

BIOSECURITY NEW ZEALAND EXPORT CERTIFICATION STANDARD

Organisation Requirements

Requirements to be met by an organisation to gain approval to undertake export certification activities

REVIEW	This Biosecurity New Zealand standard is subject to periodic review.
ENDORSEMENT	This Biosecurity New Zealand standard is hereby endorsed.
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1 INTRODUCTION

1.1 Background

This standard is one of a set of standards that comprise the Biosecurity New Zealand export phytosanitary certification system.

This export certification system operates through the delegation of authority by Biosecurity New Zealand to authorised Independent Verification Agencies (IVAs) and approved Organisations to carry out certification services and activities on behalf of Biosecurity New Zealand.

The standard “System Overview and Requirements” provides an overview of the policies and general requirements for Biosecurity New Zealand’s Export Certification system.

Biosecurity New Zealand has developed standards and technical requirements for the delegation of authority for the provision of phytosanitary export certification services and activities.

The series of export certification standards can be found on the Biosecurity New Zealand website.

1.2 Purpose

This Standard specifies the system and technical requirements that must be met by organisations undertaking export certification activities to achieve and maintain approval by Biosecurity New Zealand.

A guideline is available to organisations to assist in developing their system: “Guideline: Documenting a System to meet Biosecurity NZ Export Certification Standard *Organisation Requirements*”.

1.3 References

Refer to Appendix 1, Biosecurity New Zealand Export Certification Standard “System Overview and Requirements”

1.4 Definitions

Refer to Appendix 2, Biosecurity New Zealand Export Certification Standard “System Overview and Requirements”

2 REQUIREMENTS TO BE MET BY ORGANISATIONS TO GAIN APPROVAL

Organisation seeking approval to complete phytosanitary activities on behalf of Biosecurity New Zealand shall have documented procedures which are evaluated by

an Independent Verification Agency (IVA) and approved by Biosecurity New Zealand,

2.1 Export certification activity options

An organisation may be approved by Biosecurity New Zealand to undertake one or more of the following phytosanitary activity options:

- Option 1** Phytosanitary inspection
- Option 2** Phytosanitary treatments
- Option 3** Phytosanitary documentation (Phyto Ecert)
- Option 4** Pest survey
- Option 5** Registered certification mark (ISPM15)

2.2 Organisation approval process

An organisation seeking approval to undertake phytosanitary activities on behalf of Biosecurity New Zealand shall have engaged the services of an IVA at all times.

The process for an organisation to be approved is shown in Table 1.

Table 1. Organisation approval pathway

Step	Organisation action	IVA action	Biosecurity NZ action
1	Select an IVA.		
2	Mutually agree with your IVA an acceptable time frame for your documentation of procedures to applicable Biosecurity New Zealand standards and specifications, and subsequent audit of the procedures by the IVA.		
3	Document your system to comply with this standard and the technical requirements of the service options.		
4	Submit the system from step 3 to the selected IVA and attach your completed Contract of Approval (Appendix 1),		
5.		Assess the organisation's documented system against Biosecurity New Zealand standards.	
6.		Request any additional information.	

Step	Organisation action	IVA action	Biosecurity NZ action
7.	Provide any additional information.		
8.		Undertake a full system audit of the documented procedures to validate that the 'actual operations' correspond to the documented procedures at each of the organisations locations where export activities will be undertaken.	
9.		Notify any critical or major non-compliance and request corrective action(s).	
10.	Identify, implement and have verified the agreed corrective action(s).		
11.		Verify the agreed corrective action(s).	
12.		Make a written recommendation to Biosecurity New Zealand, attaching a copy of the organisation's system.	
13.			Biosecurity New Zealand considers the IVA recommendation and where appropriate signs the Contract of Approval for forwarding to the IVA.
14.		Notify organisation of their approval and forward a copy signed by Biosecurity New Zealand.	
15.	Organisation commences implementation of their approved system.		

2.3 Process for amendments to existing systems

The process for the approval of amendments to an existing organisation system shall

be undertaken as described in Table 2.

Table 2. Process for amendments

Step	Organisation action	IVA action	Biosecurity NZ action
1	Make request to IVA for amendment(s) to your system.		
2		Assess the amendment(s) against the appropriate Biosecurity New Zealand standard(s).	
3		Request any additional information.	
4	Provide any additional information.		
5		Validate organisations implementation of the amendment where appropriate.	
6		Make a written recommendation to Biosecurity New Zealand, attaching a copy of the amendment.	
7			Biosecurity New Zealand considers the IVA recommendation and where appropriate approves the amendment.
8		Notify organisation of the approval of the amendment.	
10	Organisation implements the approved amendment.		

2.4 Suspension of an organisation's approval

Approval of an organisation to perform phytosanitary certification activities may be suspended by Biosecurity New Zealand in full or for a specified period, where one or more of the following occurs:

- i. An audit by their contracted IVA identifies critical non-compliance findings; or
- ii. Agreed corrective actions for critical non compliance are not implemented by the organisation within agreed timeframes; or
- iii. An organisation fails to make full payment of fees to Biosecurity New Zealand unless in dispute; or
- iv. Requested by the organisation.

Biosecurity New Zealand shall formally advise the organisation of their suspension.

During the period of the suspension, the organisation shall not offer or perform any phytosanitary certification activities on behalf of Biosecurity New Zealand.

All product inspected, produced or packaged by the organisation from the date of initial suspension is ineligible for export phytosanitary certification by Biosecurity New Zealand unless subjected to end point consignment inspection.

Certification of product that was produced since the last successful audit and the date of suspension is at the sole discretion of Biosecurity New Zealand.

2.5 Process for termination of approval

Termination of an organisation's approval shall occur:

- i. At the request of the organisation;
- ii. If the conditions for reinstatement in the suspension notice are not met within the specified time.

The organisation shall be formally advised through their IVA of the reasons for the termination of the approval, and the effective date of the termination.

All Biosecurity New Zealand approved marks, including contract of approval, shall be returned to Biosecurity New Zealand (or through the IVA) within five working days of the approval being terminated.

2.6 Reinstatement of an organisation following suspension

Reinstatement of an organisation's approval by Biosecurity New Zealand to perform export certification activities shall occur only when all conditions prescribed by Biosecurity New Zealand and or its representatives have been met.

The IVA shall formally advise the organisation the date from which their approval will be reinstated.

2.7 Process for appeals

An organisation may appeal an IVA decision in the following manner:

- i. Organisation is to formally notify the IVA of their request to appeal;
- ii. The organisation and IVA shall cooperatively attempt to resolve the appeal in accordance with the IVA appeals process;
- iii. If a mutually satisfactory resolution of the appeal cannot be achieved, the organisation and the IVA shall jointly meet with Biosecurity New Zealand to resolve the appeal;
- iv. Costs associated with mediation of appeals by Biosecurity New Zealand shall be borne by the organisation;
- v. If a mutually satisfactory resolution is not possible, follow the disputes resolution procedure in clause 11 of the contract of approval.

2.8 Organisation transfer to an alternative IVA

An organisation may elect to transfer to another IVA.

An organisation has responsibility to notify the existing IVA of their decision to transfer to a new IVA.

The organisation must continue with the existing IVA until the new IVA has formalised the transfer.

2.8.1 Eligibility for transfer

Organisations shall not be eligible for transfer until all non compliance findings have been closed out to the existing IVA

3. ORGANISATION SYSTEM REQUIREMENTS

Organisations seeking approval to undertake phytosanitary activities on behalf of Biosecurity New Zealand shall document procedures (risk management programme) that address the following minimum requirements.

3.1 System overview

- i. Name and contact details of the organisation;
- ii. Physical address and contact details of sites/locations;
- iii. The name and contact details of person(s) responsible for:
 - a) Management of the organisation's documented system;
 - b) IVA liaison;
 - c) Audit arrangements;
 - d) Implementation of contingencies.
- iv. The organisational structure of the organisation;
- v. The scope of activities, and references for the relevant technical requirements for which the organisation is approved (refer to Section 2.1).

3.2 Management review

The organisation shall review their system at least annually to ensure its ongoing suitability and effectiveness to comply with Biosecurity New Zealand standards. A record of the review shall be kept.

3.3 Document control

The organisation shall document within their system the procedures to:

- i. Provide document control of all Biosecurity New Zealand approved procedures;
- ii. Ensure the documented system of operating procedures are available to relevant personnel;
- iii. Ensure all amendments to their documented system are approved prior to implementation.

3.4 Maintenance of records

All records pertaining to phytosanitary activities shall be complete, accurate, legible, and readily accessible. The organisation shall maintain the following minimum records:

- i. Complete copy of their current documented system approved by Biosecurity New Zealand;
- ii. Register of Biosecurity New Zealand recognised competent personnel undertaking phytosanitary activities, including competency assessment which identifies by name the scope of activity undertaken by the specific person;
- iii. Training records of personnel and competency assessments of personnel undertaking phytosanitary activities;
- iv. Performance history of personnel undertaking phytosanitary activities;
- v. All records specified in the applicable technical requirements;
- vi. All interceptions of their produce by importing countries;
- vii. New importing country requirements, from sources other than Biosecurity New Zealand.

3.5 Staff competency

The organisation shall:

- i. Have a sufficient number of personnel with the necessary competence to undertake the scope of phytosanitary activity options for which they are approved.
- ii. Implement safeguards for personnel engaged in making phytosanitary decisions from commercial interest in their decisions.

The organisation shall document the following:

- i. The person(s) with overall responsibility for the management of the organisation's system, the competency required and their job description.
Minimum competencies for the position:
 - a) Demonstrable knowledge of Biosecurity New Zealand phytosanitary standards and quality management systems
 - b) Demonstrable ability to apply Biosecurity New Zealand standards within the organisation system
- ii. Method used to assess personnel competency to undertake specified phytosanitary activities within the organisation's system.
- iii. How competencies of personnel undertaking phytosanitary activities are maintained on an ongoing basis.

3.6 Supplier audit

Organisations that elect to undertake internal audits of their suppliers of phytosanitary activities shall meet the following requirements:

1. Operating procedures for supplier of phytosanitary activities

The approved organisation must ensure their suppliers of phytosanitary activities are in receipt of and are implementing the approved organisation's operating procedures for the phytosanitary activities.

2. Audit procedures

The approved organisation shall document, and implement audit procedures meeting the requirements of the relevant parts of Section 4 of this standard, and all other relevant requirements contained within Biosecurity New Zealand standards.

Audit records, must be uniquely identified, dated and traceable to the site of audit, and retained for two years.

Audit records shall include the following minimum information:

- i. Product type(s);
- ii. Audit location;
- iii. Organisation personnel assessed;
- iv. Audit scope;
- v. Non-compliance identified and their classification;
- vi. Agreed corrective actions and their implementation date;
- vii. Future audit status and frequency;
- viii. Auditor name and signature.

3. Audit frequency

The organisation shall complete audits of their individual suppliers of phytosanitary activities as per Table 4, Section 4.

4. Audit reports

The organisation shall ensure their audit reports are available to their nominated IVA.

In the event of a critical non-compliance being detected, the organisation shall submit to their IVA within 24 hours a written report containing the following minimum information:

- i. Name of organisation
- ii. Description of the critical non compliance and implication for export certification
- iii. Organisation action(s) taken
- iv. Organisation recommendation to IVA.

3.7 Technical requirements of certification activity options

The organisation shall implement documented procedures relevant to the scope of the certification activity options for which it is seeking approval.

The technical requirements are specified in the following Biosecurity standards (Table 3).

Table 3. Technical requirements for service options

Option	Reference Biosecurity New Zealand standard	Applicable sections
1	Technical Requirements: Phytosanitary Inspection	All
2	Technical Requirements: Phytosanitary Treatments	See Section 3.7.1 below
3	Technical Requirements: Phytosanitary Documentation (Phyto Ecert)	All
4	Technical Requirements: Pest Survey	All
5	Technical Requirements: Regulated Certification Mark (ISPM15)	All

3.7.1 Phytosanitary treatments

3.7.1.1 Official treatments

When an importing country officially prescribes a treatment as part of their import requirements, organisations shall develop documented procedures for the treatment that meets the requirements of Sections 4.6, 4.7, 5.1.1, 5.1.3, 5.2, 5.3, 5.6, 5.7, 5.8, and Appendix II 1.0 of the Biosecurity New Zealand standard “Requirements for the supplier of official treatments”.

Note:

- i. “Treatment Supplier” is synonymous with “Organisation”
- ii. “Treatment Technician” is synonymous with “Treatment staff member”

The organisation’s documented procedures for treatments, shall become part of the organisation’s system, and shall be subjected to the audit regime of the approved organisations system.

3.7.1.2 Use of Biosecurity New Zealand approved treatment suppliers

Treatment suppliers may be subcontracted in by an organisation to undertake official treatments for export certification. In this circumstance the treatment supplier must comply with the requirements of the Biosecurity New Zealand Standard “Requirements for the supplier of official treatments”.

3.7.1.3 Other treatments

Organisations which carry out treatments as part of their documented systems, but the treatment being applied is not specifically required by an importing country, may opt to develop procedures which are equivalent to the technical requirements of Section’s 4.6,

4.7 and 5.6 and Appendix II 1.0 of the Biosecurity New Zealand Standard “Requirements for the supplier of official treatments”.

Where the organisation is seeking Biosecurity New Zealand recognition of the treatment process to be equivalent to phytosanitary inspection, procedures and technical justification for equivalency shall be documented within their approved organisation system.

3.8 Operating procedures and process control

3.8.1 Technical requirements of certification service options

The organisation shall reference the relevant technical requirements applying to the options covered by their system scope (see section 2.1 and 3.7).

3.8.2 Importing country’s phytosanitary requirements

The organisation shall reference and undertake phytosanitary activities in accordance with requirements contained within:

- i. Importing Country’s Phytosanitary Requirements (ICPRs);
- ii. Phytosanitary import permits;
- iii. Work plans for pre-clearance programmes;
- iv. Special phytosanitary programmes.

3.8.3 Development of Critical Control Point (CCP) procedures

The organisation shall:

- i. Identify their product pathway(s);
- ii. Identify hazards and risks within this pathway, and the CCP’s where hazards and risks are managed;
- iii. Develop procedures for activities within each CCP to control, prevent, remove or reduce the identified hazards and risks.

3.8.3.1 Product Pathway

The organisation shall define and document the product pathway applicable to the scope of the organisations operation which may include, but not be limited to the following stages:

- i. production site (e.g. forest, farm or orchard)
- ii. places of handling initially harvested plant products (e.g. packhouses, seed cleaning plants, log yards, saw mills)
- iii. storage
- iv. treatment
- v. processing
- vi. dispatch and inventory control
- vii. transport
- viii. export documentation to obtain phytosanitary certification

3.8.3.2 Hazards and risks

Within each stage of the product pathway the organisation shall identify and document hazards and risks which will affect the phytosanitary status of the product. In particular the organisation shall maintain the integrity of the certification status product has gained through consideration of the following:

- i. the method used for the traceability of plant products from inspection to the point of export from New Zealand (defined as the date on which the consignment was loaded onto a vessel or aircraft).
- ii. the method used for ensuring post inspection product security:
 - (a) how product contamination by pests after inspection is prevented;
 - (b) how mixing/substitution of certified product with non certified product is avoided ;
 - (c) how the certification status resulting is maintained when products are transferred between organisations;
 - (d) how time periods specified by the importing country, between inspection and time of export, are maintained.
- iii. contingencies for any breakdown in their product security procedures.
- iv. corrective actions to bring any non-complying plant product or operational process back into compliance with specifications.

The organisation shall identify and document each CCP where hazards and risks are managed.

3.8.3.3. Procedures for activities

The organisation shall develop and document procedures for activities within each CCP for managing hazards and risks. The procedures must state:

- (e) What activity(s) is to be done;
- (f) How the activity is to be undertaken;
- (g) Where the activity(s) is undertaken;
- (h) When the activity(s) is to be undertaken;
- (i) Who is responsible for completing the activity(s).

4. AUDIT FREQUENCY AND SCOPE

4.1 IVA audit of organisations

The organisation's nominated IVA shall audit the organisation's documented and approved system for ongoing compliance. The audit frequency and scope applied shall be determined by the level of:

- i. Risk posed by the particular system and/or product type being exported;
- ii. Confidence attained through prior audits.

4.1.1 Risk categorisation of product types:

Level 1 Manufactured or processed product where the approved process is recognised as rendering the product and/or pests non-viable.

Where there are no critical non-compliance findings within the initial system and the subsequent three surveillance audits per year, the approved organisation shall be eligible for Risk Category 1 as identified within Table 4.

Level 2 All other products and export documentation (Phyto Ecert)

Where there are no critical non-compliance findings within the initial systems audit and the subsequent six surveillance audits per year, the approved organisation is eligible for the reduced level (3) of ongoing surveillance audits (Table 1).

Specific commodities within Level 2 risk category may be considered for a lower frequency of surveillance audits below three per year, if it can be demonstrated that a new process (other than those specified as necessary for Level 1) have significantly lowered the plant products risk containing and transferring quarantine pests. Such reduction is at the sole discretion of Biosecurity New Zealand and on a case-by-case basis.

Table 4. Initial and reduced audit frequencies

Risk category	System audit	Initial entry surveillance audit frequency	Qualifying criteria for reduction	Reduced surveillance audit frequency
1	1 per yr (ongoing)	3 per year	One year without a critical non-compliance.	1 per year
2	1 per yr (ongoing)	6 per year	One year without a critical non-compliance.	3 per year

Note: Where an organisation undertakes phytosanitary activities for a period of two months or less within one calendar year, the audit frequency shall be reduced to the following minimum levels during the period of operation:

- i. one system audit;
- ii. two surveillance audits.

4.2 Audit scope

A systems audit is of the organisation's full system for compliance with documented procedures.

Surveillance audits are of specific parts of the organisation's system and include:

- i. Confirmation that phytosanitary activity is performed to documented procedures by the competent staff;
- ii. Confirmation that, where applicable, the product is correctly identified as being in compliance with the ICPR, for the countries of import, and segregated from non-complying product;
- iii. A phytosanitary inspection of product, where applicable, to confirm compliance with the organisation's inspection results and the importing countries phytosanitary requirements.

4.3 Classification of non-compliance

Non-compliance incidents shall be classified as critical non compliance or other non compliance depending on its effect on the IVA confidence in an organisation's system.

4.3.1 Critical non-compliance

A critical non-compliance is an incident(s) that results in no confidence that an organisation's system is in place to deliver product that meets the specified phytosanitary requirements of the importing country.

Examples of Critical non-compliances are:

- i. Falsification of any record impacting on a phytosanitary certification request;
- ii. No official treatment undertaken when required;
- iii. No inspection undertaken when required;
- iv. Organisation fails to identify, classify or record phytosanitary status correctly;
- v. Non- export certified product exported or intended for export;
- vi. Non-export product not separately identified from export product;
- vii. Unlabelled or erroneously labelled product following phytosanitary inspection;
- viii. Incorrect information on certificates affecting phytosanitary status;
- ix. Maximum pest limits exceeded during inspection/audit and not actioned correctly;
- x. Required inspection facilities, equipment and calibration thereof (where applicable) not used or applied;
- xi. Amendments to approved procedures not notified to the IVA prior to implementation;

- xii. ICPRs and approved procedures not available to appropriate personnel;
- xiii. Product traceability requirements incomplete;
- xiv. Non-competent staff operating without supervision where the results of their activities lead to certification of products;
- xv. Failure to rectify an other non-compliance identified in a previous audit within the agreed timeframe;
- xvi. Any re-occurrence of an other non-compliance detected in the two previous consecutive audits;
- xvii. Failure to meet annual registration conditions including payment of applicable fees.

Under exceptional circumstance and if the IVA considers it warranted, critical non compliances not on this list may be identified. Such critical non-compliances shall be agreed with Biosecurity New Zealand prior to being confirmed.

Where a critical non-compliance is identified during any audit, the audit frequency shall immediately increase to either:

- i. Daily audits for a maximum of three days, during which time the organisation must identify, implement and have verified agreed corrective action(s); or
- ii. Production throughput subjected to endpoint consignment inspection for the three days during which time the organisation must identify, implement and have verified agreed corrective action(s).

Where the IVA finds a critical non-compliance, an organisation's system shall immediately revert to the initial audit frequency.

The organisations failure to manage the critical non-compliance in accordance with the IVA audit report shall result in the organisations system immediately reverting to End Point Consignment Inspection until:

- i. An agreed corrective action strategy has been verified by the auditor as having been implemented; and
- ii. A targeted systems audit is successfully completed.

Where two or more critical non-compliances are identified within any 12 month period, the organisation's system shall immediately revert to End Point Consignment Inspection until the organisation initiates and completes the full approval process again.

4.3.2 Other non-compliance

An other non-compliance is an incident(s) that creates doubt and a decrease in confidence that an organisation's system is in place to deliver product that meets the specified phytosanitary requirements of the importing country.

Other non-compliance findings include but are not limited to the following examples:

- i. Significant difference between auditor and organisation findings;
- ii. Failure to notify start or recommencement of operation, where applicable;
- iii. Staff competencies incorrectly documented and maintained;
- iv. Incomplete inspections records.

4.3.3 Corrective actions for other non-compliances

A corrective action and a time frame for its implementation are to be agreed between the auditor and organisation for each non-compliance finding. The auditor shall verify that the corrective action has been implemented and is effectively addressing risk within the agreed time frame.

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APPENDIX 1

Application for authorisation and Contract of approval are under legal consideration.

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