Ministry for Primary Industries
Manatū Ahu Matua

Treatment Requirement

Treatment Supplier Requirements

15 November 2018

Issued by the Ministry for Primary Industries

New Zealand Government

TITLE

Treatment Requirement: Treatment Supplier Requirements

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

Director, Plants and Pathways
Ministry for Primary Industries

Contact for further information
Ministry for Primary Industries (MPI)
Regulation & Assurance Branch
PO Box 2526
Wellington 6140

Email: standards@mpi.govt.nz

Contents

Introduction

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

Purpose

This standard sets out requirements that treatment suppliers seeking MPI approval to provide official treatments under a programme of surveillance without direct IVA supervision must follow.

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

Background

This standard sets out requirements that treatment suppliers seeking approval to operate under a quality management system and a programme of surveillance without direct IVA supervision for all treatments must follow.

Treatment suppliers are required to demonstrate their ability to consistently provide product(s) and services that meet applicable regulatory requirements by operating a quality management system. Treatment suppliers must develop and implement a quality management system in compliance with this standard, and apply to an IVA for audit and to MPI for approval.

The requirements for a treatment supplier's quality management system are based upon the principles of the ISO 9000 series of quality management system standards, but recognise that small businesses may require less formal structures and systems.

When an IVA is satisfied that all the requirements of this standard are met, the IVA will recommend to MPI that the treatment supplier be approved to undertake those services within the scope of the treatment supplier's system. MPI will consider that recommendation and, if appropriate, will accept it and approve the treatment supplier. Once approved, whenever a treatment is carried out, the approved treatment supplier can carry out treatments without direct supervision by an IVA, and may issue its own treatment certificates.

When the treatment suppliers system has been submitted to their chosen IVA and passed a desk audit, they must operate under a heightened audit regime while going through the process of gaining approval.

All treatment suppliers are subject to legislation administered by other government departments; this standard does not cover those responsibilities e.g. HSNO Act and health and safety requirements.

Who should read this Treatment Requirement?

This Treatment Supplier Requirement applies to those organisations that want to apply official treatments.

Why is this important?

Official treatment measures on imports or exports need to be properly applied and within New Zealand. The treatment must be carried out by a treatment provider approved by MPI, if not under supervision.

Document History

Version Date	Section Changed	Change(s) Description
1 July 2013		Treatment Supplier Programme - Requirements for the Supplier of Official Treatments
15 November 2018	All	New format Updated MPI contact details to standard contacts. Removed references to transition schedule. Changed "shall" to "must" throughout. Updated References (1.3). Added requirement for contract between treatment suppliers and MPI (2.1.2). Removed reference to sachets (4.6 (iv)). Referenced audit requirement to Audit frequencies (5.0, Table 2) Removed reference to Clause 4.1.1 (6.4(iii)). Added "Fails to comply with this standard" as an additional criterion for suspension of a treatment supplier (9.1). Updated definitions (Schedule 1). Updated contact details and position titles in Approval Application template (Appendix 1). Updated Approval Application, contract titles and removed reference to "on behalf of MPI" (Appendices 1 and 2).

Other information

References

(1) Biosecurity Act 1993

(2) Hazardous Substances and New Organisms Act 1996

(3) ISO Guide 2: *Standardisation and related activities – General vocabulary*

(4) AS/NZS ISO 9000: 2000 Quality *management systems – Fundamentals and vocabulary*

(5) AS/NZS ISO 9001:2000. *Quality management systems - requirements*.

(6) ISO 17020: *General criteria for the operation of various types of bodies performing inspection*.

(7) ISO 19011:2003 *Guidelines for quality and/or environmental management systems auditing*

(8) MPI Certification Standard: *IVA Requirements*

(9) MPI Standard: *Approved Biosecurity Treatments*

(10) MPI Standard: *Requirements for suppliers of official treatments*

(11) Technical Requirements: Registered Certification Mark (ISPM 15)

(12) International Plant Protection Convention 1992

(13) Export specifications ICPR

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 standard specifies the requirements to be met by a treatment supplier in order to become approved to carry out treatments:

a) As directed by MPI for imported risk goods;
b) As required to meet export certification requirements (for the inclusion as an additional declaration on phytosanitary certificates);
c) As required to treat and apply the ISPM 15 mark to wood packaging material that is in accordance with the international ISPM 15 standard. Reference should be made to MPI export certification standard: Technical Requirements: Registered Certification Mark (ISPM 15) to comply with this standard.

(2) Treatment Suppliers may elect to operate under supervision, or seek approval under this standard.

1.2 Definitions

(1) For the purpose of this document, definitions found in Schedule 1 must apply.

Part 2: System Requirements

2.1 General

(1) The treatment supplier must establish, document (where appropriate), implement and maintain a quality management system and continually improve its effectiveness in accordance with the requirements of this standard.

(2) The treatment supplier must:

a) Ensure that there is a signed contract with MPI covering the scope of treatment services;
b) Ensure it has an IVA appointed at all times;
c) Identify the processes to be followed;
d) Ensure that both the operation and controls of the processes are effective;
e) Monitor, maintain and analyse the results of these processes; and
f) Maintain adequate records as evidence that the processes are effective.

(3) The treatment supplier must

a) Appoint one of its staff members to have overall responsibility for establishment, implementation and maintenance of the treatment supplier's quality management system.
b) Clearly define the responsibility and authority for this role in a written job description or similar document

Note 1: In a small business the Owner/Manager will usually fill this role.

(4) Management must review the quality management system annually to ensure its suitability and effectiveness to continue to meet the requirements of this standard. Records of the management review are to be maintained.

(5) The review must include:

a) Results of internal and external audits;
b) Communication from external parties, including complaints;
c) Changes in this standard, regulation or legislation and their impact on treatments;
d) Status of corrective and preventive actions;
e) Recommendations for improvements.

(6) Where a treatment supplier is operating over multiple locations, they must conduct at least an annual internal audit to verify that practices comply with planned activities. Where non compliances are identified, the root cause of the non-compliance must be determined, and appropriate actions taken to ensure that the cause(s) of problems are corrected [corrective action] and that potential problems are averted [preventive action]. All possible consequences that may have arisen from the root cause of a problem must be identified and, if needed, corrected.

(7) Records of internal audit and corrective and preventive actions must be maintained.

2.2 Control of documents and records

(1) Quality management system documentation must include:

a) A quality manual, which must include procedures to address the following:

i) Segregation of treated and untreated material;
ii) Traceability of treated material from the treatment stage through to storage and despatch;
iii) Recording of transfers or sales to other approved facilities, such as manufacturers of wood packaging materials;
iv) Application of any relevant certification marks (if applicable);
v) Maintenance of records;

vi) The training provided to staff members responsible for quality control or involved in the treatment of material to ensure understanding of the requirements for approval to treat material and/or apply any relevant certification marks;
vii) Procedures for administering the required treatment that assures that the minimum requirements are achieved;
viii) Procedures for monitoring the treatment;
ix) Mechanisms to detect treatment failure and the appropriate corrective action(s) that may be applied;
x) Calibration of monitoring or measuring equipment;
xi) Procedures for issuing treatment certificates;
xii) A site plan of the facility (if permanent);
xiii) An organisational structure clearly identifying the person(s) responsible for quality control activities;
xiv) Response to corrective action requests.

b) Documents needed by the treatment supplier to ensure complete control of its processes;
c) Records required by this standard.

i) A copy or copies of your quality manual or relevant procedures/work instructions must be available for use by all employees that have a role or perform a function in the approved system.
ii) Any alterations, amendments or corrections to the quality system or quality manual that may affect compliance with the requirements of approval must be submitted in writing to your IVA for approval prior to their implementation. A record of approval must be maintained by the approved facility.

Note 2: The amount of documentation required can vary depending on the complexity of the treatment.

Note 3: Documentation may be electronic, hard copy or any other form of medium.

(2) The treatment supplier must have a system for uniquely identifying and controlling all its documents (required under 2.2 (1)) to ensure that only the current editions are in use and that no unauthorised changes are made.

(3) The treatment supplier must ensure that current editions of documents (required under 2.2 (1)) are available to everyone who needs them.

(4) Records must be sufficient to demonstrate that all required processes have been carried out and that all treatments have been undertaken in compliance with the quality management system and the requirements of this standard. They must be legible, stored in a manner that allows their retrieval, and protected from deterioration.

(5) Records must be maintained for a minimum of two years.

2.3 Resources

(1) Management must ensure that sufficient appropriate human, physical and financial resources are available to ensure that each treatment can be performed effectively.

2.4 Contract review

(1) Prior to accepting an order to undertake a treatment, a treatment supplier must review the order to ensure that:

a) The correct treatment to be applied is identified;
b) The treatment supplier holds current approval for that treatment;
c) Staff who are qualified to undertake that treatment are available to perform or supervise the treatment;
d) The treatment supplier has the continuing capability to meet the treatment requirements, and

e) The owner of the goods is informed and is given the option of continuing with the treatment or not if there is any likelihood of damage to the good being treated.

2.5 Staff competence, awareness and training

(1) The treatment supplier must ensure that its staff are fully trained and competent for the work they do, and that treatment technicians meet the personnel qualification criteria set out in Appendix 3 of this standard at all times.

(2) An up-to-date register of treatment technicians, showing the treatments that they are competent to perform, must be maintained;

(3) Where necessary, staff must be provided with written work instructions setting out how the treatment supplier requires critical jobs or tasks to be carried out;

(4) In house training of staff must be carried out by competent treatment technicians;

(5) Training by other providers may be recognised as adequate for the purposes of this standard. Recognised training courses include:

a) Grow Safe Programme. (Application of chemicals);
b) Individual Pest Control. Open Polytechnic of New Zealand Unit Standards;
c) HSNO approved handler course.

(6) Records of training must be kept and staff competence must be regularly reviewed by management to determine whether training is required.

2.6 Treatment materials

(1) The treatment supplier must establish and maintain documented specifications for all treatment materials required;

(2) When purchasing materials, specifications of requirements for purchase must be clearly stated on purchase documents;

(3) On delivery of materials, treatment suppliers must verify that the material delivered meets purchase specifications;

(4) Safety information and handling and application procedures must be obtained from suppliers, and manufacturer's stated requirements regarding storage, safety and use must be followed. If manufacturer's stated requirements differ from MPI specifications, MPI must be notified and no treatment is to occur until the reason for the difference has been resolved by MPI;

(5) Records of raw material specifications and manufacturer's requirements must be maintained.

2.7 Measuring and monitoring equipment

(1) All measuring, test and inspection equipment used for measuring or monitoring treatment activities must be routinely calibrated at least annually, and/or verified to levels of accuracy appropriate to its use;

(2) Measuring and monitoring equipment must be stored, transported and used in a manner that protects it from loss of accuracy;

(3) All equipment and products used in treatment processes must be inspected before use to ensure that they meet the specification for the treatment to be applied, and are suitable for use;

(4) Should equipment calibration and/or verification show that equipment is not capable of the required accuracy of measurement, the treatment supplier must review all measurements that have been made

using that equipment since the last calibration and/or verification, and determine what actions should be taken as a consequence of this inaccuracy. Appropriate actions, including re-treatment if required, must be taken. Records of this review must be kept for two years;

(5) Equipment calibration records must be maintained.

2.8 Process control

(1) Where the absence of documented instructions creates a risk to effective performance of a treatment, documented procedures and instructions must be provided;

(2) The treatment supplier must document how the necessary checks on equipment, application and product handling will be done to ensure the treatment is successful.

2.9 Emergency response procedures

(1) Treatment suppliers must develop and document emergency response procedures to be followed in case of an emergency event. Staff must be trained in those procedures and must be aware of what actions they should take in case of an emergency event at all times. Procedures must cover:

a) What to do if personnel, auditors or the public are at risk;
b) Actions to be taken to protect the environment;
c) Actions to be taken to protect the product being treated;
d) Means of notifying emergency services and, if needed, MPI.

Part 3: Subcontracting

(1) Treatment suppliers must normally perform the treatment services for which they hold approval. Where any part of their treatment service is sub-contracted, the treatment supplier must ensure, and be able to demonstrate, that their sub-contractor's documented procedures are either a part of their own approved system/procedures, or are independently approved by MPI.

3.1 Reporting

(1) The Treatment supplier must provide the following reports to their IVA, which must contain information as stated within Table 1.

Table 1. Reporting requirements

Topics	Time frame
Changes to their register of competent staff.	Within 5 working days of change
Critical non-compliance detections and corrective actions to be applied.	Within 5 working days after detection
Interceptions of MPI phytosanitary certified produce by importing countries or on cleared risk goods.	Within 5 working days of interception
Issues raised by importers or off-shore organisations identifying risks relating to export phytosanitary certification or clearance of goods	Within 5 working days of receipt of issue
Importing countries requirements obtained from sources other than MPI.	Prior to undertaking export treatments
Number of official treatments carried out.	Monthly

Part 4: Technical Requirements

4.1 Treatment specifications

4.1.1 For export certification

(1) Post-harvest treatments of produce for export must be carried out to the importing country's specifications (ICPRs) and/or international standards, such as ISPM 15.

(2) Treatments being applied to export plants, forest and plant products or regulated articles will be those specified by the importing country as a condition of entry.

(3) Only a treatment supplier or wood packaging manufacturer who is listed on the MPI register for certification mark, can apply the certification mark, as per the Technical Requirements: Registered Certification Mark (ISPM 15).

4.1.2 For import clearance

(1) Treatments being applied to imported plants, forest and plant products or regulated articles to obtain biosecurity clearance must be an MPI approved treatment as outlined in the appropriate MPI Standard.

(2) If the proposed treatment differs from an MPI supplied specification, it must be approved by the Director before the goods are given biosecurity clearance.

4.1.3 Access to information

(1) Treatment suppliers must document how they access up-to-date specifications for each type of treatment to be applied, and these specifications must be readily available to treatment technicians and the IVA at the time of deciding to apply specific treatments.

4.2 Treatment plan

(1) For each treatment to be provided, the treatment supplier must develop a treatment plan setting out the critical control points for effective control of the treatment. Each treatment type must have a monitoring procedure (see section 4.6).

4.3 Treatment facilities

(1) Facilities used for undertaking treatments of consignments must be capable of delivering the specified treatment to the required specifications. Facilities must allow the treatment technician to ascertain that the entire treatment achieved the required outcomes, eg: nil leaks if fumigating, heat is maintained, spillages and risk goods are contained etc.

(2) Treatment of imported risk goods must take place at an approved transitional facility or a place where an inspector has authorised those goods to proceed.

(3) Treatments must take place at the closest appropriate and practicable point of entry or departure, where possible, or a satisfactory method of segregation and transportation maintained, as per section 4.5.

4.4 Product identification

(1) The treatment supplier must uniquely identify all products being treated by suitable means throughout the treatment process. This may be by individual item or batch identification;

(2) The processes used for product identification must be documented;

(3) The product's status, with respect to the stage of treatment (for example untreated, treated but not released, or treated and approved for release), must be clearly identified by label, location or other suitable means;

(4) Product must be traceable from at least producer or point of entry into New Zealand to point of export certification or biosecurity clearance;

(5) ISPM 15 treated product must be identified, as per MPI export certification standard: Technical Requirements: Registered Certification Mark (ISPM 15).

4.5 Product segregation and post treatment security

4.5.1 Product segregation

(1) The treatment supplier must document their method(s) used to ensure product segregation while the products are under their control to ensure it is:

a) Segregated from other untreated products, so as to avoid possible release of unwanted Organisms or cross contamination;
b) Protected from possible release of unwanted organisms (imports) or contamination during storage and transport (exports);
c) Protected from possible product substitution.

4.5.2 Post treatment security

(1) The treatment supplier must document their method used to transfer the responsibility for the security of treated product to the owner of the product.

4.6 Treatment monitoring

(1) Each critical control point identified in the treatment plan (see section 4.2) must be monitored.

(2) The procedures for ensuring treatment have been applied to the required standard must be documented and results recorded by the treatment supplier.

(3) Temperature monitoring and recording methods must be documented, and equipment used must be accurate to ± 1°C. Examples of suitable equipment are: thermographs for kiln sterilisation, temperature data loggers for fumigants, temperature-sensitive bacteria in steam sterilisation. Mercury maximum/minimum thermometers are not acceptable as the prime method for monitoring temperature.

(4) Where product is being treated, the product's temperature must be measured in accordance with the treatment specification for the pests of concern.

(5) For application of fumigants, a method must be used to verify the correct concentration of gas, e.g. detector tubes, thermal conductivity analysers, interference refractometers/gas chromatography, fumiscope, control insects (only of a similar genus to the target insects or in e) below). A halide lamp is not acceptable for measuring concentration levels.

(6) Where an easily discernible organism is the reason for treatment, a re-inspection option may be carried out to verify pest mortality in lieu of the above methods to ensure effectiveness of a particular treatment beyond all doubt.

4.7 Treatment records

(1) Approved treatment suppliers must keep and maintain a treatment register that must be:

a) Kept up to date;
b) Available at all times for the purpose of MPI or IVA audit;

c) Kept for a period of at least two years from the date of treatment.

(2) The register must capture the following information:

a) The unique product identification number;
b) Treatment date;
c) Treatment location;
d) Treatment type (e.g. fumigation, active ingredient or physical action);
e) Dose rate, time, product temperature (specification where declaration is required by importing country);
f) Product description;
g) Who carried out the treatment (including signature) at commencement and completion (if different person);
h) Monitoring results;
i) Treatment certificate number (if issued);
j) Other marks of identification on the product;
k) Client;
l) Reference to other biosecurity documents (e.g. Biosecurity directive);
m) Records of any certification numbers assigned to the facility by MPI;
n) Traceability records, retained to a level that allows the fate of all treated material to be traced from the treatment stage, right through to storage and despatch to clients.

4.8 Provision of treatment certificates

(1) The treatment supplier must sign a “certificate of treatment” with the appropriate information from section 4.7 (as required to obtain clearance or export certification) on completion of each treatment. All monitoring results must be shown on the treatment suppliers register. The certificate must be signed by a treatment technician.

(2) When a treatment supplier is treating wood packaging material in accordance to ISPM 15, where the wood is to be on-sold or transferred to a wood packaging manufacturer, and the treatment supplier elects not to apply the certification mark directly to the treated wood, a treatment certificate must be supplied for each batch or lot of treated timber that is on-sold or transferred to the wood packaging manufacturer.

(3) As a minimum this treatment certificate must contain the following:

a) Name of treatment supplier;
b) Type of treatment performed e.g. heat treatment;
c) Date of treatment;
d) Details of treatment e.g. core temperature, duration of treatment, etc.;
e) Certification number of the heat treatment facility;
f) Description of wood packaging treated e.g. type of packaging, quantity, etc.;
g) Details of any distinguishing marks present on wood packaging; and
h) Signature of the treatment technician.

Part 5: The Audit Process

(1) The treatment supplier's nominated IVA must audit their documented and approved system for ongoing compliance.

(2) The audit frequency and scope applied (as per Table 2) must be determined by the level of:

a) Confidence in the validation of the treatment;
b) Confidence attained through prior audits.

5.1 Risk categorisation of treatment supplier:

Level 1: Treatment suppliers with automated and tamper-proof monitoring equipment recognised as validating that the treatment specification has been achieved.
Refer to Table 2 for qualifying criteria for reduction in audit frequency.

Level 2: All other treatment suppliers.
This category of treatment supplier will be audited at the rate in Table 2 based on the number of treatments per year (n) undertaken. Refer to Table 2 for qualifying criteria for reduction in audit frequency.

Table 2. Audit frequencies

Risk category	System audit	Entry level surveillance audit frequency	Qualifying criteria for reduction	Medium reduced surveillance audit frequency	Qualifying criteria for reduction	Low reduced surveillance audit frequency
Level 1	1 per year (ongoing)	3 per year	One year without a critical non-compliance.	2 per year	Six months without a critical non-compliance.	1 per year
Level 2	1 per year (ongoing)	$1.5\sqrt{n}$	One year without a critical non-compliance.	$1.0\sqrt{n}$	Six months without a critical non-compliance.	$0.5\sqrt{n}$

5.2 Changes in audit frequency

(1) Where a critical non-compliance is identified during any audit, the audit frequency must immediately increase to:

a) Daily audits for a maximum of three days, during which time the treatment supplier must identify, implement and have verified, agreed corrective action(s).
b) The treatment supplier's failure to manage the critical non-compliance in accordance with the IVA audit report must result in the treatment supplier's system immediately reverting to supervision until an agreed corrective action strategy has been verified as having been implemented by the IVA auditor through a targeted systems audit.

(2) Following satisfactory completion of the above corrective action process, the treatment supplier's system must resume at the entry-level audit frequency.

(3) Where a major non-compliance is identified, the treatment supplier must move up one frequency.

(4) An IVA may determine that the frequency of audit should be increased or reduced. In such cases, they must justify their reasons to MPI, in writing. Such change is at the sole discretion of MPI and on a case-by-case basis.

Part 6: Non-compliances

(1) Non-compliances must be graded by an IVA or by MPI as critical, major and minor.

6.1 Critical non-compliance

(1) A critical non-compliance will be caused by actions or inactions that lead to the total loss of confidence in the treatment supplier's compliance with the requirements of its approved quality management system, or that will lead to treatments not complying with specifications.

(2) Critical non-compliances must be addressed as soon as practical and within three days of the event occurring.

(3) Examples of critical non-compliance include:

a) Incorrect treatment applied;
b) Failure to follow approved procedures that will impact on the effectiveness of the treatment;
c) Registered treatment technicians not meeting the competency criteria;
d) Undertaking a treatment without a treatment suppliers registered, competent treatment technician;
e) Required treatment monitoring not been undertaken;
f) Required treatment facilities and/or equipment not used;
g) Equipment calibration not carried out;
h) Equipment not working to specification;
i) Live target pests (above the allowable maximum pest limits) found during inspection of the treated product (once the required mortality time has elapsed).
j) Product being certified without being treated;
k) Incorrect information on certificates;
l) Untreated product not segregated, or separately identified, from treated product;
m) Three or more major non-compliance faults detected in the current and immediate past audit;
n) Agreed actions to address major non-compliances not being completed within agreed timeframes without justification.

6.2 Major non-compliance

(1) A major non-compliance will be caused by actions or inactions that, if not attended to urgently, will lead to the total loss of confidence in the 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.

(2) Major non-compliances must be addressed as soon as practicable, and within one week of the event occurring.

(3) Examples of major non-compliance include:

a) Auditee fails to identify, classify or record defects correctly;
b) Amendments to documented procedural details of treatment supplier's system not notified to the IVA;
c) Failure to apply document control procedures;
d) Actions taken following treatments not recorded;
e) Failure to follow approved procedures that are not immediately impacting on the effectiveness of the treatment, but if left unattended will erode confidence in the treatment suppliers system;
f) Treatment specifications (when specified) not available to treatment technicians.
g) Corrective action for a minor non-compliance not implemented within the agreed time frame;
h) Three or more minor non-compliance in any one audit;

i) Agreed actions to address minor non-compliances not being completed within agreed timeframes;
j) Failure to notify start or recommencing of seasonal operations (where applicable).

6.3 Minor non-compliance

(1) A minor non-compliance will be caused by actions or inactions that are not considered to result in total loss of confidence in the treatment supplier's quality management system, or that that do not lead to treatments not complying with specifications.

(2) Minor non-compliances must be addressed within a period of one month of the event occurring.

6.4 Three majors makes one critical

(1) Should three major non-compliances be raised during the current and preceding audit, a critical non-compliance will be raised on:

a) For treatment suppliers under the supervision programme – clause 6.1 of this document;
b) For treatment suppliers under the approved treatment supplier programme – clause 6.1 of the treatment supplier standard;
c) For IVAs - the IVA standard.

6.5 Three minors makes one major

(1) Should three minor non-compliances be raised during any one audit, a major non-compliance will be raised on:

a) For treatment suppliers under the Supervision Programme – clause 6.3 of this document;
b) For treatment suppliers seeking under the approved treatment supplier programme – clause 6.3 of the treatment supplier standard.

6.6 Not addressing non-compliances

(1) Any non-compliance not satisfactorily addressed by the agreed time will be upgraded to the next level of classification, i.e. minor to major, major to critical.

Part 7: Costs

(1) All costs incurred by MPI or an IVA (including time and any travel associated with evaluation of the approved treatment supplier's system, audit of the approved treatment supplier, communication and reporting) must be met by the treatment supplier.

Part 8: Use of the MPI logo and claims of MPI approved status

(1) The MPI logo or the word “MPI” must not to be used in certification. When approved, a treatment supplier can use the following words "Ministry for Primary Industries approved", provided that the wording is specific as to what the approval is for. For example a fumigation company could display on its certificate:

Approved by the Ministry for Primary Industries to carry out official fumigations.

(2) Where an approved treatment supplier provides treatments not required by importing countries, or directed by MPI to treat imports, no claim of MPI approved status may be made for that treatment and in no circumstances can a certificate be issued that, in any way, indicates MPI approval of the treatment.

Part 9: Suspension or Termination of approval

9.1 Suspension of a treatment suppliers approval

(1) Approval of a treatment supplier to perform official treatments may be suspended by MPI in full or for a specified period, where one or more of the following occurs:

a) Where a treatment supplier's system has not been active for more than 12 months;
b) A treatment supplier has not contracted the services of an IVA;
c) A treatment supplier fails to make full payment of fees to MPI, unless in dispute;
d) Requested by the treatment supplier;
e) Fails to comply with this standard.

(2) MPI must formally advise the treatment supplier of their suspension.

(3) During the period of the suspension, the treatment supplier must not offer or perform any official treatments.

(4) Certification of product that was produced since the last successful audit and the date of suspension is at the sole discretion of MPI.

9.2 Reinstatement of a treatment supplier following suspension

(1) Reinstatement of a treatment supplier's approval by MPI to perform official treatments following suspension must only occur when all conditions prescribed by MPI and or its representatives have been met.

(2) MPI must formally advise the treatment supplier of the date from which their approval will be reinstated.

9.3 Process for termination of approval

(1) Termination of a treatment supplier's approval must occur:

a) Where falsification of any record is found;
b) Where the treatment supplier is wrongfully claiming MPI approval;
c) Where more than two critical non-compliances are identified within any 12 month period;
d) If the conditions for reinstatement in the suspension notice are not met within the specified time;
e) At the request of the treatment supplier.

(2) MPI must formally advise the treatment supplier of the reason(s) for the termination of the approval, and the effective date of the termination.

(3) MPIs contract of approval must be returned to MPI (or through the IVA) within five working days of the approval being terminated. In addition, any equipment for the application of certification marks or material advertising MPI approval status must be disposed of and verified to MPI.

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' 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).

Director

A Director, 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 Oversee, 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 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 of 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;
   ii) Types of treatment that may be applied;
   iii) Locations of treatments; and
   iv) Names of qualified Treatment Technicians.

b) For Independent Verification Agencies

   i) Locations of major offices at which recommendations for Approval are made;
   ii) Names of qualified auditors; and
   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.

a)

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.

Appendix 1 – Application for Approval of Treatment Supplier

for the provision of Official Treatment Services on Import Risk Goods and Export Goods

Complete this application form and forward to your chosen IVA who will then:

POST THIS APPLICATION TO:

Standards, Facilities and Pathways
Ministry for Primary Industries New Zealand
PO Box 2526
Wellington

Treatment Supplier Name		
Address		
Locations of operation		
Scope of service	Type of Treatments	Tick which treatment type ☐ Imports ☐ Exports
	Registered certification mark (ISPM15)	Tick which mark you will be applying ☐ Fumigation ☐ Heat treatment
Contact name		
Phone		
Mobile phone		
Email		
Name and title of person responsible for Treatment Suppliers System		

TREATMENT SUPPLIERS STATEMENT

I, ... (Treatment Supplier), wish to apply for approval under the requirements set down in Ministry for Primary Industries (MPI) Treatment Supplier Requirements.

(1) I agree to meet the requirements of MPI Treatment Supplier Requirements.

(2) I agree to document my Treatment Suppliers System meeting the requirements specified by MPI Treatment Supplier Requirements.

(3) I agree to operate to the above documented system and procedures as approved by the Director, Plants and Pathways, MPI.

(4) I agree to MPI making enquiries and using the information supplied by me, in connection with this application or any contract entered into as a result of this application, for the following purposes:

   a) To ensure that I am a fit and proper person to hold the approved status conferred by the Contract;
   b) To ensure that I have appropriate consents, permits, licences and authorities in respect of my business operations and my business premises that are required;
   c) To notify the public of my approved status.

(5) I consent to such enquiries being made to or by the Police, Customs Department, New Zealand Horticulture Export Authority, and any statutory Board involved in import and export of products. I consent to publication of my approved status in any publication available to the public.

(6) I agree to afford MPI or MPI's representative's reasonable co-operation and access necessary to carry out audits.

(7) Included with this application is a non-refundable application fee of $480.00 (+ GST) for processing the application.

(8) I note that any contract of approval will be subject to desk evaluation and subsequent audits and that the above fee excludes these costs. I agree to pay any reasonable costs of such evaluation and audits as may be charged to me from time to time.

(9) I understand that if I fail to provide all or any of the information requested in connection with this application, I may be denied approval.

(10) I understand that under the Information Privacy Principles of the Privacy Act 1993, I have rights of access to, and correction of, personal information held in connection with this application.

NOTE TO APPLICANT

MPI means any officer or agent of MPI including MPI's Representative.

This application does not in itself entitle the applicant to provide treatment services for MPI Biosecurity. Approval may be given by MPI once the requirements of Treatment Supplier Requirements have been met.

State here the Independent Verification Agency (IVA) you are contracting to undertake preapproval evaluation and initial audits of your operator system.

..... (IVA)

....

(Signature of Treatment Supplier) (Date)

....

(Name – please print) (Title)

Appendix 2 – Approval of Treatment Supplier

for the provision of Official Treatment Services on Import Risk Goods and Export Goods

CONTRACT OF APPROVAL

Made this day of 20

BETWEEN: "**HER MAJESTY THE QUEEN IN RIGHT OF NEW ZEALAND** acting by and through the Ministry for Primary Industries ("MPI")"

AND: ("the Treatment Supplier")

WHEREAS:

A. Background

MPI is responsible for ensuring that treatments being applied to imported risk goods provide the best practicable level of control, and that treatments being applied to export goods comply with importing country requirements. MPI is also responsible for ensuring that only competent Treatment Suppliers and individuals are involved with the delivery of treatment activities.

The Treatment Supplier has demonstrated procedural ability and proficiency in the provision of Treatment services in relation to import risk goods and export goods.

MPI desires to approve the Treatment Supplier for the purpose of allowing him/her/it to provide Treatment services in relation to import risk goods and export goods.

The Treatment Supplier desires to be approved by MPI in order to provide Treatment services in relation to import risk goods and export goods.

The Treatment Supplier acknowledges that the Treatment Supplier has been advised by MPI to obtain legal advice before signing this contract, and to obtain appropriate and sufficient insurance to meet the Treatment Supplier's potential liabilities (including liabilities to MPI), whether under this Contract or otherwise.

B. Purpose of this Contract

This Contract sets out the legally binding arrangement entered into by MPI and the Treatment Supplier for the approval of the Treatment Supplier by MPI.

DEFINITIONS

"Treatment services means the services that are provided by suppliers under the attached Standard.

"Contract" means this Contract, including the Standard and any other documents and requirements incorporated by reference.

"MPI" means Ministry for Primary Industries.

"Treatment Supplier Quality Management System" refers to the "Treatment Supplier Quality Management System" defined in Appendix 1 of the Standard entitled "Treatment Programme: Overview and General Requirements".

"Standard" means the attached documents entitled "Treatment Programme: Overview and General Requirements" and "Treatment Requirements: Treatment Supplier Requirements", subject to any changes to the documents (for example, following periodic review).

PRINCIPAL TERMS AND CONDITIONS

1 Term

1.1 This Contract commences on the date it is signed by the authorised representatives of both parties and will, subject to clauses 6, 7 and 9.3, terminate as per section 9 of the part of the Standard entitled “Treatment Supplier Programme: Treatment Supplier Requirements”.

2 Correctness of Information

2.1 The Treatment Supplier warrants that the following information (including written and oral information) supplied by the Treatment Supplier to MPI is correct and adequate in all respects:

2.1.1 all information supplied in or in connection with the application form entitled "Application for approval of treatment supplier for the provision of treatment services for import risk goods and export goods”;

2.1.2 all other information supplied in connection with the approval of the Treatment Supplier under this Contract; and

2.1.3 all information required to be supplied under the Standard.

3 Treatment Supplier’s Other Warranties

3.1 The Treatment Supplier warrants that throughout the term of this Contract the Treatment Supplier will maintain its Treatment Supplier Quality Management System and all other relevant practices to substantially correspond with all the information referred to in clause 2.1, except to the extent that any changes made are approved by MPI in accordance with the Standard.

3.2 The Treatment Supplier warrants to notify MPI of any change to the Treatment Supplier’s name.

3.3 The Treatment Supplier warrants that where it is an unlisted company, it will notify MPI as soon as reasonably practicable of any:

3.3.1 change in the legal or beneficial ownership of any of its shares; or

3.3.2 issue of new capital; or

3.3.3 change to the rights and powers attaching to any of its shares; or

3.3.4 change to the composition of the board of directors (as this term is defined in section 127 of the Companies Act 1993).

3.4 The Treatment Supplier warrants to fully comply with all the requirements, and other specifications set out in the Standard.

3.5 The Treatment Supplier warrants to take all reasonable steps to enable and facilitate MPI, and any persons acting for or otherwise associated with MPI, to perform their tasks and functions as envisaged in, or otherwise in connection with, the Standard.

3.6 The Treatment Supplier warrants not providing activities for purposes not covered by this Contract. The Treatment Supplier will take all reasonable steps to ensure that these activities are not provided for such unauthorised purposes, or by unauthorised persons.

4 MPI’s Obligation

4.1 MPI hereby approves the Treatment Supplier for the term of this Contract for the purpose of enabling the Treatment Supplier to provide Treatment services in relation to import risk goods and export goods.

4.2 The Treatment Supplier accepts that nothing in this Contract or in any dealings of any kind between the Treatment Supplier and MPI, Crown officers, or agents of or other persons associated with MPI or Crown officers, represents to the Treatment Supplier or otherwise creates any kind of expectation on the Treatment Supplier’s part that:

4.2.1 any other approval or any certification of any kind will be granted by MPI or will be granted within a certain time period; or

4.2.2 any plant products, or other things that are accompanied by, or otherwise reliant on any Treatment services provided by the Treatment Supplier will be accepted by an importing country's official control authorities or will be accepted within a certain time period.

4.3 MPI Biosecurity will, and MPI will ensure that independent verification agencies, only accept valid treatment certificates

5 Exclusion of Liability

5.1 THE TREATMENT SUPPLIER ACCEPTS THAT UNDER NO CIRCUMSTANCES WILL MPI, CROWN OFFICERS, OR AGENTS OF OR OTHER PERSONS ASSOCIATED WITH MPI OR CROWN OFFICERS, BE LIABLE UNDER THE LAW OF TORT, CONTRACT, OR OTHERWISE FOR ANY LOSS, CLAIM, ACTION, DEMAND, EXPENSE, INQUIRY, HARM, OR DAMAGE, HOWEVER CAUSED, ARISING DIRECTLY OR INDIRECTLY FROM OR CONNECTED IN ANY WAY TO:

5.1.1 THE PERFORMANCE, OR AS THE CASE MAY BE, NON-PERFORMANCE OF THE TREATMENT SUPPLIER (OR ANY OF ITS CONTRACTORS, SUB-CONTRACTORS, AGENTS, OR EMPLOYEES THAT ARE NOT A PARTY TO THIS CONTRACT) OF ANY OF ITS OBLIGATIONS IN RESPECT OF THIS CONTRACT; OR

5.1.2 THE PROVISION OR NON-PROVISION OF ANY TREATMENT SERVICES BY THE TREATMENT SUPPLIER.

6 Suspension and Termination by MPI

6.1 MPI may at any time suspend approval of the Treatment Supplier in accordance with Section 9 of the part of the Standard entitled "Treatment Requirement: Treatment Supplier Requirements", in addition to any other rights of suspension provided by law.

6.2 MPI may at any time terminate approval of the Treatment Supplier in accordance with Section 9 of the part of the Standard entitled "Treatment Supplier Requirements", in addition to any other rights of termination provided by law.

6.3 MPI may at any time suspend or terminate approval of the Treatment Supplier for breach of the Standard relating to payment of fees in accordance with Section 9.1 iii of the part of the Standard entitled "Treatment Requirement: Treatment Supplier Requirements".

6.4 Where a change of a kind that is specified in clause 3.3 occurs, MPI may terminate the approval of the Treatment Supplier.

7 Extension following Audit of Treatment Supplier

7.1 Where the results of audits of compliance with the Standard indicate the requirements of the Standard are being complied with, the Contract will be deemed extended, subject to clauses 6 and 9.3, beyond the last audit date.

8 Indemnity and Insurance

8.1 The Treatment Supplier will **INDEMNIFY AND KEEP INDEMNIFIED** MPI from and against any liability, loss, damage, costs and expenses (including legal costs and any expenses of going to arbitration), which MPI may suffer or incur arising directly or indirectly from:

8.1.1 the performance, or as the case may be, non-performance of the Treatment Supplier (or any of its contractors, sub-contractors, agents, or employees that are not a party to this Contract) of any of its obligations in respect of this Contract;

8.1.2 negligent acts or omissions on the part of the Treatment Supplier (or any of its contractors, sub-contractors, agents, or employees that are not a party to this Contract);

8.1.3 suspension or termination of the Treatment Supplier 's approval in accordance with clause 6; or

8.1.4 the provision or non-provision of Treatment services for MPI by the Treatment Supplier .

8.2 The Treatment Supplier will maintain public liability insurance with a minimum sum insured of $1,000,000 (1 million).

9 Force Majeure

9.1 Notwithstanding any other provision of this Contract, neither party must be liable to the other for any act or omission, or any failure to comply with any warranty or to perform any of its obligations under this Contract, where such, act, omission, or failure is caused by fire, flood, storm, earthquake, civil disturbance, war, act of God, or any other event or circumstances reasonably beyond its control (called “Force Majeure”), **provided that** the party alleging Force Majeure has taken all reasonable precautions to avoid or mitigate the consequences of such occurrence.

9.2 The party unable to fulfil its obligations due to Force Majeure will immediately:

9.2.1 notify the other in writing of the reasons for its failure to comply with the warranty or to perform the obligation, and the effect of such failure; and

9.2.2 use all responsible endeavours to avoid or remove the cause and comply with the warranty or perform the obligation.

9.3 Upon receiving notice pursuant to clause 9.2, or upon otherwise being made aware of any Force Majeure circumstances affecting the Treatment Supplier, MPI may at its absolute discretion suspend approval of the Treatment Supplier until such time as the circumstances have been avoided, removed or abated sufficiently to enable the Treatment Supplier to comply with the warranty or perform the obligation.

10 Assignment

10.1 Neither party must assign all or any of its rights, obligations, or liabilities under this Contract. In the event of a purported assignment in breach of this clause, this Contract must terminate.

11 Disputes

11.1 The parties agree to use their best efforts to resolve any dispute which may arise under the Contract through good faith negotiations. Except as provided in clause 11.4, no party must commence any arbitration or litigation in relation to this Contract unless it has first invited the chief executive of the other party to meet with its own chief executive for the purpose of endeavouring to resolve the dispute on mutually acceptable terms.

11.2 Should resolution of the dispute not be achieved at chief executive level, the dispute will be submitted to mediation before any litigation is commenced. Any party may initiate mediation by giving written notice to the other party of their intent to do so. Should the parties be unable to agree on a mediator within two (2) working days of receipt of notice of intent to seek mediation, then the mediator will be selected by the President for the time being of the Lawyers Engaged in Alternative Dispute Resolution (LEADR) or its successor.

11.3 Any dispute arising under this Contract which cannot be settled by negotiation or mediation between the parties or their respective representatives must be submitted to arbitration in accordance with the Arbitration Act 1996.

11.4 In the absence of agreement concerning the appointment of an arbitrator, either party may request the President of the New Zealand Law Society to appoint a suitably qualified independent arbitrator to hear and determine the dispute.

11.5 Nothing in this clause must preclude either party from taking immediate steps to seek urgent equitable relief before a New Zealand Court.

12 Application of Biosecurity Act

12.1 Nothing in this Contract overrides any obligations of MPI and the Treatment Supplier under the Biosecurity Act 1993.

13 Entire Agreement

13.1 This Contract sets out the entire agreement between the parties.

Signed for and on behalf of:

HER MAJESTY THE QUEEN IN RIGHT OF NEW ZEALAND
(acting by and through the Ministry for Primary Industries)

Name:

Position:

Date:

WITNESS:

Name:

Occupation:

Address:

Signed for and on behalf of the treatment supplier)
)
)

Name:

Position:

Date:

WITNESS:

Name:

Occupation:

Address:

Appendix 3 – Treatment Technician and other Staff Competency

Treatment Technician Competency

(1) The treatment technician must be physically able to carry out the treatment process being undertaken and provide evidence that they comply with any requirements for testing (e.g. demonstrating full colour vision where colour recognition is required).

(2) The treatment technician must demonstrate the following competencies (measured during audits) relevant to the treatment being applied:

a) Sound understanding of the treatment processes;
b) Ability to determine which is the correct treatment to be provided and to obtain necessary up-to-date specifications for that treatment;
c) Knowledge of the treatment being applied. (e.g. calculations on dose rate/time/temperature relationships);
d) Facility and equipment operation and maintenance;
e) Equipment calibration procedures;
f) Security, segregation and identification of treated product (goods);
g) Treatment efficacy methods;
h) Reaction properties on products (goods) for that type of treatment;
i) Creation and filing of all required records;
j) Where required by the HSNO Act, hold an approved handler certificate, and a controlled substance license;
k) Where relevant, pest management training, must have been completed to the equivalent of TOPNZ Unit Standard 3263;
l) Understanding of relevant Legislation and Regulations;
m) Understanding of Material Safety Data Sheets (MSDS) of individual chemicals used;
n) Emergency response procedures (2.9)

Other Staff

(1) Other staff may be used for treatment work provided that:

a) Their duties are commensurate with their knowledge and experience; and
b) They are given adequate direction; and
c) Their work is under direct supervision of a treatment technician.
d) The treatment technician supervising their work is not involved in the application of the same treatment (therefore treatment technician is supervising only)

(2) Other staff must be provided with appropriate detailed procedures and checklists.