Export Eligibility Requirements

Official Agrichemical Assurance Standard for Fresh Plant Products

Prelims

October 2006

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Website

A copy of this document can be found at: http://www.nzfsa.govt.nz/plant/index.htm

Review of Export Eligibility Requirements; Official Agrichemical Assurance Standard for Fresh Plant Products

This Export Eligibility Requirements; Official Agrichemical Assurance Standard for Fresh Plant Products will be reviewed, as necessary, by the New Zealand Food Safety Authority. Suggestions for alterations, deletions or additions to this Export Eligibility Requirements; Official Agrichemical Assurance Standard for Fresh Plant Products, should be sent, together with reasons for the change, any relevant data and contact details of the person making the suggestion, to:

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1. Introduction

Amendment 0

October 2006

This standard describes the New Zealand Food Safety Authority's requirements for the registration of agrichemical management plans upon which official assurances for compliance of fresh plant products with importing country maximum residue limits can be provided. Such assurances may be provided where these are required by importing country authorities or where required to facilitate market access. The standard enables industry bodies, packhouses, or other industry operators to establish agrichemical management plans that are recognised by NZFSA as the basis for provision of these assurances. This approach provides considerable flexibility to the operators in both the scope and the manner in which agrichemical management plans are operated. The development by industry sectors of agrichemical management plans (AMPs) is strictly voluntary, and is only envisaged as becoming necessary should official assurances be required by overseas markets.

Operators are required to apply HACCP principles to identify and manage risks of non compliance with importing country residue requirements and document these within the agrichemical management plan. The agrichemical management plan is then independently evaluated by a NZFSA recognised agency, and subject to ongoing verification through independent audit. On successful confirmation of this process, NZFSA will provide official agrichemical assurances to importing country authorities that the fresh plant products covered by an agrichemical management plan are produced in accordance their requirements, when this is necessary for market access.

This standard has been produced in consultation with the Plants Market Access Council.

This standard comes into effect on 20 November 2006.

1.1 Application

This standard applies to anyone who develops, evaluates, verifies, or operates an agrichemical management plan for fresh plant products through which NZFSA provides official assurances of agrichemical compliance to importing countries.

Additional requirements, negotiated on a bilateral basis with importing countries, may be added to this standard as appendices.

1.2 Interpretation

In this standard, unless the context otherwise requires, the following meanings are adopted:

Hereinafter, use of the term 'the standard' within this document will refer to the Agrichemical Assurance Standard for Fresh Plant Products.

Accreditation - Formal granting of recognition of competence for specified categories, following assessment against a standard, by an accreditation body.

Agrichemical – In this document, the term **Agrichemical** has also been used to incorporate Agricultural Compound, a substance used in agriculture, as defined by the Agricultural Compounds and Veterinary Medicines Act 1997 (including pesticides, as defined by the Pesticides Act 1979), as well as any substance used for pest control in packhouses or stores, on packing material and during transport.

Control (noun) – The state wherein correct procedures are being followed and criteria are being met.

Control (verb) – To take all necessary actions to ensure and maintain compliance with criteria established in the agrichemical management plan.

Critical Control Point (CCP) – A step (in a process) at which a control can be applied and is essential to prevent, eliminate, or reduce a food safety hazard to an acceptable level.

Critical limit – A criterion which separates acceptability from unacceptability.

Evaluation – Assessment of an individual, plan, programme, or system to determine compliance with regulatory requirements. This will involve review of documentation and, in some cases, review of operations or observation of practice. It is undertaken by a competent individual contracted to an impartial agency.

Fresh plant products - Unmanufactured living material of plant origin (excluding grain and seeds), not dried, deep-frozen, or otherwise conserved.

HACCP – Hazard Analysis and Critical Control Point system adopted by the Codex Alimentarius Commission. HACCP is a systematic identification of hazards and the measures for their control to ensure the safety of food. It focuses on prevention rather than end-product testing.

Maximum residue limit (MRL) - the maximum concentration of a pesticide residue (expressed as mg/kg) permitted on or in food commodities and animal feeds.

Monitor – The act of conducting a planned sequence of observations or measurements of control parameters to assess whether a CCP is under control.

NZFSA – New Zealand Food Safety Authority.

NZFSA recognised agency – An individual or organisation recognised by NZFSA to undertake evaluation and verification activities under this standard.

NZQA – New Zealand Qualifications Authority.

Official Assurance – Statement made by MAF to a foreign government, or an agent of a foreign government, attesting that, as appropriate, any one or more of the following applies in respect of any product:

a. any specified process has been completed with respect to the product concerned;

b. the product concerned meets the standards set for that product;

c. any market access requirements of the importing country, which New Zealand has agreed to meet, that are stated in the assurance have been met by the system under which the product was produced or processed; and/or

d. the situation in New Zealand, in relation to any matter concerning plant material or plant products, is as stated in the assurance.

Operator – the person or organisation registering, and responsible for managing, the implementation and operation of an agrichemical management plan .

Pre-harvest interval (PHI) – minimum recommended interval between the last application of an agricultural compound to a crop and its harvesting for human consumption. PHIs that are specified on registered agrichemical labels apply to crops intended for domestic consumption and are called Withholding Periods.

Recognition – provided by NZFSA for agencies to undertake evaluation and verification of agrichemical management plans under this standard.

Registration – official process whereby NZFSA registers an agrichemical management plan as meeting the requirements of this standard.

Regulatory limits – a measurable limit related to safety or suitability.

Risk Factors – those factors that may prevent the product's compliance with overseas agrichemical residue requirements.

Verification – Application of methods, procedures, tests and other checks, in addition to monitoring, to determine compliance with NZFSA-approved plans, programmes and systems, and to confirm the ongoing applicability of those.

1.3 Additional resources

Anon, 1997

Hazard analysis and critical control point (HACCP) system and guidelines for its application. Annex to CAC/RCP 1-1969, Rev. 3. Codex Alimentarius Commission. http://www.fao.org/documents/show_cdr.asp?url_file=/DOCREP/005/Y1579E/y1579e03.htm

NZFSA, 2006

Guidelines for fresh plant product agrichemical management plans. New Zealand Food Safety Authority, 2006 (or subsequent amendment).

NZFSA, 2005

Recognised Pesticide Analytical Laboratories and residue Test Methods (Plants), New Zealand Food Safety Authority, 2005 (or subsequent amendment).

2. Agrichemical Management Plan Requirements

Operators seeking registration of an agrichemical management plan shall document a system that addresses the following requirements:

2.1 Scope of an agrichemical management plan

2.1.1 The operator must document the fresh plant products covered by the agrichemical management plan (the plan).

2.1.2 The operator must document the intended export markets for which residue assurances are requested and specify the type of assurances to be provided for the plant products specified in 2.1.1. This should be limited to the export markets for which official assurances are to be provided, unless the sector group desires a more global scope.

2.1.3 The operator must uniquely identify the location of the places covered by the plan.

2.2 Description of the process or operation

2.2.1 The operator must describe all relevant processes carried out in the growing, harvesting, packing, storage, and shipping of the products in order to identify all risk factors, including:

a. all relevant agrichemical inputs; and

b. the main activities or steps in each process; and

c. all outputs.

2.3 Identification of risk factors

2.3.1 The operator must document the following details:

a. identification and analysis of agrichemical risk factors inherent in the product (such as those arising from the use of agricultural compounds in growing, harvesting, packing, storage, and shipping of the plant products); and

b. the identification of other potential sources of agrichemical inputs to be controlled through the plan; and

c. the identification of uncontrolled agrichemical risk factors.

2.4 Identification of control points

2.4.1 The operator must document the process and risk factors listed in section 2.3, in order to identify steps at which control can be applied to prevent or eliminate these risk factors, or reduce them to acceptable levels.

2.4.2 The operator must document the following for each identified control point:

a. the justification for its identification; and

b. the parameter or critical limit (e.g., a MRL, PHI, concentration) that must not be exceeded and the justification for those limits.

2.4.3 The operator must document and implement procedures for monitoring and responding to any new risk factors that may emerge, including, but not limited to:

a. changes to New Zealand agricultural compound registrations or to changes in MRLs or residue requirements by importing countries; and

b. registration and availability of new agrichemicals in New Zealand which were not covered by the original agrichemical management plan.

2.5 Maximum Residue Limits

2.5.1 The operator must document the maximum residue limits (for each export destination and New Zealand) applicable to the plant products covered by the plan.

2.6 Control of agrichemical risk factors

2.6.1 The operator must document and implement sufficient procedures to ensure that maximum residue limits as defined in section 2.5 are not exceeded.

2.6.2 The procedures must cover:

a. the measures used to control risk factors, including compliance with guidelines or best practice for the use of agrichemicals in the production (growing, harvesting, packing, storage, and shipping) of the plant products; and

b. the critical limits that are to be met; and

c. the monitoring procedures that are to be carried out, for example:

   i. evaluation of records of agricultural compound applications and adherence to best practice; and

   ii. random residue testing; and

d. the system used to ensure traceability of products covered by the plan from place of production to export; and

e. the corrective actions that are to be applied in the event of non compliance with the plan, including:

   i. how non compliance will be contained and compliance restored; and

   ii. procedures to recall non compliant plant products, including the criteria for deciding when a recall will be initiated and how retrieval and disposal of the plant products will be managed; and

   iii. measures to prevent recurrence of non compliance; and

   iv. where non compliance is due to unforeseen circumstances and there is no specific corrective action documented, nomination of a suitably skilled person to manage the corrective action, record the issue and the corrective actions taken, and to report the matter to the NZFSA recognised agency without unnecessary delay.

2.6.3 The operator must document and implement procedures for monitoring and notifying the recognised agency of any instances of non-compliance with the plan.

2.7 Identification of competency of responsible persons

2.7.1 The operator must document the identity (either by position, designation, or name) of:

a. the day to day manager of the plan; and

b. those persons authorising all or part of the plan on behalf of the operator; and

c. those persons performing key tasks under the plan including monitoring (including sampling and testing), corrective action, and operator verification activities.

2.7.2 The operator must document the competencies needed by the persons identified under clause 2.7.1 to enable the effective operation of the plan.

2.7.3 The operator must have available records demonstrating that the competencies documented under 2.7.2 have been achieved. These records must be maintained for three years.

2.8 Internal Audit

2.8.1 The operator must document an implement internal audit procedures to demonstrate:

a. adherence to the plan

b. that the plan is effective

These procedures must include:

i. the internal audit activities to be performed and their frequency; and

ii. actions to be taken when all or part of the plan is not effective; and

iii. recording and reporting requirements.

2.9 Document control

2.9.1 Every document that forms part of the plan must be:

a. legible; and

b. dated and marked to identify its version; and

c. authorised prior to use, either directly or within the document control system, by:

   i. the operator; or

   ii. the day to day manager of the plan; or

   iii. a person nominated to do so in the plan's document control system; and

d. available, when required, to any person with responsibilities under the plan.

2.9.2 The operator must document the procedures for effective control of the documents that form the plan including how:

a. significant and minor amendments are made to the plan so that the plan is current and reflects the actual operation of the plan; and

b. the amendments, or the nature of the amendments, to the plan are identified or described; and

c. documents are authorised prior to use; and

d. all amended parts of the plan are replaced with the current versions at all distribution points without unnecessary delay after authorisation. The operator must retain for 4 years a copy of all obsolete documents from a registered plan.

2.9.3 The operator must document procedures for review and re-registration of the plan within the first year of registration or re-registration.

2.10 Records

2.10.1 The operator must include record keeping procedures in the plan and implement these to ensure that all records necessary to demonstrate compliance with the documented plan are retained for two years and are available to recognised agencies.

2.10.2 Records relating to the plan's monitoring, corrective action, and internal audit activities must include:

a. the date of the activity; and

b. a description of the results of the activity; and

c. the identity of the person who performed the activity.

2.11 Recognised agency's freedom and access to carry out evaluation and verification functions

2.11.1 Agrichemical management plans must contain provisions authorising recognised agencies to have freedom of access to documents, records, information, and premises to carry out their evaluation and verification duties required by this standard.

2.12 Reporting

2.12.1 The operator must document and implement procedures for reporting to the recognised agency:

a. any instances of non-compliance with the plan; and

b. circumstances where evidence that the plan is not effective in achieving programme objectives; and

c. the identification of new or potential risk factors (e.g., changes to MRLs) and how these will be incorporated into the plan; and

d. changes to the scope of the plan; and

e. changes to process that may affect the effectiveness of the plan; and

f. changes to the day-to-day manager of the plan.

3. Registration of Agrichemical Management Plans

3.1 Confirmation of validity of the agrichemical management plan by the operator

3.1.1 The operator must confirm, prior to application for registration of a plan, a significant amendment to a programme, or re-registration of a programme, that:

a. the documentation is complete and complies with the requirements of this standard; and

b. the participants in the plan are ready to operate in accordance with the plan; and

c. the plan will be capable of consistently producing plant products that comply with overseas market access requirements.

3.2 Evaluation and verification of an agrichemical management plan

3.2.1 A successful evaluation of the appropriateness of the plan must be undertaken by a NZFSA recognised agency in accordance with their procedures.

3.2.2 An operator whose agrichemical management plan has failed evaluation must undertake the corrective actions required by the recognised agency before resubmitting the revised agrichemical management plan for evaluation.

3.3 Registration of an agrichemical management plan

3.3.1 Following the successful evaluation, the operator must apply to the Approvals & ACVM Group, NZFSA for registration, providing all information deemed necessary by NZFSA.

3.3.2 NZFSA will send confirmation of registration of the agrichemical management plan to operator.

3.4 Amendments to registered agrichemical management plans

3.4.1 Significant amendments to the agrichemical management plan, or change in the day to day manager must be notified to NZFSA in writing, without unnecessary delay.

3.5 Re-registration of agrichemical management plans

3.5.1 The operator must review the RAP and reapply for registration annually.

3.6 De-registration

3.6.1 Operators wishing to de-register their agrichemical management plan must contact the Approvals & ACVM Group in NZFSA in writing.

3.6.2 NZFSA may de-register agrichemical management plans in the event of non-compliance, or if the operator is no longer deemed to be fit and proper persons to operate the plan.

4. Recognition of agencies

4.1 Application for recognition

4.1.1 Any agency wishing to provide services under the NZFSA Agrichemical Assurance Standard for Fresh Plant Products must be accredited, by an accreditation body, to ISO Standard 17020, and must meet other NZFSA supplementary criteria as required.

a. Accredited agencies must apply to NZFSA for recognition, providing all information deemed necessary by NZFSA.

b. NZFSA will send confirmation of recognition.

4.2 Withdrawal of recognition

4.2.1 NZFSA may suspend or withdraw recognition from an agency

a. if the agency requests it

b. if the agency or agency persons are no longer deemed to be fit and proper persons to undertake the functions for which recognition was granted

c. the agency or agency person has failed to comply with the terms and conditions of the recognition.

5. Recognition of Residue Testing Laboratories

5.1 Scope of recognition

5.1.1 Persons undertaking laboratory analysis and testing for agrichemical residues as part of a registered agrichemical management plan must be under the management of an analytical laboratory recognised by NZFSA to perform those functions.

5.2 Requirements for recognition of residues testing laboratories

5.2.1 Recognition by NZFSA will be provided in accordance with the NZFSA standard "Recognised Pesticide Analytical Laboratories and Residue Test Methods (Plants)".

6. Appendix 1

Steps to attain/maintain registration of agrichemical management plan

Step	Operator action	Recognised agency action	NZFSA action
1	Contact an NZFSA recognised agency (Agrichemical assurance) to confirm timeframes and documentation requirements.		
2	Document your plan to comply with this standard as a result of: • A new application for registration.		
3	Confirm that your plan is: • Ready to operate in accordance with your documented plan • Capable of consistently complying with this standard and any specific requirements of the importing country		
4	Submit your documented plan to the recognised agency.		
5		Evaluate the plan against the applicable standard(s). Notify the operator of any corrective actions needed to the plan.	
6	Re-document and resubmit the revised plan.		
7		Confirm the successful evaluation to the operator	
8	Apply to the NZFSA for registration (application details can be found at NZFSA website link www.nzfsa.govt.nz/plant/index.htm)		
9			Process application and send confirmation of registration to the operator.

Step	Operator action	Recognised agency action	NZFSA action
10	Commence operation as a registered Operator • Liaise with the NZFSA recognised agency regards an annual review of your plan • Notify the recognised agency of any significant amendments to your plan, prior to implementing changes.		
11		Evaluate significant amendments.	
12	Implement changes		
13		Review operator plan annually.	
14	Schedule a review of your plan and re-apply for registration on an annual basis – go to step 2.		