Submission: Biosecurity New Zealand Export Certification Standard

Pipfruit New Zealand Incorporated

19th April 2006
Introduction

The rules of Pipfruit New Zealand Incorporated (PNZI) state that it must regularly consult with its member classes. To accommodate Post Harvest Members and their relevant issues PNZI has formed two consultative groups. One based in Nelson\(^1\), and one based in Hawkes Bay\(^2\). PNZI has facilitated the groups through the support of Mike Butcher, Gary Jones and the expertise of Roger Gilbertson. The groups have met regularly over the past year to focus on the Phytosanitary Standards Review.

This document is a summary of those consultations.

PNZI thanks Biosecurity New Zealand and the project team for the opportunity to comment on these standards and importantly for the updates and feedback on its progression. Consultation has been well received and PNZI looks forward to the implementation of these standards in the spirit that they have been developed.

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Implementation Timeframe

Timeframe for implementation of the revised standard is far too short for pipfruit industry. Pipfruit also reflects a large % of the number of documented systems in the Plants industry. Packhouses are packing fruit from February through to June, with many going longer. Implementation deadline of 1st September 2007 means that in 2007, organizations have no more than 2-3 months to implement changes. System must therefore be developed this year 2006. This timeframe will put strain on organizations and IVA's to have systems up and running by time fruit is harvested.

- Recommendation: Delay implementation deadline until 15th February 2008.

General Comments on the Standards

Consistent standards – Biosecurity NZ & NZFSA

With planned implementation of NZFSA residue and grade certification standards (plus other NZFSA Plant related standards) it is important that industry can utilise a common platform of standards. The draft residue standards are almost a mirror of the phyto standards and grade is likely to be aligned closely to Phyto also.

Preference would be a “one stop” series of standards which straddles both NZFSA and Biosecurity NZ. This means IVA’s/Organisation’s can document a fully integrated system to address the requirements across both agencies.

The structure of the proposed standards is a positive step to a “one stop” approach by splitting the general requirements (ie System overview and IVA/Organisation requirements) from the specific technical requirements. NZFSA technical requirements (eg for grade) can then be easily fitted alongside BNZ technical requirements.

In a general sense the standards are very attuned to Phytosanitary certification – refer System overview & requirements standard. Therefore is there an opportunity to consider options to broaden this standard to account for NZFSA?

- Examples: definitions for generic terms (eg audit, certificate, inspection) have a very specific phytosanitary focus.

- Much of the methodology and structure between NZFSA/BNZ described in the overview is consistent (e.g. MAF principles for export certification, application regulatory model etc) hence there is a good basis for alignment.

The principles in both the IVA and Organisation standards (based on the regulatory model concept) are consistent for BNZ and NZFSA enabling a shared approach to these standards also. Where there are different approaches (eg
auditing approach and frequency) these could be accommodated in the relevant standards.

- Recommendation: That Biosecurity and NZFSA collectively review standards in their draft formats to enable/promote a shared standard format.

**Common Tools for BNZ & NZFSA**

Although not specifically covered by the standard there is an opportunity to share the tools used by both agencies to maximize efficiencies. Examples:

- E-cert could be fully integrated enabling different certificate formats, signing authorities. (It is appreciated this is already under investigation). BNZ has also included a technical requirement for e-cert. If NZFSA and BNZ are to share the e-cert platform for providing certification it also promotes the concept of a shared e-cert technical standard.
- Importing country requirements that cover both Phytosanitary and non phytosanitary (e.g. grade, organics, and residue) requirements.
- It should be noted that members were extremely concerned about the divergence of BNZ and NZFSA.

**HACCP**

There is concern that a full HACCP assessment based on the seven principles of HACCP will be required for any Organisations new system. PNZI sees this as too onerous in terms of potential risks.

- Recommendation: Organisations are able to set their own HACCP scope for defining risk.

**Standard Specific Comments**

**System Overview & Requirements**

As per comments on BNZ/NZFSA consistency comments above.

More specifically

- Surveillance audit definition: Previously the definition was very focused on monitoring of “Inspection” systems – confirming product meets specifications. The definition now has a general focus. This change has potential to impact on a range of aspects including audit frequencies for “non inspection” systems (e.g. e-cert only systems, security (PIPS) only systems).
- Lot definition: A lot may not be specific to a production area or the same pest management regime. A lot is more focused on predefining a discreet grouping of product regardless of the characteristics that make it up.
• Some recommended wording changes to definitions is included in Appendix 1.

**IVA Requirements (not specifically reviewed)**

Pipfruit members want IVA’s to have the ability to provide training for organizations and to audit them as well. The limited resources in the industry needs to be recognised. PNZI questions how specific the conflict of interest requirements under ISO 17020 are that could limit this ability.

IVA’s already has a conflict of interest in being able to fail audits and then be paid by the organization to come back to re audit.

  • Recommendation: IVA’s are able to offer training services to organizations that they audit.

Disputes resolution process requires organization to pay for process regardless of its outcome.

  • Recommendation: The party deemed to be incorrect pays.

**Organisation Requirements**

2.1 Export certification activity options

Option 5: Registered certification mark (ISPM15) is really a specific treatment that is covered by Option 3: Phytosanitary treatment, rather than a stand alone option.

  • Recommendation: That ISPM 15 is incorporated in Option 3 and the specific technical specifications (i.e. fumigation/treatment requirements and identification methods) is included in relevant ICPR’s. This is then consistent with how other official export treatments are addressed and ensures all parties are aware of all the ICPR requirements.

2.2 Organisation approval process

**Table 1: Organisation Approval Pathway**

  • Step 9. No longer a category “major”

  • Recommendation: reword to “Issue non compliance(s) and request corrective action(s)”

  • Step 12-15 has been an issue for new organisations in the past regards timeliness of response. The timeframe is affected by IVA/BNZ administrative procedures/staffing for what to all accounts is a rubber stamping process.
• Recommendation: Consider provisional approval by the IVA to enable the organisation to commence operating their system following the conclusion of a successful audit.

Table 2: Process for Amendments.

• As per above comments regards timeliness of approvals. Particularly significant as it may be a required change (i.e. BNZ driven) and the organisation is fully operational.
• Recommendation: Consider provisional approval by the IVA at or before Step 5.

2.4 Suspension of an organisations approval.
Points i) and ii) are already addressed in section 4.3.1 Critical non-compliance.
• Recommendation: Delete i) and ii) and follow actions in 4.3.1.

3.4 Maintenance of records

Training records:
It is record of competency that is pertinent. Training records are nice to know but not a requirement as part of competency.
• Recommendation: Delete reference to training records

IV. Performance history:
Are these records that demonstrate ongoing competency/ IVA audit reports?
• Recommendation: If meaning competency records delete iv) as this is covered by iii). If meaning IVA audit reports – specify as such.

3.5 Staff competency
• Recommendation: a definition for “phytosanitary activity”

3.6 Supplier audit

1. Operating procedures for suppliers:
It isn’t clear that the Organisation must specify how their supplier should undertake their role (e.g. inspection).
• Recommendation: rewording to ensure it is clear Organisations must specify their supplier procedures / specification’s.
2. Audit procedures:
- Recommendation: Minimum audit record information should be consistent with IVA audit record information.
- Recommendation: Consistency of terminology “audit record” v “audit report”
- Recommendation: Delete “Organisation recommendation to IVA” as this should be clear from actions taken above. It is the IVA’s role to confirm they agree with the actions.

3. Technical requirements of certification activity options

3.7 Phytosanitary treatments:
All other activities have a specific and targeted Technical Requirement excepting treatment. Referencing into import standards may not be relevant for an export only treatment operator. Also the technical requirements may diverge/change due to import risks rather than export risks – the risks should always reflect those pertaining to exports.
- Recommendation: Document a specific “technical requirement” for treatments so it is consistent with other technical requirements. This becomes increasingly significant as organisations look to innovative ways (ie treatments) to attain equivalence to solely inspection based systems.

3.7.1 Use of BNZ approved treatment suppliers:
Reference to sub contractors needing to develop a system which is different to those undertaking treatments in house. This is symptomatic of trying to link into a standard that has a different approach and hence the recommendation above. Any organisation may be contracted to undertake a specific function be it inspection, treatment, survey etc. Where they are contracted but not inclusive of the operator system they need to be approved/authorized in their own right and meet the same requirements as an equivalent organisation/IVA.
- Recommendation: To be consistent the contracted operator should meet the same set of criteria as the export organisation – hence linking into the export standards rather than import standards. This again reflects the same recommendation as above (i.e. document a technical requirement for treatment) to ensure all parties are treated consistently.

- PNZI understands that some contracted parties work in both imports and exports and that BNZ Imports will/may not recognize the BNZ Exports approval. This is something that needs to be sorted within Biosecurity NZ and from an industry perspective present a seamless process for treatment organisations.
3.8 Operating procedures and process control

3.8.3.3. Procedures for activities:

It isn’t normal in procedures to specify the location (ie where) the activity is undertaken. This doesn’t add to the credibility of the procedure and where specific technical requirements need to be met to complete the procedure these would be referenced or included in the “How”.

- Recommendation: Remove reference to “where”.

4 Audit Frequency and Scope

4.1 IVA audit of Organisations

Operators with systems that haven’t included “Inspection” have been audited on the basis of an annual system audit (although this has been variably applied). In the draft standard this now appears in a best-case scenario to have increased to one system audit and three surveillance audits annually (1 system and 6 surveillance audits annually for new operators). It appears audit frequency for inspection is treated as per non inspection systems.

In the pipfruit industry there are a range of operators that have Operating systems that focus solely on e-cert or post inspection security (e.g. coolstores, transport companies ports etc)

The following table is a comparison of existing (PEO.OAR) and proposed (Organisation requirement) audit frequencies.

<table>
<thead>
<tr>
<th>System scope</th>
<th>Year of operation</th>
<th>Total audits under PEO.OAR/PER</th>
<th>Total audits under Organisation Requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>Processed product</td>
<td>Yr 1</td>
<td>2</td>
<td>4</td>
</tr>
<tr>
<td></td>
<td>Yr 2+</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Ecert</td>
<td>Yr 1</td>
<td>1</td>
<td>7</td>
</tr>
<tr>
<td></td>
<td>Yr2+</td>
<td>1</td>
<td>4</td>
</tr>
</tbody>
</table>
"Inspection" system

<table>
<thead>
<tr>
<th>Year</th>
<th>Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yr 1</td>
<td>16</td>
</tr>
<tr>
<td>Yr 2</td>
<td>7</td>
</tr>
<tr>
<td>Yr 3+</td>
<td>4</td>
</tr>
</tbody>
</table>

"Security" system (eg transport, coolstore)

<table>
<thead>
<tr>
<th>Year</th>
<th>Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yr 1</td>
<td>1</td>
</tr>
<tr>
<td>Yr 2</td>
<td>1</td>
</tr>
</tbody>
</table>

Note: Historical definition of Surveillance audit has focused on checking the “Inspection” system – i.e. product sample and comparison of results with Inspector. Systems that did not have an inspection component had focus placed on systems audits.

**PEO.OAR definition of Surveillance audit:** An audit carried out at the site where inspection activities are undertaken, which examines the specific components of the Operator’s System that are related to confirming that product is meeting specifications.

**Ecert audit comment**

There have been concerns raised surrounding the interpretation of audit frequencies relating to “Ecert only” operators as new operators in this category were being subjected to up to 17 audits (plus) in their first year (ie treated the same as Inspection operators).

Under standard 159.11 (predecessor to PEO.PER) where operators were controlling the MAF logo, entry fields and printing processes prior to signing certificates an annual audit of this system was in place. This then moved to a more controlled e-cert environment which enabled greater control of information on the certificate and a more efficient and targeted validation process.

When PEO.PER was introduced there was an inconsistency in the application of audit frequency. This was first tabled with the PMAC operations working group back in 2004 subsequently tabled at PMAC and signed off by PMAC (July) which redrafted the PEO.PER to reflect an annual audit requirement. See below.
4.3 IVA Audit Frequency and Audit Scope of Certificate Production Sites

4.3.1 Frequency:

Following the initial registration process, each accredited operator with a registered certificate production site must be audited at least once within a calendar year.

It should be noted that at the very least all product presented by an e-cert operator has already been through an “inspection” or “treatment” system and subjected to system and surveillance audits. Interestingly if you attain e-cert as part of a treatment system you have a lower audit frequency than if via an inspection system.

- **Recommendation:** The definition/scope of surveillance audit, the risk categories for different systems and movement between audit frequencies based on performance be reviewed and reconsidered.

4.1.1 Risk Categorisation of Product types:

It is recommended the following approach to audit frequency is considered:

- **Level 1.** Non inspection based systems including Manufactured or processed product where the approved process is recognised as rendering the product and/or pests non-viable, export documentation (e-cert), post verification security.

- **Level 2.** Systems that incorporate inspections as a means to attain certification.
4.3 Classification of non-compliance

4.3.1 Critical non-compliance:

Should relate to actions that are likely to result in product exported/intended to be exported that fails to meet the importing country phytosanitary requirements. The problem with interpreting some of the listed critical non-compliances is that in some cases the resulting impact may be less significant than critical.

In particular these relate to examples iv., vii., x., xi., xii, xiii, xv., xvi., xvii. (Note: this one is covered under suspension of approval).

- Recommendation: That the examples of critical non-compliance be reviewed to ensure they are critical in nature or put focus on the definitions and request the auditor ensures that the non compliance found fits this definition.

**Technical Requirements: Pest Survey**

2.1 Survey design

Identification of boundaries is covered in survey implementation.

- Recommendation: Delete this requirement.

2.2 Survey implementation

Often the approved survey body does not have direct control of the production site post undertaking the survey. Are requirements vi) and vii) able to be controlled by the surveyor or should this form part of other systems (e.g. inspection, treatment?).

- Recommendation: Review the application of these two requirements.

<table>
<thead>
<tr>
<th>Risk category</th>
<th>System audit</th>
<th>Initial entry surveillance audit frequency</th>
<th>Qualifying criteria for reduction</th>
<th>Reduced surveillance audit frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Level 1</td>
<td>1 per yr (ongoing)</td>
<td>3 per year</td>
<td>At least a clear year of critical non-compliance findings.</td>
<td>1 per year</td>
</tr>
<tr>
<td>2. Level 2</td>
<td>1 per yr (ongoing)</td>
<td>6 per year</td>
<td>Ditto</td>
<td>3 per year</td>
</tr>
</tbody>
</table>
3 New Host-Crop Associations

Should this form part of Survey requirements or pest identifier requirements? The risk is incorrect identifications or crop associations could be notified by unqualified people. This could result in serious market access implications on a long term basis.

- Recommendation: Delete this requirement from Pest Survey and ensure covered under Pest identifier requirements.

Technical Requirements: Phyto ecert

The requirement seems to be written for organisations only – how do IVA’s become authorized to use e-cert?

Also reflecting early comments regards integration with NZFSA future use of ecert.

3.2 Certificate requests

This section is controlled by e-cert itself – hence it is not really a requirement of the certificate requestor

- Recommendation: Delete this section

3.3 Phyto E-cert certificate production procedures

- Recommendation: check usage of “operator”

Technical Requirements: Phytosanitary Inspection

General comment: Consideration be given to systems put forward in the future which have an integrated quality system approach i.e. may reflect a range of treatments/processes that collectively provide confidence of the integrity of a lot meeting import requirements thereby less reliant on inspection as the sole means.

2 General Phytosanitary Inspection Requirements

The last sentence of the paragraph “and have documented procedures for the following principle activities.” is inconsistent with the other technical requirements and the organisation requirements.

The Organisation requirements already specifies the approach required in documenting procedures.

- Recommendation: Delete this last statement and the subsequent listed activities i.–viii.

Reverting back to using term “Suppliers”

- Recommendation change to Organisation
2.1 Identification of lots for inspection

Introducing another term “producer”

- Recommendation: Re word this to “Organisations shall document how inspection lots are identified and differentiated from other inspection lots to ensure each lot being inspected is homogeneous.”

2.1.1

References made to specific seed requirements and specifically identification of seed lines, arable seed sampling plans, removal of quarantine pests are all recognized and approved processes. This is the same as any other product group where BNZ has approved “inspection” processes. By specifically defining approved seed procedures within the inspection standards applies an inconsistent means of addressing an approval process for other plant products.

- Recommendation: That product specific approvals be held in a specific and accessible location by BNZ (accessible on the web). It is more appropriate to reference where approved inspection processes are maintained rather than include in the standard, otherwise the list will become exhaustive when every approved identification system, sampling plan, decision criteria etc is included in the standard.

2.2 Sampling of plant products

- Recommendation: To address issues raised above around industry approved sampling plans, include a further option which points organisations to the place where specific industry approved plans are held (eg documented compliance programmes).

2.5 Management of non conforming product

To ensure this requirement is outcome focused, managing non conforming product should be left to the organisation to define.

- Recommendation: Change wording to “The organisation shall document how non-complying product following inspection is managed” only.

2.5.1 Removal of quarantine pests

This is outside the scope of the “Inspection” technical requirements as it describing actions that are already captured by “Phytosanitary treatments”. When the Organisation defines it scope in the Organisation requirements it specifies what technical requirements it looks to get approved. If they propose to use treatments they should identify it at this point.

- Recommendation: Delete 2.5.1 Removal of quarantine pests.
2.7 Post Inspection product security

There is a duplication of intent between this section and Organisation Requirements 2.8.3.2. Both look to address the same requirements. Inclusion of PIPS at the inspection level could lead to inconsistent approaches with other technical requirements that need to address the maintenance of security.

- Recommendation: Delete section 2.7. The Organisation requirements intends to cover all phytosanitary activities in a consistent manner.

2.8 Records

There appears to be a substantive list of records, how valid are these records?

What is the purpose in keeping records of?

- plant products and time of export.
- Storage locations for inspected and passed product (sites/locations already covered by the system are specified in Organisation requirements 3.1 System Overview).
- The organisations grower suppliers where an Additional Declaration is required. It is more important that the organisation understands how these need to applied in their system and where they can find the officially recognised list.

Import permits are already covered by Organisation requirements 3.4 vii).

Why specify the details required on the inspection record when this is not consistent with treatment, survey records?

- Recommendation: Review the records list for intention and application to ensure there are justified reasons and beneficial outcomes from maintaining these records.

**Technical Requirements: Registered certification mark**

As per previous comments – this technical requirement fits in with Technical Requirement: Phytosanitary treatments (with some specific technical features that could be captured in an Appendix or in ICPR’s).
Appendix 1 – System Overview and Requirements: Definition
Recommendations

Audit

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

Pertaining to phytosanitary certification:

- **A System Audit** is an evaluation of the entire organisation’s phytosanitary system for compliance with the certification system’s requirements.

- **A Surveillance Audit** is an evaluation carried out at the site where inspection activities are undertaken, which examines specific parts of the organisation’s system, to confirm that product meets required specifications.

Auditor

A person who carries out an audit to determine the degree of conformity with prescribed criteria.

Authorised

Formally recognised by Biosecurity New Zealand as competent to provide specific phytosanitary service(s) in accordance with the requirements specified in the relevant Biosecurity New Zealand standard(s).

Biosecurity New Zealand

Biosecurity New Zealand is the body within MAF that is responsible for providing official assurances to control authorities in importing countries through export phytosanitary certification.

Contract of “Delegated Authority”

A document forming part of this certification system’s standards which sets out the legally binding arrangement entered into by Biosecurity New Zealand and an agency and/or an organisation to formalise the delegation of authority to act on Biosecurity New Zealand’s behalf to provide specific phytosanitary service(s).

Decision Maker ?????

The person or committee within Biosecurity New Zealand that reviews and makes recommendations regarding the formal delegation of authority to
another organisation or recognition of individuals and makes decisions on whether authorisation or recognition shall be granted.

**End Point Consignment Inspection**
An officially recognised phytosanitary inspection of plant product at a point just prior to loading for export.

**Equivalence**
Measures which are not identical but have the same effect.

**HACCP**
(Hazard Analysis and Critical Control Point) A system that identifies, evaluates and controls hazard(s).

**Inspection**
A visual examination of plant products or other regulated articles to determine if pests are present and/or to determine compliance with phytosanitary regulations.

**Inspector**
A person who carries out inspection activities.

**National Plant Protection Organisation (NPPO)**
Official service established by the government to discharge the functions specified by the International Plant Protection Convention (IPPC). In New Zealand MAF is the NPPO.

**Non-compliance**
Failure to comply with requirements specified in the relevant standards, or specifications.

**Organism**
As defined by the Biosecurity Act (1993) (as amended by the Biosecurity Amendment Act (1997) and for the purposes of this standard:

a) Does not include a human being or a genetic structure derived from a human being;

b) Includes a micro-organism;

c) Subject to paragraph (a) of this definition, includes a genetic structure that is capable of replicating itself (whether that structure comprises all or only
part of an entity, and whether it comprises all or only part of the total genetic structure of an entity);

d) Includes an entity (other than a human being) declared by the Governor-General by Order in Council to be an Organism for the purposes of this Act;

e) Includes a reproductive cell or developmental stage of an Organism;

f) Includes any particle that is a prion.

Commodity Pest list
A list of all pests recorded in New Zealand associated with the commodity to be exported.

Plant Products
A material of plant origin.

Procedure ISO definition

Test
Examination, other than visual, to determine if pests are present or to identify pests.

Treatment
Procedure, for the killing, removal or rendering pests infertile.

Note: For the purposes of this certification system, treatment also includes rendering the pests and/or plant products non-viable or devitalising a consignment of plant products.