Fresh Plant Products

Agrichemical Assurances

Guidelines for the Development of Agrichemical Management Plans

Prelims

Amendment 0

October 2006

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Website

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Review of Fresh Plant Products Agrichemical Assurances; Guidelines for the Development of Agrichemical Management Plans

This Plant Products Agrichemical Assurances; Guidelines for the Development of Agrichemical Management Plans will be reviewed, as necessary, by the New Zealand Food Safety Authority. Suggestions for alterations, deletions or additions to this Plant Products Agrichemical Assurances; Guidelines for the Development of Agrichemical Management Plans, 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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Preliminary Statement

These guidelines explain the New Zealand Food Safety Authority's "Official Agrichemical Assurance Standard for Fresh Plant Products" and provides examples of ways in which industry groups might approach the development of an agrichemical management plan.

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

Carol Barnao

Director (Export Standards)

1. Introduction

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The purpose of these guidelines is to assist industry organisations, exporters, and other industry participants to develop, document and register agrichemical management plans under the New Zealand Food Safety Authority (NZFSA) "Official Agrichemical Assurance Standard for Fresh Plant Products". It also identifies criteria that NZFSA deems to be acceptable practice for the documentation and operation of agrichemical management plans.

The structure of the guideline follows the headings and text of sections 2 & 3 of the standard with explanatory text in highlight text boxes.

1.1 Purpose of the plant products agrichemical assurance programme

Official assurances of agrichemical compliance may be required by importing country authorities or be requested by an industry body, exporter, or other industry participant to facilitate market access. The NZFSA document "Official Agrichemical Assurance Standard for Fresh Plant Products" describes the system through which NZFSA is able to provide these assurances to trading partners. The development of an Agrichemical Management Plan (AMP) is voluntary, and is envisaged as only being necessary should an official assurance be required by an importing country.

The basic elements of the official agrichemical assurance programme are:

- industry organisations develop agrichemical management plans which identify agrichemical non-compliance risk factors and effectively manage these to ensure importing country maximum residue limits (MRLs) are not exceeded and/or related overseas market access requirements are complied with;
- agencies recognised by NZFSA evaluate and verify agrichemical management plans and ensure that requirements are met on an ongoing basis;
- NZFSA registers agrichemical management plans that have been evaluated and verified by recognised agencies;
- NZFSA provides official agrichemical assurances to importing countries for the commodities covered by the agrichemical management plans, should these be required.

1.2 What is an agrichemical management plan

An agrichemical management plan (AMP) is a documented system for managing the risks of exported plant products either exceeding the maximum residue limits established by importing countries or otherwise not meeting the overseas market access requirements relating to agrichemicals. It involves an analysis and documentation of agrichemical risk factors using HACCP principles and identification of ways in which these risk factors can be controlled. The risk factors and control measures are documented by an operator (the person or organisation registering and responsible for managing the implementation and operation of an AMP), evaluated and verified by a recognised agency, and registered by NZFSA. The AMP is subject to ongoing review by the operator to ensure that changes in risk factors and importing country MRLs are reflected in the AMP. Adherence to the AMP is subject to ongoing verification by a recognised agency to confirm industry compliance with the AMP and NZFSA standards.

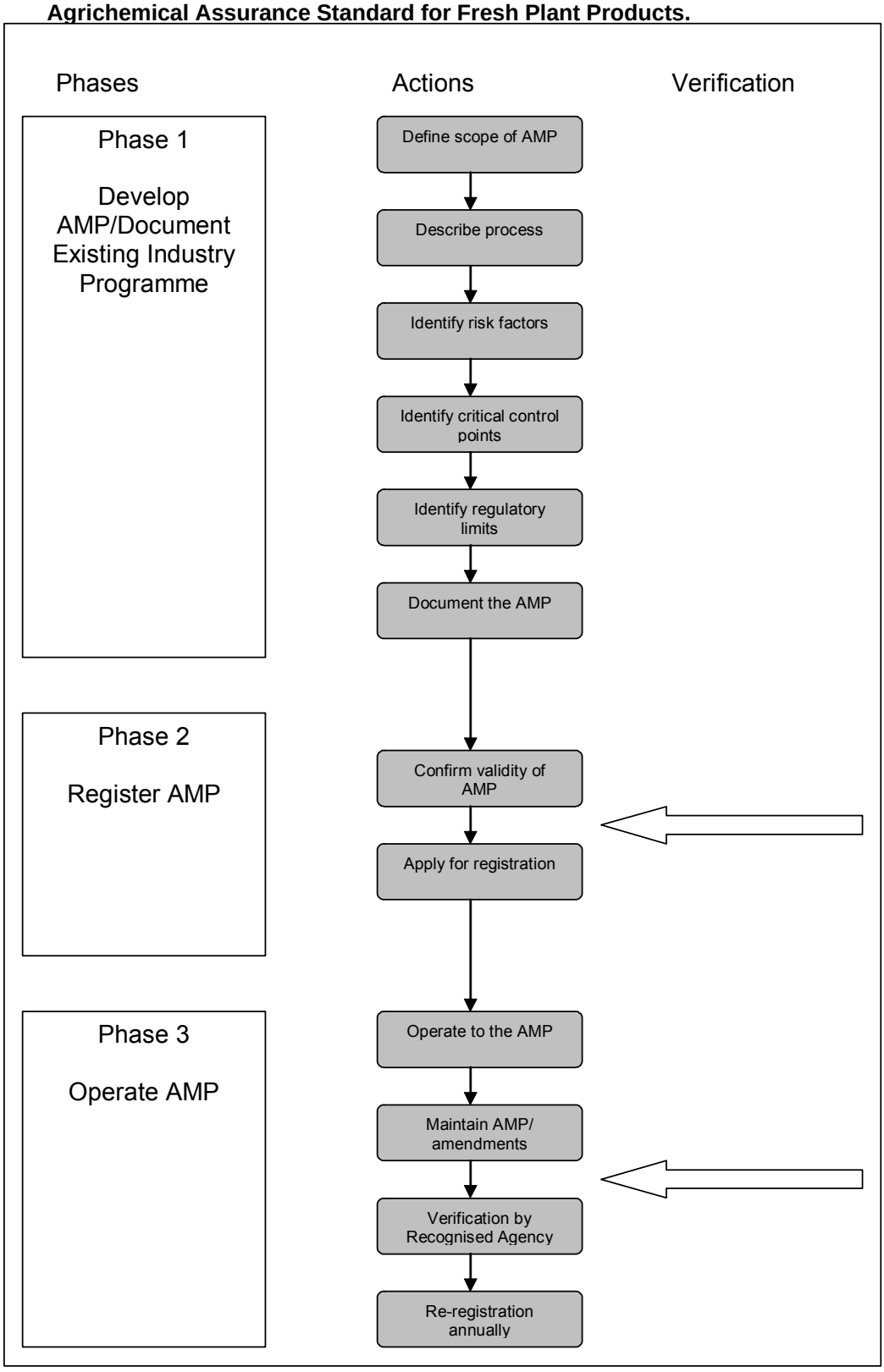
1.3 Who may operate an AMP

An agrichemical management plan is developed and documented by an "operator". This is the person or organisation responsible for managing the implementation and operation of an agrichemical management plan. The operator needs to be in a position to exert control over the critical control points, monitoring, and corrective actions identified within the AMP. Examples of operators include:

- a packhouse manager;
- a group of packhouses;
- an exporter;
- an industry body;
- a management agency.

For any given industry there may be more than one AMP operator, and more than one AMP.

1.4 Summary of process for developing an agrichemical management plan. An expansion of Phases 2 and 3 can be found in Appendix 1 of the NZFSA Official Agrichemical Assurance Standard for Fresh Plant Products.



1.5 Definitions

In this guideline and associated Agrichemical Residue Assurance Standard for Fresh Plant Products. 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 – An assessment of a Food Control Plan that is independent of the 'person' responsible for the Plan, to determine compliance with regulatory requirements and appropriateness for the operation to which the Plan is to apply; involves review of documentation and, in some cases, review of operations or observation of practice; when undertaken by a party other than the regulator, that individual or agency must be recognised by the regulator as competent.

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 the standard

NZQA – New Zealand Qualifications Authority.

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

- a specified process has been completed with respect to the product concerned;
- the product concerned meets the standards set for that product;
- 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
- 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 permissible time between the last application of an agricultural compound to a crop and its harvesting for human consumption.

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

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

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

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

Standard – Agrichemical Assurance Standard for Fresh Plant Products.

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 (adapted from the NZFSA DFR Glossary of terms where "verification" is defined as "the application of methods, procedures, tests and other checks to confirm:

- compliance of the Food Control Plan to the legislation and
- compliance of the operation to the documented Food Control Plan and
- the applicability of the Food Control Plan to the operation").

1.6 Additional resources

There are many sources of information that will assist with development of agrichemical management plans, and HACCP. Some useful resources are listed below:

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

Faulkner, L; Bunting, S; Walker, S; Mill, A; Breckell, M; Dingle, M; Goodwill, H; Wilkund, C; and Joe, B. 2001. Generic HACCP Models for Food safety Assurance Programmes. Operational research contract FMA169. Interim report to MAF Policy, Wellington. 91pp.

NZFSA, 2006
Official Agrichemical Assurance Standard for Fresh Plant Products. New Zealand Food Safety Authority.

2. Agrichemical Management Plan Requirements

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This section of the guideline links to Section 2 of the Official Agrichemical Assurance Standard for Fresh Plant Products for ease of cross referencing. It guides the operator through the process of developing, documenting, and registering an agrichemical management plan for their business/industry. Explanations and examples of acceptable AMP components are contained within highlight boxes (such as this) at relevant places within the text of the guidelines. The development of an AMP follows HACCP principles. A risk factor analysis worksheet (Appendix 1) is provided to assist operators to record the outcomes of the risk factor analysis, and a critical control point worksheet (Appendix 2) is also provided.

2.1 Scope of an agrichemical management plan

This is the description of what the AMP will apply to – the product(s) that will be exported under the plan, where they are produced and packed, and where they will be exported to. This is a first step in the process and it may be necessary for an operator to revise the scope after the completion of the risk factor analysis.

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

The definition of the product should specify the common name, the scientific name, and the plant part, e.g., Potato (Solanum tuberosum) tubers.

2.1.2 The operator must document the intended export markets for which agrichemical 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 operator desires a more global scope.

The operator may choose to limit the AMP to the export markets for which NZFSA official agrichemical assurances are currently sought, or may choose to include all export markets in the plan. The operator should also identify the types of NZFSA assurances that will be

sought for the products produced under the AMP. These could include assurances on specific agrichemical residues, all agrichemical residues, agrichemical use (or non-use) etc.

For plans designed to meet the European Union (EU) requirements it may be helpful, but not mandatory, to specify member states where product will be landed, as some member states have MRLs that are not harmonised across the EU. Whilst the EU is working towards harmonisation, there is still some variation at the current time.

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

Accurate description of the places covered by the AMP is an important component of the traceability requirements of the NZFSA agrichemical assurance programme. The description should include the places where the AMP will be operated – e.g., fields, orchards, packhouses, treatment facilities, storage facilities. Areas of properties or parts of properties excluded from the AMP should be identified. It may be necessary to provide maps to identify the properties, or parts of properties, covered by the AMP. For an AMP covering a registered production site, operators should reference their registration PIN.

Operators are required to describe in the Agrichemical Management Plan (AMP) how they will uniquely identify the location of the places covered by the plan. For an AMP covering only one or few businesses the plan could describe the properties within the text of the AMP, or include this in an appendix.

For AMPs covering many businesses (e.g., industry wide plans), NZFSA may approve alternative arrangements to improve the flexibility of the registration system. Alternative arrangements may include registration systems in which participants in the plan (growers, packers) identify their production sites and packhouses and provide these to the plan operator. AMPs may then refer to a separate register of places covered by the AMP – such as a website where registration details are maintained.

All operators are encouraged to utilise existing identification systems, for example registration PINs, and those in use for phytosanitary purposes or other programmes such as the New Zealand Fresh Produce Approved Supplier Programme and EurepGap.

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

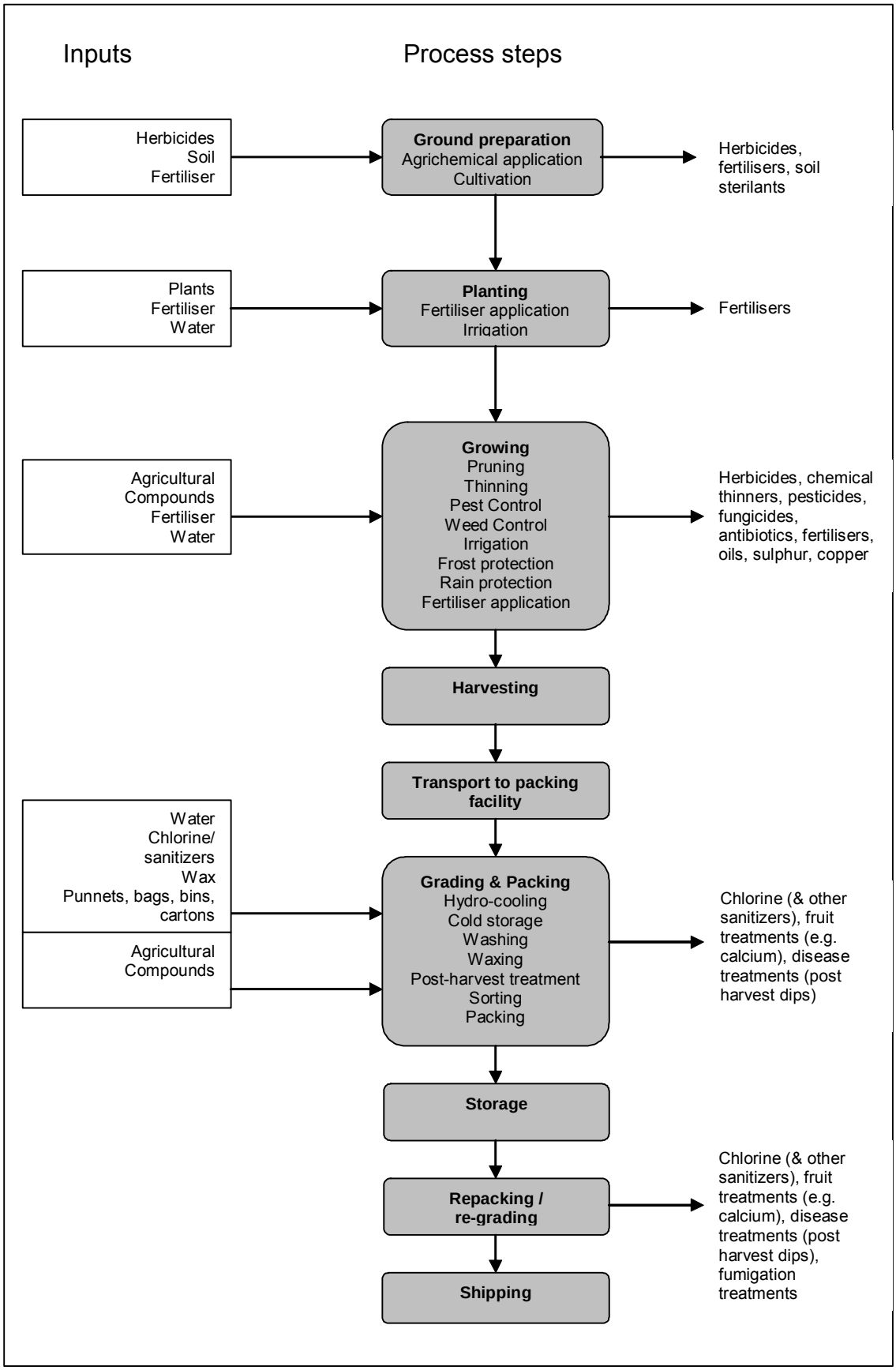
c. all outputs.

The purpose of describing the process of growing, harvesting, packing, storage and shipping is to enable the operator to identify where agrichemicals may be applied to the crop or product, or used in a manner that could result in residue contamination, identify other sources of risk, and identify ways of monitoring or controlling those risk factors.

The operator only needs to document the process in as much detail as is necessary to identify these risk factors. However, care should be taken that relevant processes are not omitted. A number of templates of process descriptions are available, e.g., Faulkner et al. (2001).

The documentation can be done using flowcharts and diagrams, with notes or bullet-points for each main step. An example of an acceptable form of documentation follows.

Description of process (process flow) for fruit crops (based on Faulkner et al. (2001))



2.3 Identification of risk factors

2.3.1 The operator must document the following details:

a. identification and analysis of agrichemical risk factors associated with the production, harvest, handling, storage and transport of the product (such as those arising from the use of agrichemicals); 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.

As this programme is restricted to agrichemical assurances, other food safety risks (such as microbiological contamination) are not addressed in these guidelines or the standard. Operators may wish to consider these other factors as part of their analysis, but it is not mandatory.

Three groups of agrichemical risk factors need to be identified:

a) Those that are associated with the intentional use of agrichemicals as part of the production process and are known;
- includes all of the herbicides, pesticides, fungicides and other agrichemicals that are currently used in growing, harvesting, packing, storage and shipping of the product. This includes all registered uses and off-label uses of agricultural compounds and the use of other agrichemicals not requiring registration.

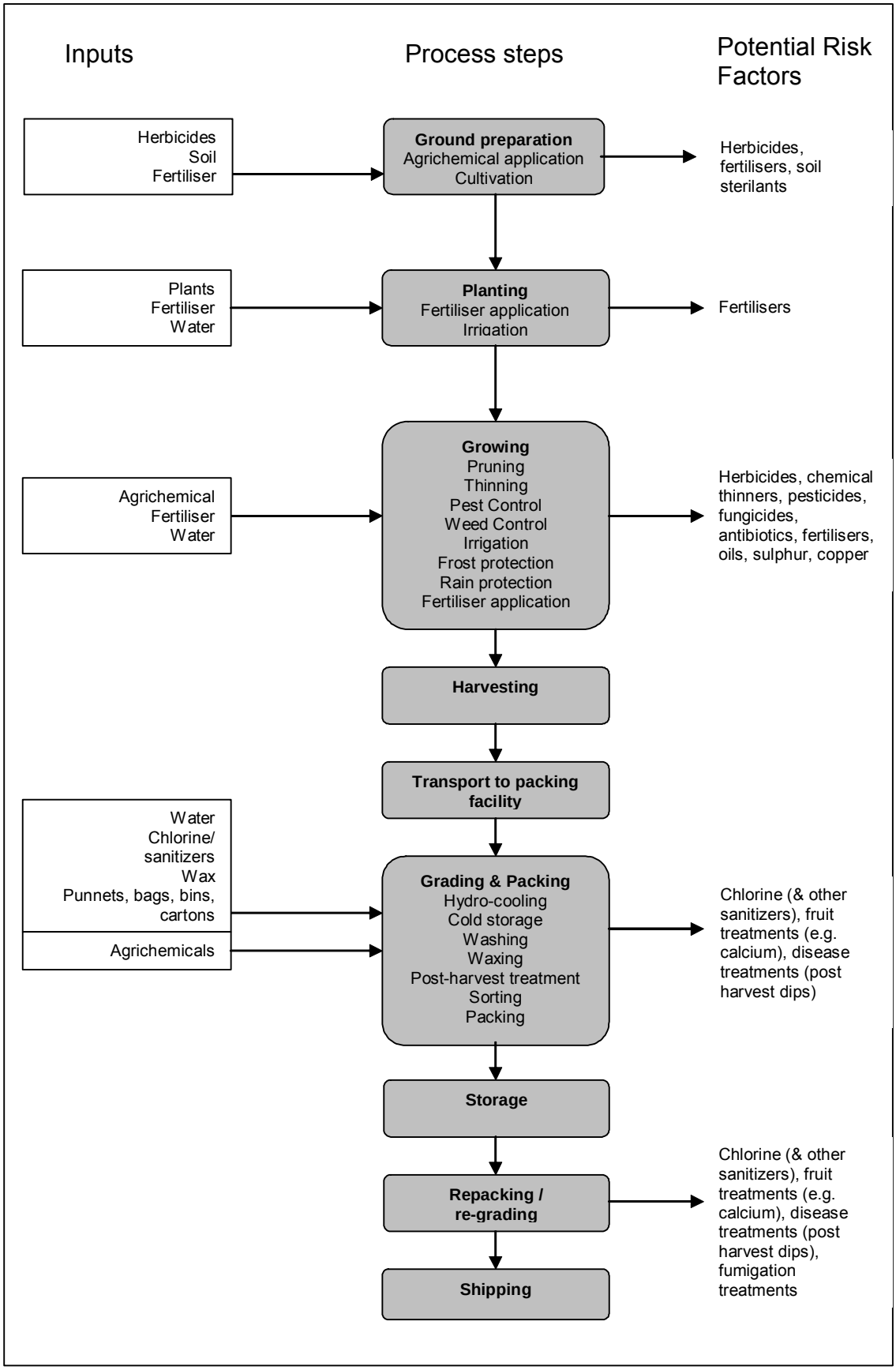
b) Those that are associated with the use of or exposure to agrichemicals not applied to the product;
- includes any other source of risk factors that can be controlled by the AMP, such as pesticides or heavy metals potentially present in soil adhering to field crops, contamination of groundwater used in washing, spray drift from neighbouring orchards or fields, pest control in packhouses, stores, packaging, etc..

c) Those that cannot or will not be controlled by the operator;
- includes those risk factors that the AMP operator chooses to not manage through the AMP. These could include very low risk hazards (e.g., fertiliser inputs, herbicides in orchards, heavy metals in soil of orchards). The operator must justify the exclusion of these potential risk factors and the justification will be evaluated by a recognised verification agency and subject to approval by NZFSA.

Analyse the description of the process (process flow) that was developed in section 2.2 to identify where risk factors occur and add these to the process description. List all of the risk factors that may be reasonably expected to occur at each step, as in the following flow diagram.

Identification of agrichemical risk factors for fruit crops.

The inputs identified in the flow-chart (below) are the agrichemicals that could create a potential risk factor. The operator needs to identify whether there is an aspect of their use that creates a risk of exceeding importing country MRLs. For example, incorrect use of agrichemicals create the risk factor – not the agrichemical itself. This is further discussed in section 2.4.


Inputs
Process steps
Potential Risk Factors
Herbicides
Soil
Fertiliser
Ground preparation
Agrichemical application
Cultivation
Herbicides, fertilisers, soil sterilants
Plants
Fertiliser
Water
Planting
Fertiliser application
Irrigation
Fertilisers
Agrichemical
Fertiliser
Water
Growing
Pruning
Thinning
Pest Control
Weed Control
Irrigation
Frost protection
Rain protection
Fertiliser application
Herbicides, chemical thinners, pesticides, fungicides, antibiotics, fertilisers, oils, sulphur, copper
Harvesting
Transport to packing facility
Water
Chlorine/ sanitizers
Wax
Punnets, bags, bins, cartons
Agrichemicals
Grading & Packing
Hydro-cooling
Cold storage
Washing
Waxing
Post-harvest treatment
Sorting
Packing
Chlorine (& other sanitizers), fruit treatments (e.g. calcium), disease treatments (post harvest dips)
Storage
Repacking / re-grading
Chlorine (& other sanitizers), fruit treatments (e.g. calcium), disease treatments (post harvest dips), fumigation treatments
Shipping

2.4 Identification of control points

2.4.1 The operator must identify steps at which control can be applied to prevent or eliminate these risk factors listed in 2.3 above, or reduce them to acceptable levels, including those points where control is essential in order to ensure products meet the overseas market access requirements (i.e. critical control points), should they exist in a specified process.

Guidelines for hazard analysis and identifying critical control points can be found in Anon (1997) and Faulkner et al. (2001).

Analyse each step in the process in terms of the agrichemical risk factors to be managed through the AMP. There may be several types pf risk factor for each process step. In conducting this analysis, wherever possible the following should be considered:

- the likely occurrence of risk factors and severity of their effects (how likely is it that the risk would occur and, if it did occur, how serious would the results be); and
- a qualitative and/or quantitative evaluation of the presence of risk factors (is there any evidence from past experience to indicate that a risk factor may be present? For example, how often have herbicides resulted in MRLs being exceeded?); and
- the conditions leading to the above (if certain risk factors occurred often, why did they occur? This information is useful in identifying ways of controlling that risk).

If a risk factor is very unlikely to occur or unlikely to have a significant impact on agrichemical compliance it can be eliminated as a risk factor at this point.

For potential risk factors consider what control measures, if any, exist which can be applied for each one. More than one control measure may be required to control a specific risk factor(s) and more than one risk factor may be controlled by a specified control measure.

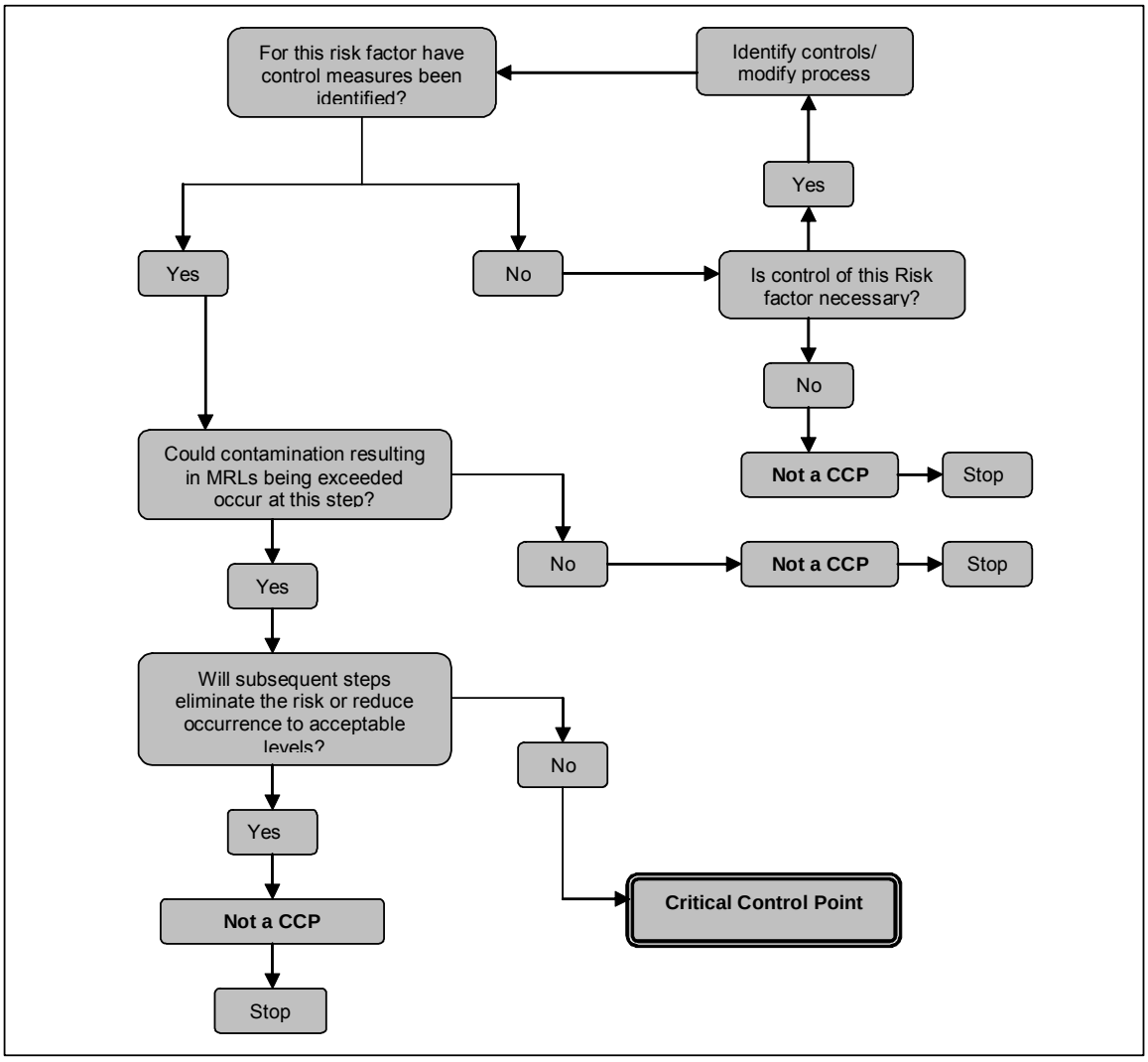
In this example we have examined the process step “Growing” and identified a risk factor associated with incorrect application of pest control sprays. Potential control measures for this risk factor are identified in the table below.

Process Step	Potential Risk Factor	Control Measures	Critical Control Point
Growing – application of agrichemical sprays	Incorrect application	▪ applicators trained in use of chemicals ▪ calibration of equipment ▪ chemicals applied according to directions (PHI observed) ▪ applications recorded ▪ records checked before packing	
Packing	Use of chlorine in dump tanks ▪ unlikely to be a risk factor as rinsing occurs later in process ▪ chlorine generally recognised as post-harvest treatment	No measures necessary, not a significant hazard	

Once this information has been gathered the operator must assess whether the process step is a critical control point – a point at which control must be exerted to ensure that the risk factor can be controlled or managed. In our example we have identified that incorrect application of pest control sprays is a potential risk factor and we have identified several ways in which this risk can be managed (or controlled). The following decision tree can be used to determine whether these measures are critical to ensuring agrichemical compliance, or whether they would be ineffective, or whether some later actions would be a better control point.

Identification of critical control points.

The selected control points are points at which control can be exerted over the process. If the process can only be weakly influenced at the control point, there may be little point in using this as a control point. A decision tree, such as that below, can assist operators to determine whether control points exist within their process.



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

a. the justification for its identification; and

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

In our example of the potential risk factor from incorrect application of agrichemicals, the decision tree outcome would be yes, this process step contains a critical control point.

The questions and answers are:

▪ For this risk factor, have control measures been identified?

-Yes, several control measures have been identified in the table.

▪ Could contamination resulting in agrichemical non compliance occur at this step?

-Yes, if pesticides are applied at the wrong rate or too close to harvest the non compliance could occur.

▪ Will subsequent steps eliminate the risk or reduce occurrence to acceptable levels?

No. In general, subsequent processes will not reduce residue levels on the product to acceptable levels (although in some processes washing may have some effect on residues of some agrichemicals and could be considered). Residue testing is not a step that will reduce or eliminate the risk, simply a monitoring activity that can detect agrichemical non compliance.

The justification for inclusion of the critical control point can be documented in the table, as below.

Process Step	Potential Risk Factor	Control Measures	Critical control point
Growing – application of agrichemical sprays	Incorrect application of agrichemical sprays	▪applicators trained in use of agrichemicals ▪calibration of equipment ▪agrichemicals applied according to directions (PHI observed) ▪applications recorded ▪records checked before packing	Yes - CCP ▪control measures have been identified ▪contamination at this stage could result in agrichemical non compliance ▪subsequent steps do not reduce or eliminate the risk.

Packing	Use of chlorine in dump tanks ▪unlikely to be a risk factor as rinsing occurs later in process ▪chlorine generally recognised as post-harvest treatment	No measures necessary, not a significant risk	No – not a CCP ▪control of risk factor not necessary

For each critical control point selected, the operator is also required to define certain critical limits that will be met or not exceeded at the control point. These could be MRLs, PHIs, concentrations (e.g., for a post harvest dip), or some other testing regime or tolerance.

In our first example above (timing of application of agrichemicals) the critical limit is the appropriate pre-harvest interval from date of application of chemicals (as recorded in the spray diary and subsequently verified). A list of PHIs would be maintained for each export market, as required in section 2.5 below.

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 changes to MRLs or agrichemical market access requirements by importing countries; and

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

Agrichemical management plans operate within a dynamic environment. Importing countries actively review their MRLs and chemical registrations, and new agrichemicals become available in New Zealand as others are phased out. The AMP operator must be aware of, and respond to, these changes as they affect the AMP.

NZFSA provides an updated and comprehensive list of importing country MRLs, but operators need to monitor this database for changes and modify the AMP as needed.

Examples of how industries could manage this process include:

- annual update of MRLs and PHIs by NZFSA under contract to the operator;
- in-house monitoring of changes;
- use of an external contractor to monitor registration changes in NZ and overseas and advise on relevant changes.

2.5 Maximum residue limits

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

MRLs for most countries are available from the NZFSA website. The website information does not include the relevant PHIs to meet those MRLs. This information can be provided to the operator by NZFSA (a fee is charged for this service) or by other agencies. Where an agency provides PHI information to the operator, the competency of the persons providing the information has to be specified in the operator's procedures (section 2.7.1(c) of the standard).

The MRLs and PHIs may be attached to the AMP as an appendix, or contained in a grower/packhouse manual, or maintained on a website.

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.

This section of the standard describes the requirements for documentation of procedures in the AMP to ensure that importing country requirements are met. Note the emphasis on best practice in the application of agricultural compounds as a primary tool in achieving agrichemical compliance.

The control measures, critical control points and critical limits were identified in section 2.4. These should now be used to document how the control measures will be applied and what monitoring will be carried out to ensure the procedures are effective.

The standard provides operators with a great deal of flexibility in how they meet these requirements. The example described in 2.6.2 below is one approach that has been used successfully in the past (with variations) by a number of industry sector groups. An operator may choose to place heavy emphasis on best practice and auditing of spray diaries, with less emphasis on residue testing. Or, the operator may place more emphasis on residue testing as a means of validating best practice. This enables operators to design systems that reflect current practice and customer requirements.

2.6.2 Procedures must cover points a – e below:

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

This may include procedures that are contained in an industry manual, or separate sections of a manual (e.g., grower manual, packhouse manual, exporter manual) or which already exist in other food safety programmes. Using our example of application of pest control sprays, procedures for control measures should be developed:

Process Step / Hazard	Control Measures	Control Procedures
Growing – application of agrichemicals (incorrect application of sprays)	▪applicators trained in use of agrichemicals ▪calibration of equipment	▪register only production sites where the applicator is GrowSafe registered
	▪agrichemicals applied according to directions (PHI observed)	▪provision, by the operator, of lists of permitted agrichemicals for export markets (and the domestic market) with corresponding MRLs and PHIs
	▪applications recorded ▪records checked before packing	▪evaluation of spray diaries

These critical limits (as identified in section 2.4.1) are factors that separate what is acceptable from what is unacceptable. Examples of critical limits to be monitored in the monitoring programme could include:

▪ timing of application (with respect to predicted harvest date)

- a list of PHIs for each chemical and each export market is the critical limit

▪ residue levels in packed product

- the MRL of each importing country could be established as the critical limit

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

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

This addresses how the effectiveness of the control procedures and compliance with critical limits identified in (b), above, are to be monitored. The monitoring procedures must be able

to detect loss of control of the process. Ideally, loss of control should be detected in time to make corrections to the process; however this is not always feasible. In such instances the monitoring procedures should be able to detect loss of control in time to remove product from the plan.

NZFSA suggests (as examples) that both spray diary checks and random residue testing could be used as elements of monitoring as neither element alone provides a sufficient level of assurance. It is NZFSA policy that programmes are primarily based on best practice and quality improvement, rather than end-point testing. It is known that there is considerable variability in residue test results, as only a small sample can be tested from comparatively large consignments. In addition, the time and cost of testing a sample from every consignment for every compound may be prohibitive. Similarly, a plan relying solely upon best practice confirmed through spray diaries checks does not provide sufficient assurance as compliance cannot be guaranteed. A combination of both measures is required but the weight given to either factor can be determined by the operator.

- evaluation of records of agrichemical applications and adherence to best practice; and

Evaluation of records of agricultural compound applications and adherence to best practice can be verified through:

- packhouse operators checking that the agrichemicals recorded in spray diaries are approved for the destination market and that PHIs have been observed; or
- growers submitting spray diaries to an independent organisation (an industry body, service provider, or exporter) for checking; or
- random checks on a percentage of spray diaries.

- random residue testing; and

Random residue testing should serve only to confirm (or drive) overall compliance with best practice in the application of agrichemicals. It is likely that all AMPs will involve some residue testing, however it may be appropriate to place a heavier emphasis on testing in some industries and less emphasis in others. For example, there may be instances where the breakdown of an agrichemical has a great degree of variability as a result of application or environmental effects and there is weak data to support the PHI. In these circumstances a high level of testing (a high percentage of consignments) may be justified.

The onus is on the operator to justify the proposed testing programme. Multi-residue tests do not detect all agrichemical residues, so operators should describe the justification for selecting the compounds to be tested for. This will be evaluated by a recognised verification agency.

Residue testing programmes should consider two components – the percentage of consignments that are to be sampled for testing and the range of chemicals that are to be tested for. Examples of current testing programmes include:

- random testing of a percentage of growers' harvested product on a random basis (current industry practice ranges from one sample per grower every 4 years to one sample per grower twice per year) plus some targeted sampling (based on past non-compliance); or
- random testing (as above) for multiple compounds (multi-residue plus specific tests for known high risk agrichemicals or those that have been detected in the past); or
- random testing using only multi-residue (on the basis that if a grower is violating best practice it is likely to occur across all agrichemicals not just one); or
- testing of every type of product from every production site.

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

NZFSA requires that products for which agrichemical assurances are to be provided are traceable from export consignment back to place of production. This is so that their compliance with programme requirements can be verified.
In section 2.1.3 the operator described a system for identifying places where plant products are grown, packed, or stored and may have included registration processes for production sites and/or packhouses. In this section the operator needs to describe and document how packed produce can be traced back to the place of production (and/or packhouse). This may be through the use of a unique production site identification system applied to cartons or pallet cards.

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

- how non compliance will be contained and compliance restored; and
- 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
- measures to prevent recurrence of non compliance; and
- 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.

As a minimum, the AMP should document corrective actions to address foreseeable non-compliances. In our example of incorrect application of agrichemical sprays, corrective

actions could be applied as in the following table. Procedures for these corrective actions must be fully documented specifying what is to be done and who it is to be done by.

Risk Factor	Monitoring Procedures	Critical Limits	Corrective Actions (examples)
Incorrect application of agrichemical sprays	▪evaluation of spray diaries	▪PHIs observed	▪packhouse to reject consignment ▪notify operator ▪operator undertakes non-compliance investigation to determine if non-compliance potentially extends to other product, and reasons for non-compliance ▪check diary for other earlier non-compliance ▪provide advice on what markets the harvested crop may be diverted to and ensure segregation ▪enhanced residue monitoring of grower for remainder of season and following season
	▪random residue testing	▪MRLs not exceeded	▪operator undertakes non-compliance investigation to determine cause (check spray diary for non-compliance with PHIs) ▪notify NZFSA ▪recall product if in NZ and divert to other market if appropriate ▪implement enhanced residue monitoring of grower for remainder of season and following season ▪review monitoring procedures to ensure adequacy

The operator must also specify how unforeseen non-compliance is dealt with by:

▪identifying who would undertake a non-compliance investigation; and

▪ describing the sort of actions they would take (trace back to the cause, recall, notification); and

▪identifying who would manage the implementation of the corrective actions.

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.

Documentation should identify how instances of non-compliance will be identified, the circumstances in which notification of non-compliance is given to the recognised agency, the individual responsible for notifying the agency, and timeframes within which notification will be made.

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. 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 (e.g. sampling and testing), corrective action, and operator verification activities.

Everyone that undertakes actions specified in an agrichemical management plan must be identified (either by name, designation or position) in the plan. An AMP must have an operator (e.g., an industry body) and may also have a day-to-day manager. The day-to-day manager could be a staff member of the industry body who has the responsibility for managing the plan, or the operator may contract out the day-to-day management of the plan to an external party (a person or organisation). This person should be identified in the operators procedures and the AMP.

Anyone who authorises minor amendments to the AMP must be identified. Minor amendments to the plan (e.g., appendices of MRLs and PHIs, or registers of places covered by the AMP) need to be approved and issued by someone on behalf of the operator. This could be the operator, the day-to-day manager, or some other qualified person.

The AMP also needs to identify the persons undertaking “key tasks” in the plan. These tasks may include:

- recording chemical applications;
- checking spray diaries for compliance with PHIs;
- sampling for residue testing;
- auditing for compliance;
- monitoring and notifying the agrichemical management plan verifier of any new hazards;
- undertaking corrective actions;
- communication with the recognised agency and NZFSA.

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.

The main areas where operators will need to identify competencies are those listed in section 2.7.1(c): Examples of appropriate competencies include:

Day-to-day manager

- knowledge of the requirements of NZFSA standards;
- knowledge of HACCP principles;
- familiarity with the content and operation of the AMP;
- knowledge of export market requirements and PHI standards.

Spray applicators
- GrowSafe certification;
- spray diary completion;
- knowledge of PHIs.

Spray diary checking
- knowledge of the requirements of NZFSA standards;
- knowledge of export market requirements and PHI standards;
- knowledge of corrective actions and notification requirements.

Sampling for residue testing
- knowledge of Codex sampling procedures.

Auditing (internal)
- knowledge of the requirements of NZFSA standards;
- familiarity with the AMP and its procedures;
- auditing skills.

2.7.3 The operator must have available records demonstrating that the competencies documented under 2.7.2 have been achieved and maintained.

It may be necessary for the operator to run a training programme covering the requirements of the AMP and requirements of persons performing tasks under the AMP.

The records to be kept by the operator need only be those that are sufficient to confirm that competencies have been achieved and maintained. It does not need to extend to maintaining a database of training records and competency evaluations.

An operator will need to keep records of training and competency assessments of the day to day manager and persons authorising minor modifications to the AMP on behalf of the operator. Where actions (such as spray application, spray diary checking, sampling for residue testing, or auditing) are carried out by individuals within the operator's organisation the operator should also maintain these records. However, where many activities are carried out by other parties (e.g., packhouse quality controllers taking samples for residue testing) it may be less onerous to arrange for these other parties responsible for maintaining the records. Statements of competence could be made by these parties to the operator when

they register to participate in the AMP and the accuracy of these records could be subject to audit by the operator.

Alternatively, an operator could contract an external organisation to maintain training records for the AMP.

2.8 Internal Audit

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

a. adherence to the plan; and

b. that the plan is effective.

These 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 agrichemical management plan is not effective; and

iii. recording and reporting requirements.

This section describes the actions that will be taken by the operator to confirm that the AMP is being adhered to by industry participants and, if the plan is found to be not effective, describes what will be done to correct the situation.

Audits of compliance with the AMP are a high level check that participants in the plan are doing the things they are required to do in the documented procedures. Audits may be carried out by the operator or an external independent party. The level of auditing required will depend on the independence of parties undertaking activities such as spray diary checks and sampling for residue testing. For example an AMP where the grower is the packer and checks their own spray diary and takes their own samples for testing may require a high level of auditing. Or, an AMP where spray diaries are checked independently and an independent party takes samples may justify a low level of auditing.

The operator should document how instances of non-compliance, identified through audits, are dealt with.
This section of the standard also deals with the detection of flaws in the design of the AMP itself that have resulted in a loss of control. This could occur in circumstances where:

▪ an operator error resulted in an incorrect critical limit (e.g. PHI or MRL) being entered into the AMP; or

▪ an operator error resulted in a change in critical limit not being detected by the operator and the AMP was not updated accordingly.

The operator will need to document what actions are to be taken in these circumstances (actions such as traceback investigation), and how the AMP will be modified to ensure it is effective in the future.

2.9 Document control

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

a. legible;

b. dated and marked to identify its version; and

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

- the operator; or
- the day to day manager of the plan; or
- a person nominated to do so in the plan's document control system; and

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

2.9.2 The operator must document and implement 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.

A procedure for document control should be developed and implemented covering:

▪ who may authorise changes to the AMP;

▪ who is responsible for having significant amendments evaluated;

- how amendments are identified (such as by using "track changes", margin bars, or shaded text) to identify changed sections;
- how versions are to be numbered and stored;
- how amended versions are distributed to participants and old versions replaced;
- how participants are made aware of changes to the AMP.

2.9.3 The operator must retain for three years a copy of all obsolete documents from a registered plan.

2.9.4 The operator must document and implement procedures for review and re-registration of the plan within the first year of 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 three 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 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.

This could be achieved by the AMP including provisions requiring participating businesses to provide freedom of access to documents, records, information, and premises as a condition of participation in the AMP.

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, including immediate notification in the event of non-compliant product exported with an official assurance; and

b. circumstances where evidence that the plan is not effective in achieving objectives, within 5 working days of detection; 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

Amendment 0

October 2006

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 plan, or re-registration of a plan, 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.

This is an internal check of the AMP by the operator to ensure that:
- when an application for registration is made the programme will pass scrutiny; and
- when operational the programme will provide the necessary outcomes.

This self verification may involve a desk audit (a check that documentation is complete and, in the view of the operator, meeting the programme requirements) and internal audits of participants (growers/packhouses) to ensure that the programme is being operated to meet requirements.
One of the more difficult aspects to confirm is (c), above, that the programme will be capable of consistently producing plant products that comply with MRLs. For industries where residue monitoring or compliance programmes have been in place prior to the introduction of this standard, their past performance may be used as part of the self verification process.

3.2 Evaluation and verification of an agrichemical management plans

3.2.1 An evaluation and/or verification of the agrichemical management 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 or verification must undertake the corrective actions required by the recognised agency before resubmitting the revised agrichemical management plan for evaluation or verification.

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.

In applying for registration of an agrichemical management plan, the operator must submit the following documentation to a recognised agency for evaluation:

- An application for registration of an agrichemical management plan
- One copy of the documented agrichemical management plan
- Sufficient evidence to confirm the validity of the plan and other information as may be required by NZFSA.

"Sufficient evidence" is the information gathered during the internal confirmation carried out at 3.1.1 above, and anything else that may be required for a particular plan.

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.

Change in the day to day manager of an agrichemical management plan

The operator must notify the NZFSA recognised agency in writing, without unnecessary delay, of any change to the name, position, or designation of the person responsible for the day-to-day management of the agrichemical management plan.

Significant amendments to an agrichemical management plan

The following activities that result in changes to the agrichemical management plan require evaluation by a NZFSA recognised agency as an amendment to an agrichemical management plan:

- making changes to the measures used to control hazards and other risk factors, including guidelines or best practice for the application of agricultural compounds; or
- making changes to the monitoring parameters (critical limits) that are to be met; or
- making changes to the monitoring procedures that are to be carried out; or
- making changes to the scope of the agrichemical management plan; or
- modification of agrichemical inputs or critical limits (e.g. PHIs or MRLs) that may require re-evaluation of monitoring activities; or
- modification of the corrective actions that are to be applied in the event of loss of control or if monitoring parameters or regulatory limits are not met.

3.5 Re-registration of agrichemical management plans

3.5.1 The operator must review the plan, arrange for verification of the plan by a recognised agency, 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 an agrichemical management plan in the event of non-compliance, or if the operator is no longer deemed to be a fit and proper person to operate the plan.

4. Appendix 1. Hazard analysis worksheet

Process Step	Hazard	Control Measures	CCPs	Critical Limits	Monitoring Procedures	Corrective Actions	Records

5. Appendix 2. Critical control point worksheet

Process Step	**Potential Hazard**	**What control measures can be identified for this hazard?** If measures have been identified, proceed to next column. If no measures exist then the process may need to be revised to enable control measures to be applied.	**Could contamination resulting in MRLs being exceeded occur at this step?** If yes, move to next column. If no, this is not a CCP. Justify why contamination could not occur and move to the next hazard.	**Will subsequent steps eliminate the hazard or reduce occurrence to acceptable levels?** If yes, this is not a CCP. Move to next hazard. If, this is a CCP. Move to next column and identify critical limits.	**Critial Limits**