The Approved Treatment Supplier Programme is based on an internationally accepted and recognised model as shown in Figure 1 (overleaf). This model is used world-wide for conformity assessment processes, and is in compliance with World Trade Organisation Technical Barriers to Trade (WTO TBT) agreements.

The documents associated with this programme are structured as in Figure 2.

All of the MPI treatment supplier programme operates to one set of policies and procedures which set out its roles and responsibilities for participating parties, with appropriate detailed work instructions provided where required.

Within the treatment supplier programme the main parties involved take the following responsibilities:

- (1) MPI has the following major roles:

¹ Official treatments are those required by MPI for import risk goods and for export goods to comply with Importing Countries Phytosanitary Requirements (ICPRs). In all MPI documents where "treatment" is referred to this means "official treatments", and does not include those treatments that may be provided outside the scope of this programme.

- a) Standard setting;
 - b) Sets specifications for treatments of import risk goods;
 - c) Identifying and validating importing countries specifications;
 - d) Authorisation of IVAs and approval of Organisations;
 - e) Over sight of compliance processes;
 - f) Keeping of registers.
- (2) IVAs providing supervision and verification (audit) services must comply with all requirements of the MPI Plant Export Requirement: IVA Requirements to gain authorisation to undertake import and plant export certification services". Their operations, as set out in their quality management systems, are subject to audit by an ISO recognised body and MPI and/or their representatives. Once their compliance with requirements is confirmed, they will be authorised to act as an IVA by MPI.
 - (3) The primary role of approved treatment suppliers is to complete specific treatment activities on behalf of MPI in accordance with appropriate standards and specifications.
 - (4) MPI may provide services such as treatment supervision where an IVA is not available to provide this service, and in doing so will charge for those services on a full cost recovery basis. MPI will direct risk goods for treatment and issue clearance when all biosecurity conditions are met.

It is important to note that an IVA does not approve or withdraw approval of a treatment supplier; this is a role that MPI performs itself – an IVA has no authority to delegate this to an external third party. An IVA acting as an audit body operates as MPI's Agent.

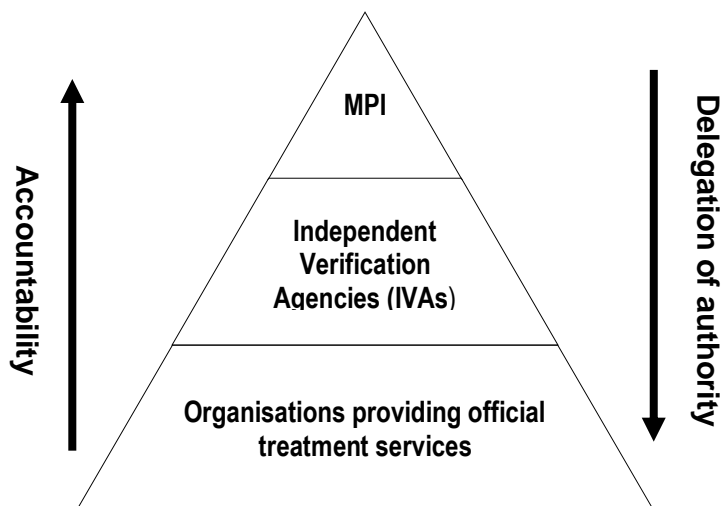


Figure 1. Simplified model of Approved Treatment Supplier Programme

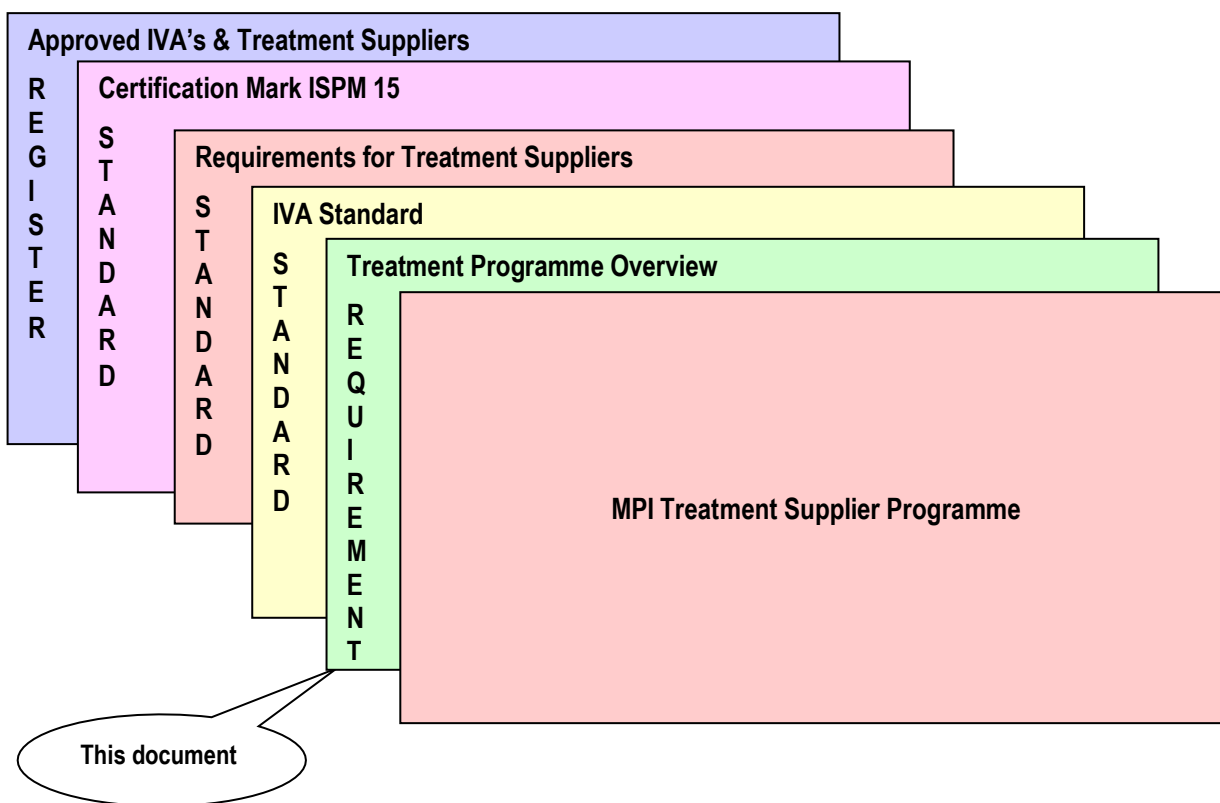


Figure 2. Treatment supplier programme documentation

Who should read this Treatment Requirement?

This treatment requirement applies to exporters, importers, IVA's, MPI and treatment suppliers.

Why is this important?

All official treatments for exports and imports need to be carried out under the treatment programme.

Document History

Version Date	Section Changed	Change(s) Description
2014	Updated to MPI	Treatment Programme - Overview and General Requirements for the Supply of Official Treatments
15 November 2018	All	New format. Added Amendment section and Table. Changed title to "Overview and General Requirements for the Supply of Official Treatments" to reflect that the Standard covers guidance, information and requirements. Amended scope (1.2) to reflect that the Standard includes guidance, information and requirements, including requirements for the supervision programme. Updated References (1.3). Changed "shall" to "must" throughout. Updated Schedule 1 - Definitions.

Version Date	Section Changed	Change(s) Description
		<p>Clarified requirement for unapproved treatment suppliers to operate under the treatment supplier supervision programme (3.0).</p> <p>Clarified that treatments must be supervised by MPI or IVA where a treatment is not approved by MPI (3.3).</p> <p>Amended table in 5.1 to clarify that complaints about the IVA audit process will be followed up by MPI at the next scheduled audit of the IVA.</p> <p>Removed reference to Biosecurity Amendment Act (1997) in definition of Organism (25).</p>

Other information

References

- (1) Biosecurity Act 1993
- (2) ISO Guide 2: *Standardisation and related activities – General vocabulary*
- (3) AS/NZS ISO 9000: 2000 *Quality management systems – Fundamentals and vocabulary*
- (4) ISO 17020: *Conformity assessment – Requirements for the operation of various types of bodies performing inspection.*
- (5) MPI Certification Standard: *IVA Requirements*
- (6) MPI Standard: *Requirements for suppliers of official treatments*
- (7) MPI Technical Standard: *Certification mark for wood packaging*
- (8) FAO guidelines Paper 54 - Manual of fumigation for insect control 1984
<http://www.fao.org/docrep/X5042E/x5042E00.htm>

MPI Standards are available on the MPI website at: <https://www.biosecurity.govt.nz/importing/border-clearance/transitional-and-containment-facilities/>

Part 1: Requirements

1.1 Application

- (1) This document applies to those that apply or require official treatments.

1.2 Definitions

- (1) For the purpose of this document, definitions found in Schedule 1 must apply.
- (2) Where terms relating to quality management or conformity audit are not defined, definitions found in Schedule 1, ISO 9000 and ISO Guide 2 respectively must be used.

Part 2: Overall Scheme Operation

2.1 Role of the parties – summary

2.1.1 MPI

- (1) MPI is responsible for:
 - a) Preparation and publication of all standards and guidance documents associated with this programme;
 - b) Audit and authorisation of IVAs carrying out supervision, evaluation and verification (audit) services of approved treatment suppliers;
 - c) Approval of treatment suppliers based upon IVA recommendations;
 - d) Maintenance of databases of all authorised IVAs, approved treatment suppliers, and treatment specifications.

2.1.2 Independent Verification Agencies (IVAs)

- (1) An IVA providing services on behalf of MPI must be:
 - a) Accredited to: [AS/NZS ISO/IEC 17020: 2012 'General criteria for the operation of various types of bodies performing inspection'](#), and comply with the independence criteria of a Type A inspection body;
 - b) Authorised as meeting the applicable technical requirements as prescribed by [MPI Export Certification Standard: "IVA Requirements: Requirements to be met by an Independent Verification Agency \(IVA\) to gain authorisation to undertake import and plant export certification services"](#)
- (2) IVAs act as MPI's Agents and are responsible for:
 - a) Supervision of treatments being undertaken by non-approved treatment suppliers;
 - b) Making recommendations to MPI for approval of treatment suppliers who meet the requirements set out in the treatment supplier standard;
 - c) Audit of approved treatment suppliers;
 - d) Making recommendations to MPI for suspension and/or termination of treatments supplier's approvals.

2.1.3 Treatment Suppliers

- (1) Treatment suppliers complying with the treatment supplier standard are responsible for carrying out treatments of products in compliance with MPI specifications for imports or importing country requirements (ICPRs) for exports, including ISPM 15 and associated country requirements.
- (2) Treatment suppliers may elect to operate under one of two programmes:
 - a) **The Supervision Programme**
A treatment supplier will perform all treatments under direct IVA supervision, complying with this MPI document, or be an approved treatment supplier.
 - b) **The Approved Treatment Supplier Programme**
A treatment supplier will comply with the requirements of the MPI standard "Treatment Supplier Requirements", undergo evaluation and audit by an IVA and, once there are no major or critical non-compliances outstanding, be recommended to MPI for approval by their IVA. If approval is granted by MPI, the approved treatment supplier may then operate without direct supervision of all treatments under a monitoring programme which involves random sampling of treatments and quality management system surveillance to monitor continued compliance with stated requirements.

2.1.4 Verification by MPI

- (1) Verification responsibilities of MPI are for:
 - a) Identification of imported risk goods requiring official treatment;
 - b) Directing goods for treatment;
 - c) Issuing a clearance following successful treatment when all biosecurity requirements are met.
- (2) MPI may provide other services, such as treatment supervision (as a last resort) and, in doing so, will charge for those services on a full cost recovery basis.

2.2 Scope of authorisation and approval

- (1) IVAs and treatment suppliers must define the scope of their operations, describing what verification services and types of official treatments they are competent to undertake. The ability of the IVA and treatment supplier to perform the activities described in their scope statements will be verified during audits.
- (2) Where a treatment supplier claims a treatment to be official and it is not, or claims to be MPI approved for treatments outside of the authorised or approved scope, immediate suspension of the treatment supplier's approval will be implemented.

2.3 Interaction of the parties

2.3.1 Model process

- (1) The model process for IVA authorisation and treatment supplier approval is set out in Figure 3.

2.3.2 IVA authorisation process

- (1) The steps to gain authorisation to operate as an IVA are in the [MPI Export Certification Standard: "IVA Requirements to gain authorisation to undertake import and plant export certification services"](#)

2.3.3 Treatment supplier approval process

- (1) The steps to gain approval to operate as an approved treatment supplier are:
 - a) Selection of an IVA, and application to that IVA;
 - b) Application form and payment of fees provided to MPI;
 - c) Submission of documents to the IVA for desk review to ensure that documented procedures meet the specifications set out in the treatment supplier standard;
 - d) Undergoing a system audit to validate that the 'actual operations' correspond to the documented procedures at each of the locations where treatments will be undertaken. For treatment suppliers with less than three locations, two additional consecutive on site audits will be undertaken (see Part 5 of the Treatment Supplier Standard for minimum audit frequencies once approved);
 - e) Satisfactorily addressing any non-compliances raised by the IVA (see Part 6 for information on non-compliances);
 - f) Gaining MPI approval following a recommendation from an IVA.

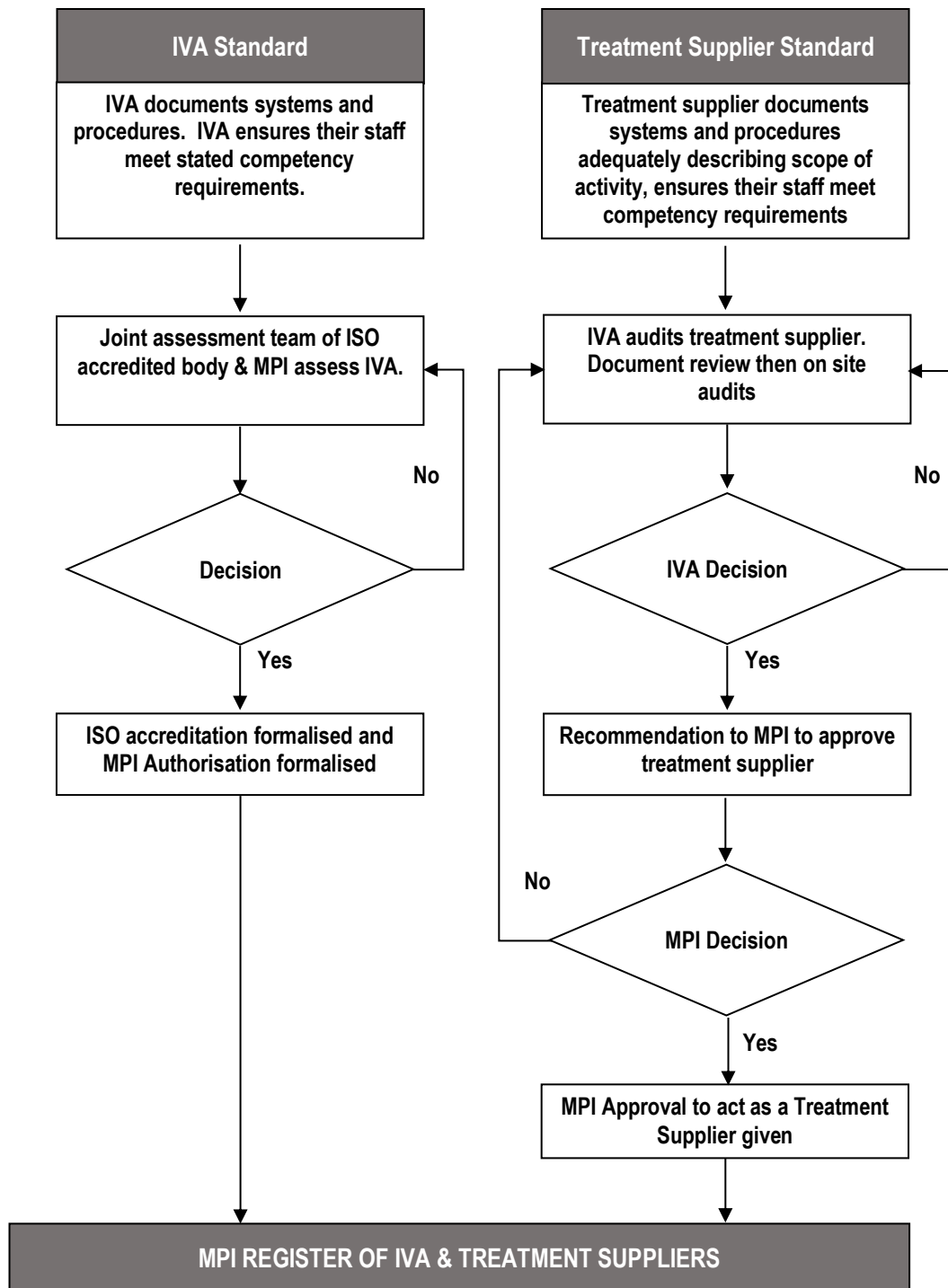


Figure 3. Model process for IVA authorisation and treatment supplier approval

2.4 Process for provision of official treatments

- (1) The process for the provision of official treatments is set out in Figure 4.

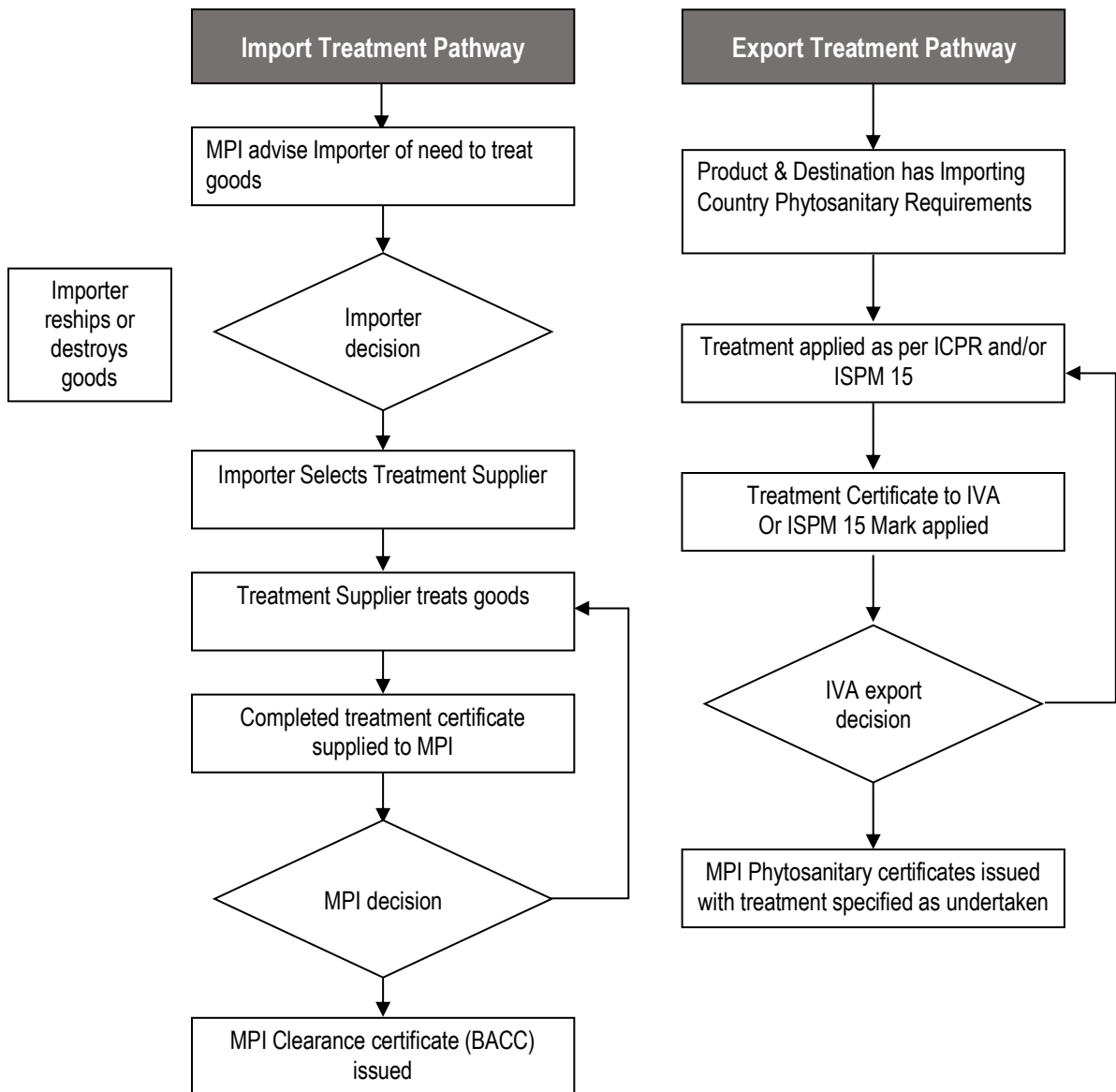


Figure 4. Process for the provision of official treatments

2.5 Contractual relationship between MPI Authorised IVAs and Treatment Suppliers

- (1) All treatment suppliers must enter into a contract with a MPI authorised IVA of their choice.
- (2) If the approved treatment supplier programme option is taken, once the treatment supplier has been audited, and recommended by its chosen IVA to MPI for approval, and that recommendation has been accepted by MPI, the treatment supplier must enter into a contract with MPI prior to commencing treatment services.
- (3) **The contracts between the treatment suppliers and MPI must, amongst other things, establish the fees payable and any relevant time frames, together with the rights and responsibilities of all parties.**
- (4) A signed contract is required between MPI and an IVA.

Part 3: Treatment Supplier Supervision – General Requirements

- (1) If the treatment suppliers is not approved, they must operate under the treatment supplier supervision programme.

Note: For best fumigation practice, treatment suppliers and IVAs should reference [FAO guidelines Paper 54 - Manual of fumigation for insect control](#).

3.1 Summary

- (1) The main steps to operate as a treatment supplier working under supervision are:

- a) Selection of an IVA, and application to that IVA;
- b) Undergoing an on-site supervision each time a treatment is performed;
- c) Satisfactorily addressing any non-compliances raised by the IVA;
- d) Issue of a treatment certificate countersigned by the IVA after each official treatment.

Note: The IVA remains responsible for verifying treatments carried out under supervision and must ensure that it, or it and the treatment supplier, comply with the requirements for supervision set out in this document.

3.2 The IVA supervision process

- (1) The IVA must have documented procedures to ensure that treatments carried out under supervision meet the requirements of Section 4.0 Technical requirements and sections 4.6 and 4.8 of the standard Treatment Supplier Requirements.
- (2) The treatment supplier must provide advance notice of treatments for which it requires supervision, adequate to ensure that the IVA has time to ensure that a qualified person is available to perform supervision.
- (3) The IVA's qualified representative must perform an on-site supervision for each treatment to verify that the treatment supplier's performance of the treatment complies with MPI specifications and all the relevant requirements of the treatment supplier programme. At a minimum, it must be verified that:
 - a) The treatment technician is qualified to undertake the treatment;
 - b) The treatment is the appropriate one, i.e. as specified by MPI or by ICPRs;
 - c) The aspects of the treatment observed meet the specifications for the treatment required;
 - d) The required unique identification of the material being treated is in-place;
 - e) That all measuring and monitoring equipment used is suitable for use, and is correctly verified or calibrated;
 - f) The required records are being created;
 - g) The treatment certificate details are correct.
- (4) The duration of the on-site supervision need not match the duration of the treatment, but must be of sufficient duration and be at a time during the treatment when required information and activities may be verified.
- (5) After the completion of all supervised treatments, the IVA must sign, or otherwise endorse, a treatment certificate verifying that they have observed the treatment and that the treatment complied with the requirements of the relevant parts of the treatment supplier standard in all ways and the relevant treatment. The treatment certificate must bear, amongst other things, the name of the supervisor, the name of the IVA, and the date.
- (6) During all treatment supervision, the IVA must check that the treatment supplier is not making claims of MPI authorisation that is not in compliance with its agreed scope, and that it is not using the MPI or

MPI logo. Claims of approval must not be used in such a way that they are misleading to any other parties, and must comply with MPI requirements regarding use of its logo and claims of approved status.

- (7) Any non-compliances identified during surveillance must be addressed.
- (8) Should a non-compliance be raised, a closing meeting must be held to explain the non-compliance(s) and to obtain the treatment supplier's acknowledgement of those non-compliance(s), and to agree a timeframe for resolving them. At, or immediately following, the closing meeting a written report must be provided to the treatment supplier identifying the non-compliance(s) and how it is to be resolved in order to prevent a reoccurrence.
- (9) The treatment supplier must be invited to respond to any report of non-compliance and to take specific action, within a defined time, to resolve any identified non-compliances.
- (10) Once the treatment supplier has advised that corrective action has been completed, the IVA must verify that effective action has been taken to address the cause(s) of non-compliance and to ensure that all critical and major non-compliances have been corrected within agreed and appropriate timeframes.

3.3 Supervision frequency

- (1) All official treatments must be supervised by MPI or IVA where a treatment supplier is not approved by MPI.

Part 4: Personnel competencies

- (1) Personnel competencies for treatment technicians and IVA staff are set out in each of the appropriate standards

Part 5: Complaints

- (1) Complaints about aspects of the operation of the treatment supplier approval programme should be directed to the appropriate party, as set out in the table below:

	Complaint	Responsible body for first response	MPI follow up needed?
1	Performance of a treatment relating to level of service quality provided by treatment supplier	Treatment Supplier	No
2	Performance of a treatment relating to apparent non-compliance with treatment supplier standard	IVA	Yes, after IVA has investigated
3	Performance of a treatment relating to ineffectual treatment	MPI	Yes, with IVA
4	Treatment supplier complaint about IVA service quality	IVA	No
5	Treatment supplier complaint about IVA audit process not being followed	IVA	Yes, at next scheduled audit of IVA
6	Treatment supplier complaint about MPI decision making processes and outcomes	MPI	Yes

Part 6: Appeals

6.1 Process for appeals

- (1) A Treatment Supplier may appeal an IVA decision in the following manner:
 - a) Treatment Supplier is to formally notify the IVA of their request to appeal;
 - b) The Treatment Supplier and IVA must cooperatively attempt to resolve the appeal in accordance with the IVA appeals process;
 - c) If a mutually satisfactory resolution of the appeal cannot be achieved, the Treatment Supplier and the IVA must jointly meet with MPI to resolve the appeal.

Note: Treatment suppliers considering an appeal should first discuss that appeal with their chosen IVA, who has an appeal process to deal with appeals on the audit process.

- (2) MPI has procedures to address appeals made by IVAs and treatment suppliers regarding granting or not granting of authorisation or approval. Appeals will only be considered once the complaint procedure process has been tried and has proven ineffective in addressing the problems.
- (3) Appeals should be sent to the Director.
- (4) MPI costs associated with mediation of appeals must be borne equally by the Treatment Supplier and the IVA.
- (5) If a mutually satisfactory resolution is not possible, follow the disputes resolution procedure in clause 11 of the contract of approval (MPI Standard: Treatment Supplier Requirements Appendix 2).

Part 7: Treatment supplier transfer between IVAs

- (1) A treatment supplier may elect to transfer to another IVA, provided that the treatment supplier:
 - a) Notifies the existing IVA of their decision to transfer to a new IVA;
 - b) Continues with the existing IVA until the new IVA has formalised the transfer;
 - c) Recognises that the newly selected IVA will be undertaking a systems audit within one month of accepting the transfer and this system audit to be regarded as the annual system audit.

7.1 Eligibility for transfer

- (1) Treatment suppliers must not be eligible for transfer until all non-compliance findings have been closed out to the existing IVA.

Schedule 1 – Definitions

All definitions are as per the Biosecurity Act unless described below:

Approval

Having been formally recognised by the Director as competent to act on MPI's behalf to provide a service in accordance with the requirements specified in the relevant MPI Standard(s).

Audit

A systematic and independent process for obtaining information and examining it objectively to determine the degree of conformity with prescribed criteria.

- a) A **System Audit** is a comprehensive evaluation of the entire Quality Management System and compliance with that system. A full system audit usually has two stages, a desk audit or desk review, and an on-site audit;
- b) A **Surveillance Audit** is an evaluation of specific parts of the organisation's system, to confirm that the product or service meets the required specifications. These audits are unannounced.

Auditor

A person with the competence to carry out an Audit to determine the degree of conformity with prescribed criteria.

Authorised

Having been formally recognised by the Director as competent to act on MPI's behalf to provide a service in accordance with the requirements specified in the relevant MPI Standard(s).

Certificate

An official document which attests to the status of any consignment affected by regulations.

Certification

All those activities leading to, but not including, the issuance of Certificates

Competence

Demonstrated ability to apply knowledge and skills.

Consignment

A quantity of plants, plant products or other regulated articles being moved from one country to another and covered by a single Certificate (a consignment may be composed of one or more lots).

Decision Maker

The person or committee within MPI that reviews recommendations for Approval and Authorisation and makes decisions on whether Approval or Authorisation must be granted.

Director

The Director, MPI of the Ministry for Primary Industries (MPI) and is appointed as a Chief Technical Officer under section 101 of the Biosecurity Act 1993 or delegate.

Event Reports

A written report submitted to MPI by an Independent Verification Agency or Treatment Supplier in response to specific situations defined in the standard being followed.

ICPR

Importing Countries Phytosanitary Requirements, available at: <https://www.mpi.govt.nz/law-and-policy/requirements/importing-countries-phytosanitary-requirements/>

Independent

Not having a commercial interest in the operation and not depending on another body for its validity.

Independent Verification Agency (IVA)

An organisation accredited as meeting ISO 17020 and its independence criteria type A, and MPI supplementary technical requirements, and authorised by MPI to carry out services associated with import and plant export certification.

Inspection

An official visual examination of plant products or other regulated articles to determine compliance with regulations. For phytosanitary regulations inspection is to determine if pests are present.

Inspector

Means a person who is appointed an inspector under section 103 of the Biosecurity Act 1993.

Location

An operational site, within a MPI approved Organisation's system, where phytosanitary activities are undertaken, or reference documents, or records, or fixed equipment are kept, or if the phytosanitary activity involves a mobile facility then that mobile facility.

Non-compliance

An action or inaction by an Independent Verification Agency or Treatment Supplier that results in the Organisation not complying with requirements specified in this programme's standards, or in Treatment specifications/ Non compliances must be classified into one of three categories:

- a) **Critical Non-compliance**
Actions or inactions that lead to the total loss of confidence in the Independent Verification Agency's or Treatment Supplier's compliance with the requirements of its Approved or Authorised Quality Management System, or that will lead to Treatments not complying with Specifications Overseer, through direct observation, pre-determined activities being undertaken by another party, to confirm compliance with specifications and/or procedures.
- b) **Major Non-compliance**
Actions or inactions that, if not attended to urgently, will lead to the total loss of confidence in the Independent Verification Agency's or Treatment Supplier's compliance with the requirements of its Approved or Authorised Quality Management System, or that will lead to Treatments not complying with Specifications.
- c) **Minor Non-compliance**
Actions or inactions that are not considered by MPI or the Independent Verification Agency to result in total loss of confidence in the Independent Verification Agency's or the Treatment Supplier's Quality Management System, or that do not lead to Treatments not complying with Specifications.

Official

Established, authorised or performed by MPI.

Official treatments

Those required by MPI for import risk goods or for export goods to comply with Importing Countries Phytosanitary requirements (ICPRs).

Organisation

The legal entity, be it an individual, partnership, company or other form of legal entity, responsible for the performance of the system approved by MPI.

Pest

Any species, strain or biotype of plant, animal, or pathogenic agent, injurious to plants, plant products or animals.

Phytosanitary Certificate

Certificate patterned after the model certificates of the International Plant Protection Convention (IPPC).

Plant Products

Any material of plant origin

Procedure

A description that specifies the purpose and scope of an activity; what must be done and by whom; when, where, and how it must be done; what materials, equipment, and documentation must be used; and how it must be controlled and recorded.

Quality Management System

A set of interrelated or interacting elements (procedures and/or processes) within an organisation to establish policy and objectives and to achieve those objectives, used to direct and control an organisation with regard to fulfilling requirements.

Regulated Article

Any plant, forest or plant product, storage place, packaging, conveyance, container, soil or any other organism, object or material capable of harbouring or spreading pests, deemed to require phytosanitary measures, particularly where international transportation is involved.

Scope of Approval or Authorisation

The specific tasks for which Approval or Authorisation is sought or has been granted. Scope must be described as a combination of:

- a) For Treatment Suppliers ,
 - i) whether they are choosing the Supervision Programme, or the Approved Treatment Supplier (34) Programme; and
 - ii) Types of treatment that may be applied; and
 - iii) Locations of treatments; and
 - iv) Names of qualified Treatment Technicians; or
- b) For Independent Verification Agencies
 - i) Locations of major offices at which recommendations for Approval are made;
 - ii) Names of qualified auditors.
 - iii) Types of treatment that the agency has proficiency in.

Specification

A prescription of the requirements with which the product or service has to conform.

Supervision

Oversee, through direct observation, pre-determined activities being undertaken by another party, to confirm compliance with specifications and/or procedures.

Treatment

Officially authorised procedure, for the killing, removal or rendering infertile of pests; and also for the purposes of this standard rendering non-viable or devitalising a consignment of plants, forest or plant products, and animals.

Treatment Supplier

The legally identifiable Organisation responsible for performance of the Treatment Supplier's Quality Management System.

Treatment Supplier Quality Management System

The organisational structure, responsibilities, operational procedures, processes and resources for implementing activities associated with the application of Treatments.

Treatment Technician

A person familiar with the Treatment methods and procedures, the objectives of the Treatment and the Audit of the Treatment results but operate under effective oversight by the Treatment Supplier.

Treatment Certificate

A uniquely numbered certificate issued by a Treatment Supplier verifying that an approved Treatment has been completed in accordance with this Standard and includes a description of the Treatment.