BIOSECURITY NEW ZEALAND

RISK ANALYSIS PROCEDURES

Version 1

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These procedures have been approved by:

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The review of the Biosecurity New Zealand risk analysis process and methodology was to a large extent a review of the procedures provided in *Murray, N (2002). Import Risk Analysis. Animals and Animal Products. New Zealand Ministry of Agriculture and Forestry* and as such, much of the text contained in this review document is similar to that contained in these procedures.

INTRODUCTION

These procedures have been developed for use by Biosecurity New Zealand staff, or those contracted to provide services to Biosecurity New Zealand, to undertake risk analyses to support the New Zealand biosecurity risk management decision making process.

The procedures are presented in six main chapters:

Chapter 1:	Provides an overview of the risk analysis framework and includes the principles behind the framework
Chapter 2:	Provides information on the prioritisation setting process for the risk analysis work programme
Chapter 3:	Provides information and guidance on the management of risk analysis projects
Chapter 4:	Details the steps required to complete a risk analysis to appropriate standards
Chapter 5:	Provides guidance on how the risk analysis should be documented, and the information used to developed the risk analysis recorded
Chapter 6:	Provides a glossary of terms used in the procedures

The Appendices provide:

- Information on the legislative requirements for risk analysis development;
- A check list for recording project and risk analysis development; and
- Process diagrams for risk analysis.

REVIEW TIMETABLE

These procedures are considered a living document, and as such it is expected improvements will be made to these procedures as and when required. A full review of these procedures will be undertaken once they have been implemented and sufficient experience has been gained in their use. Any significant changes to these procedures will be consulted with key stakeholders.

ACKNOWLEDGEMENTS

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1. Risk Analysis for Biosecurity in New Zealand

1.1 Introduction

The key deliverables for the Ministry of Agriculture and Forestry are:

- encouraging high-performing sectors;
- developing safe and freer trade;
- ensuring healthy New Zealanders; and
- protecting our natural resources.

Within the Ministry of Agriculture and Forestry, Biosecurity New Zealand has been tasked with a 'whole of system' leadership role, encompassing economic, environmental, social and cultural outcomes in the management of biosecurity risks to New Zealand[1].

Biosecurity for New Zealand has been defined as:

> "The exclusion, eradication or effective management of risks posed by pests and diseases to the economy, environment and human health." (Biosecurity Strategy 2003[2])

Risk analysis undertaken for biosecurity is concerned with supporting the risk management decision making process to effectively manage the biosecurity risks to New Zealand's economy, environment and human health associated with the movement of goods or conveyances[3] into New Zealand and the eradication or management of unwanted organisms or diseases[4] established in New Zealand. In this context risk analysis can be thought of as a process to provide recommendations on the likelihood of an organism or disease entering, establishing or spreading in New Zealand, its likely impact on animal, plant or human health, the environment and the economy, and the options available for managing the identified risk. While some form of risk analysis has always been undertaken, it is only in the last decade, particularly following the implementation of the World Trade Organization's Agreement on the Application of Sanitary and Phytosanitary Measures (the so-called SPS Agreement), that formal methodologies have been developed and transparent processes have emerged (Murray 2002[5]).

The primary design objective for the new framework is to ensure that stakeholders, risk analysts and decision-makers can be confident that recommendations, on the level of protection required to manage the risks posed by unwanted organisms and diseases, are being developed appropriately. The risk analysis activities covered by the new framework are focused mainly on the movement of goods or conveyances into New Zealand. Procedures for risk analysis activities associated with the management or eradication of unwanted organisms and diseases established within New Zealand will be provided in a separate document.

1 http://www.biosecurity.govt.nz/about-us/about-us
2 The Biosecurity Strategy for New Zealand. 2003. http://www.biosecurity.govt.nz/strategy-and-consultation/strategy/strategy
3 A conveyance can include packaging (material used to support the goods during transport**)** and any containers associated with a commodity, passengers, and any vessel (sea vessel or aeroplane) in or on which a commodity might be transported.
4 "Disease" is included with "organisms" to ensure syndromes of no known cause are included in the scope of the risk analysis programme.
5 Murray, N (2002). Import Risk Analysis. Animals and Animal Products. New Zealand Ministry of Agriculture and Forestry. pp183. The review of the Biosecurity New Zealand risk analysis process and methodology was to a large extent a review of the procedures provided in this publication and as such, much of the text contained in the review documents is similar to that contained in this publication.

1.2 MAF's Domestic and International Responsibilities

MAF's domestic and international responsibilities and obligations for the effective management of biosecurity risks are provided principally by the Biosecurity Act (1993), the SPS Agreement (1994), and the relevant international standard setting bodies recognised under the SPS Agreement; namely the *World Organisation for Animal Health* and the *International Plant Protection Convention*. There are however other international articles that also provide further related responsibilities or obligations, most notably including the *Convention on Biological Diversity*, the *International Health Regulations*, and publications produced by the *International Maritime Organization*. Further information on the above is provided in Appendix 1.

Before attempting to describe the New Zealand biosecurity system as it relates to the management of risks related to trade, it is important that the four terms that result in most confusion are defined: risk, risk assessment, risk management, and risk analysis.

i) *Risk:* the likelihood of the occurrence and the likely magnitude of the consequences of an adverse event.

ii) *Risk assessment*: the evaluation of the likelihood, and the biological and economic consequences, of entry, establishment, or exposure of an organism or disease.

iii) *Risk management*: the process of identifying, selecting and implementing measures that can be applied to reduce the level of risk.

iv) *Risk analysis*: the process comprising hazard identification, risk assessment, risk management and risk communication.

Within New Zealand biosecurity there are three main risk analysis-related processes to support or inform the biosecurity risk management system. The three processes can be summarised as:

1. *Import risk analysis*: to identify appropriate risk-mitigating options for the development of import health standards. These risk analyses can focus on an organism or disease, a good or commodity, a pathway, or a method or mode of conveyance such as shipping, passengers or packaging.

2. *Pest risk assessment*: to measure the level and nature of biosecurity risk posed by an organism. A pest risk assessment can be used to inform biosecurity surveillance activities or identify pests of high risk to New Zealand.

3. *Organism consequence assessment*: to measure the level and nature of the consequences of an organism or disease that has established in New Zealand. An organism consequence assessment is most often used to inform response and/or pest management programs within New Zealand.

This document provides an overview of the process to be used for import health standard-related risk analysis activities undertaken by Biosecurity New Zealand. As pest risk assessment is a subset of the risk analysis process, this document also incorporates the process and methodology for pest risk assessment activities. While the organism

consequence assessment process and methodology is equivalent to aspects of the risk analysis process, it is undertaken to inform pest and disease eradication or management programmes, and as such will be developed separately.

1.3 Key Principles behind the Framework

The following key principles define the nature and performance of the risk analysis programme delivered by Biosecurity New Zealand:

Effective: That each risk analysis accurately measures the risks to the extent necessary and identifies mitigation options that achieve a level of protection appropriate for New Zealand.

Efficient: The risk analysis programme avoids duplication and unnecessary use of resources, meets agreed timeframes, and focuses on the areas of greatest priority.

Transparent: That the reasoning and evidence behind the decisions recommended by the risk analysis, and areas of uncertainty and their possible consequences to those recommendations, are clearly documented and made available to stakeholders.

Consistent: That all risk analyses completed by Biosecurity New Zealand achieve the same high level of performance and provide recommendations that deliver to the appropriate level of protection for New Zealand using a common process and methodology.

Comprehensive: That the full range of values, including economic, environmental, social and cultural, are considered when assessing risks and determining mitigation options.

Risk Management: That zero risk is not obtainable and as such risk is managed through deciding in each instance what should be considered an acceptable level of risk.

Precautionary: That the risk analyst will incorporate a level of precaution in the import risk analyses to account for uncertainty; for instance when making a professional judgement on whether available information is sufficient, when making assumptions, and when selecting risk management options. Where there is insufficient information, provisional measures may be recommended recognising the obligation to seek additional information.

Science based: The risk analysis should be based on the best available information that is in accord with current scientific thinking. The risk analysis process and the determination of the appropriate level of protection should not be compromised by pressures of trade or protection.

Compliant: That the risk analysis process and methodology meets the needs of and complies with New Zealand's domestic legislation and international obligations.

The following risk analysis framework has been developed to provide the greatest opportunity for risk analysts working within the Biosecurity New Zealand risk management programme to deliver to these principles.

1.4 Scope of a Risk Analysis

As mentioned above, a risk analysis can focus on an organism or disease, a good or commodity, a pathway, or a method or mode of conveyance.

The scope of an import risk analysis will include organisms or diseases potentially associated with a good or conveyance entering New Zealand, or a particular pathway for a good or goods entering New Zealand. Under New Zealand's key piece of biosecurity-related legalisation, the Biosecurity Act (1993), "risk goods" are defined as:

> …. any organism, organic material, or other thing, or substance, that (by reason of its nature, origin, or other relevant factors) it is reasonable to suspect constitutes, harbours, or contains an organism that may:
> (a) Cause unwanted harm to natural and physical resources or human health in New Zealand; or
> (b) Interfere with the diagnosis, management, or treatment, in New Zealand, of pests or unwanted organisms.

Risk goods can be of plant or animal origin, or they can be inanimate objects. A conveyance can include packaging (material used to support the goods during transport**)** and any containers associated with a commodity, passengers, and any vessel (sea vessel or aeroplane) in or on which a commodity might be transported.

The scope of a pest risk assessment will include all or selected pathways for the entry of a particular pest or disease or group or class of pests or diseases.

Any framework for undertaking risk analyses to identify appropriate measures must consider risks from all risk goods or organisms to the following, as defined in the Biosecurity Act (1993) (section 22):

> The nature and possible effect on people, the New Zealand environment, and the New Zealand economy of any organisms that the goods specified in an import health standard may bring into New Zealand

"Environment" is further defined to include:

> (a) Ecosystems and their constituent parts, including people and their communities; and
> (b) All natural and physical resources; and
> (c) Amenity values; and
> (d) The aesthetic, cultural, economic, and social conditions that affect or are affected by any matter referred to in paragraphs (a) to (c) of this definition.

1.5 International Risk Analysis Frameworks

The Biosecurity Act (1993) does not itself provide a framework for undertaking assessments or analyses of risk, but in the case of developing import requirements for risk goods for example, requires that the Chief Technical Officer recommending the import health standard for approval must have had regard to New Zealand's international obligations. The international risk analysis frameworks most relevant to establishing measures in the trade of risk goods are provided under the *World Organisation for Animal Health* (OIE) and the *International Plant Protection Convention* (IPPC) as follows:

OIE: The risk analysis chapter in the *Terrestrial Animal Health Code* provides guidelines for the placement of measures to prevent the introduction of organisms that may have negative consequences for animals, humans, and environment (including plants), through the importation of animals and animal products.

IPPC: The *International Standards for Phytosanitary Measures* (ISPM) Nos. 2, 11 and 21 together provide a risk analysis process on which to base the consideration of the risks to plant health from pests or diseases imported on plants and plant materials, and regulated articles, including inanimate objects.

It is important to note that under these two standard setting bodies, application of the risk analysis frameworks are limited by the mandates of the organisations. The OIE framework can not be applied to animal and human health pests carried on inanimate objects and plants or plant products, while the IPPC framework can only be applied to the placement of measures for pests and diseases carried by these products if they impact plant health. As such, pests and diseases that can be carried by plant products or inanimate objects that impact on human and animal health are not covered under either the OIE or the IPPC.

However, although the SPS agreement requires international guidelines to be followed where they exist, the SPS agreement provides for measures to be developed in the absence of standards provided a risk analysis is performed that supports the measures. The agreement also allows consideration of the economic consequences resulting from introduction of an organism into an animal, human, or plant population. Note the SPS definition of 'animal' includes fish and wild fauna and 'plant' includes forests and wild flora.

1.6 The Biosecurity New Zealand Risk Analysis Framework

To meet the requirements of the Biosecurity Act (1993) for issuing import health standards[6], the Biosecurity New Zealand framework for undertaking a risk analysis builds on the existing international frameworks (OIE and IPPC), and extends the scope under SPS to include all of the values required by the Biosecurity Act (1993). Table 1 lists the stages of the OIE and IPPC risk analysis frameworks, and provides an overview of the integration of both processes and the titles adopted for the Biosecurity New Zealand risk analysis framework.

6 Section 22 of the Biosecurity Act 1993

Table 1: Biosecurity New Zealand framework relative to OIE and IPPC frameworks

Biosecurity New Zealand Framework	IPPC Framework	OIE Framework
1. Managing a risk analysis	***1. Stage 1: Initiation***	***Scoping the risk analysis***
1.1 Initiation and prioritising	*1.1 PRA Initiated by a pathway (may include review of a policy)*	
1.2 Project management (scoping, planning, communication strategy)	*1.2 Identification of PRA area*	
2. Hazard Identification		***1. Hazard Identification***
2.1 Formation of a hazard list		*1.1 Formation of hazard list*
2.2 Hazard scoping	*1.3 Information*	
	1.4Conclusion of initiation	
	2. Stage 2: Pest risk assessment	
	2.1 Pest categorization	*1.2 Categorization of hazard*
3. Risk assessment		***2. Risk assessment***
3.1 Entry assessment *3.2 Exposure and establishment assessment*	*2.2 Assessment of the probability of introduction and spread*	*2.1 Release assessment* *2.2 Exposure assessment*
3.3 Consequence assessment	*2.3 Assessment of potential economic consequences*	*2.3Consequence assessment*
3.5 Risk estimation	*2.4 Degree of uncertainty* *2.5 Conclusion of the pest risk assessment stage*	*2.4 Risk estimation*
3.6 Assessment of uncertainty		
4. Risk management options	***3. Stage 3: Pest risk management***	***3. Risk management***
4.1 Risk evaluation	*3.1 Level of risk* *3.2Technical information required* *3.3 Acceptability of risk*	*3.1 Risk evaluation*
4.2 Option evaluation	*3.4 Identification and selection of appropriate risk management options* *3.5 Phytosanitary certificates and other compliance measures*	*3.2 Option evaluation*
4.3 Estimating residual risk	*3.6 Conclusion of pest risk management*	*3.3 Implementation*
4.4 Monitoring and review	*3.7 Monitoring and review of phytosanitary measures*	*3.4 Monitoring and review*
5. Risk communication and documentation	***4. Documentation of Pest Risk Analysis***	***4. Risk communication***

1.6.1 Managing a risk analysis

There are four main steps to managing a Biosecurity New Zealand risk analysis project. The first step, *prioritising*, is made necessary by insufficient resources to fully manage all risks. It is completed prior to undertaking a risk analysis project and seeks to identify from a range of projects in the work programme, which risks to manage and to what levels, to make most effective and efficient use of the resources available.

Once a project is begun the second step is to decide on the *scope* of a risk analysis. There are a number of options to choose from when deciding on the scope of a risk analysis. Each has its own advantages and disadvantages. Market access requests, reviewing existing import health standards, ensuring consistency and resource constraints all influence which option is chosen. A risk analysis may be based on a particular commodity, a category of commodities,

a particular organism or disease, or group of organisms or diseases that share common epidemiological characteristics, or one or more forms of conveyance. The analysis may apply to a particular exporting country (bilateral) or a trading block, such as the European Union (multilateral) or, in some cases it may not apply to any particular country.

The third step is to *plan* the risk analysis project. The overarching purpose of the project plan is to clearly define the roles, responsibilities, processes, and activities which will result in the project producing the deliverables required, on-time, within budget, and to the agreed standard(s). It addresses the strategies, scope, roles, responsibilities, timetable, costs, and risks and issues appropriate to the project's management activities, and identifies the impact of the project on the business.

The fourth and final step is to develop a *communication strategy*. A communication strategy details how the developing project is reported to stakeholders and decision makers to ensure adequate and appropriate involvement and governance oversight is achieved. Each step of the project is recorded in a check sheet (see Appendix 2) to provide a record of how the project progressed.

1.6.2 Undertaking a risk analysis

The risk analysis process is itself divided into four main steps: *Hazard Identification*, *Risk Assessment*, *Risk Management Options*, and *Risk Communication and Documentation*.

Hazard identification is an essential step that must be conducted prior to a risk assessment. To effectively manage the risks associated with pathways or imported risk goods, organisms or diseases which could be introduced into New Zealand that are capable of, or potentially capable of, causing unwanted harm must be identified. In the case of a single hazard, a pest risk analysis, all or many of the potential pathways of entry may be identified.

In the *risk assessment* step the risk analyst evaluates the likelihood and environmental, economic, and human health consequences of the entry, exposure and establishment of a potential hazard within New Zealand. The aim is to identify hazards which present an unacceptable level of risk, for which risk management measures are required. A risk assessment consists of four inter-related steps:

i) Assessment of likelihood of entry

ii) Assessment of likelihood of exposure and establishment

iii) Assessment of consequences

iv) Risk estimation.

The uncertainties and assumptions identified during the preceding stages are also summarised and considered for further research with the aim of reducing the uncertainty or removing the assumption.

Risk management options, in the context of risk analysis, is the process of deciding upon biosecurity measures to effectively manage the risks posed by the hazard(s) associated with the commodity under consideration. Possible options are identified, and the likelihood of the entry, establishment or spread of the hazard is evaluated according to the option(s) that might

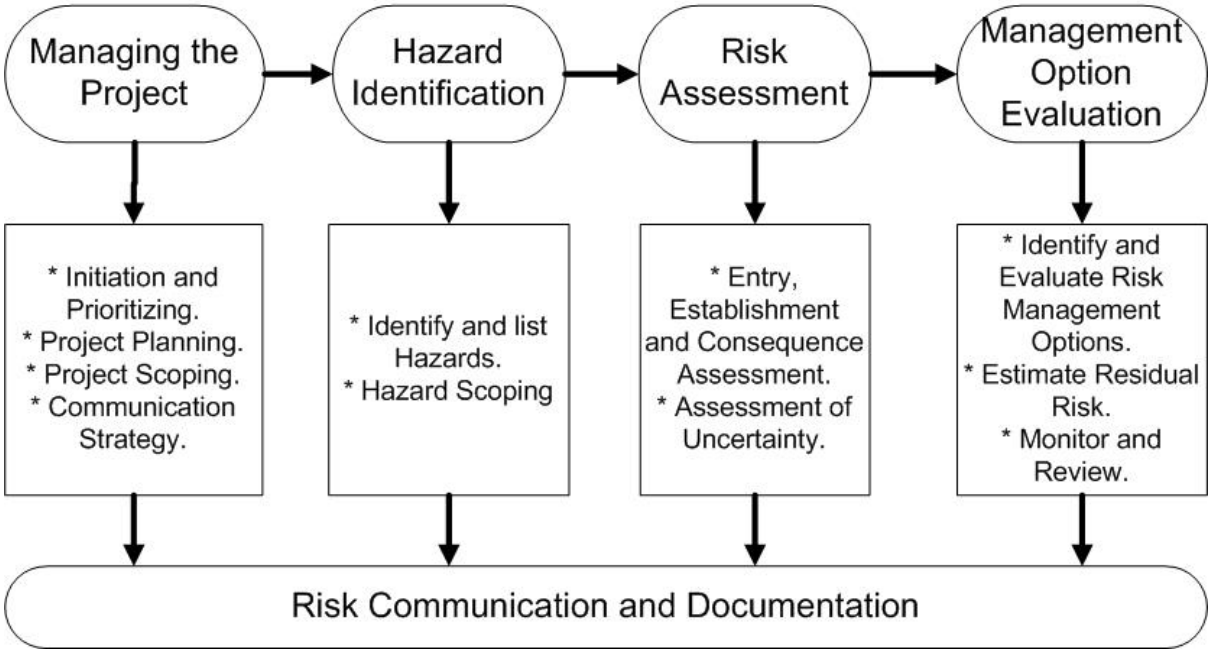
be applied. An appropriate option or combination of options is then selected. Residual risk remaining after the selected options have been successfully implemented is then estimated and becomes the basis for developing a monitoring protocol that may, for instance, interpret interception data to determine if risk thresholds are being exceeded.

Risk communication is undertaken throughout the life of the risk analysis project in the manner described in the communication strategy developed at the beginning of the project.

Each risk analysis is then *documented* to facilitate the understanding of a risk analysis, to ensure that the reasons for the conclusions reached and recommendations made are obvious, and to allow for the review of the risk analysis when additional information becomes available.

The main steps of the Biosecurity New Zealand risk analysis framework are summarised in figure 1. A set of process diagrams and short procedural descriptions are also provided in Appendix 3, with links to the procedures included in the following chapters of this handbook.

Figure 1: The Biosecurity New Zealand risk analysis framework



2. Prioritising Risk Analysis Projects

A risk analysis may be undertaken to:

- support the development or review of import health standards,
- assist in the development of surveillance programmes,
- support incursion responses to new organisms, or
- assist in prioritizing established pests for national management.

Requests for risk analysis projects for completion by the risk analysis group therefore need to be prioritized in a manner that allows consistency and transparency in decision-making.

Prioritisation is made necessary by insufficient resources to fully manage all risks. It seeks to identify, in the context of resource management, which risks to manage and to what levels, to make most effective and efficient use of the resources available. Improved resource allocation can enable the same total level of risk management to be achieved using fewer resources or greater management of risks to be achieved with the same level of resources.

Prioritisation requires:

- identification of the outcomes sought and the (business) risks to their attainment;
- recognition of resource constraints;
- consideration of competing uses of resources;
- willingness to reallocate resources from lower to higher priorities.

To be effective, the formal framework for assessment and prioritisation in allocating resources in risk analysis must be:

- robust – systematic, objective and rational, informed by reliable information and analysis and people with appropriate expertise and experience;
- discriminating – able to differentiate, as useful, between relative levels of priority;
- flexible – to accommodate the range of contexts, inherent uncertainty, inevitable trade-offs between risk and benefit and complexity of biosecurity decision-making;
- consistent – across applications, types of risk and time, such that decisions differ only to the extent that there is valid reason and not due to differences in assessment approach;
- transparent – such that the basis for decisions is explicit, facilitating effective communication and understanding;
- practical – simple, inexpensive and, for urgent decisions, quick to apply; and
- dynamic – able to accommodate changing risks and values and continuously improving as better practices are developed.

2.1 Requests for Risk Analyses

Risk analysis requests may come from Senior Managers (through strategic projects) or Group Managers (Border Standards, Surveillance and Response, Pest Management). As stated above, requests may be for risk analyses to identify appropriate measures for import health

standard development, or for risk assessments to support surveillance and response or pest management activities.

2.1.1 Requests for risk analyses to determine measures

These requests will come through the import health standard application prioritization panel in accordance with annual planning cycles and the agreed import health standard development process of Biosecurity New Zealand. The committee will identify which import health standards require further risk analyses and the risk analysis group will do a preliminary scope of these analyses. This scope will include an approximation of the level of resourcing and timeline required to undertake the analysis.

2.1.2 Requests for risk analyses to support surveillance and response or pest management activities

The process for developing and receiving requests for risk analysis work in support surveillance and response or pest management activities has yet to be developed. It is likely this process will be developed in a separate project and integrated into these procedures when completed.

2.1.3 High priority strategic projects requiring risk analysis input

During the annual planning cycle, Senior Managers will identify new high priority projects for Biosecurity New Zealand. Where input or leadership is required from the risk analysis group, these projects will also be prioritized within the work programme.

2.2 Process for Prioritizing Risk Analyses

All requests for risk analyses will be collated from the above sources within the appropriate timeframe of the annual business planning process.

The requests will be assessed by the Group Manager and Team Managers (Risk Analysis) with input from all team members and appropriate members from other business groups.

2.3 Criteria for Prioritizing Risk Analyses

The criteria for assessing priority in allocating resources in risk analysis are:

- technical;
- practicality;
- benefit-cost;
- strategic; and
- acceptability.

The first of these concerns, ***technical feasibility***, looks at the suitability and probability of achieving the risk management objective. Factors considered include the likely complexity of task to complete the import health standard and the availability of information to support the identification and development of appropriate measures.

Practicality provides for consideration of logistics, resourcing, including current capability (e.g. staff skill set) and the extent to which the ability to manage other risks would be constrained, timing, such as urgency or time awaiting action, opportunities and risks associated with the risk management option, including consideration of risks in deferring or rejecting the risk management option, and past achievements and sunk costs.

Benefit-cost is defined broadly as the net impact of the risk management option, most directly the reduction in risk achieved less the resources required. This criterion requires the systematic identification and consideration of the full range of positive and negative effects across all sectors. This is provided in the overall benefit-cost rating. It brings together risk analysis and operational activity and effectiveness in assessing options to manage risks to what New Zealanders value.

Criteria in assessing costs and benefits comprise the scope of effects to be considered. This encompasses the full range of effects across all sectors:

- commercial, including primary production, industry and service sectors;
- environmental, including valued indigenous and introduced species, biological systems and biodiversity;
- social, including personal property and lifestyle;
- human health and well-being;
- Māori cultural and spiritual values; and
- public, in terms of Crown resources.

The above are accorded equal weight, with distributional considerations reflected in the priority assessment criterion of acceptability. At this stage the scoring attributed to these criteria will be approximate only, given that in many cases a more complete analysis will occur in the risk analysis still to be undertaken.

Strategic factors include contribution to or alignment with the goals and key priorities for New Zealand biosecurity and of the government, agency, sector and group and investment for long-term benefits, including development of capability and potential future growth sectors, relative to addressing more immediate needs.

The final criterion of ***acceptability*** reflects stakeholder interest or concern, responsiveness to the needs of Māori, international interests, including trade (encompassing wider trade implications), environmental and human health, distributional considerations, including the interests of particular groups and the incidence of costs and benefits.

These generic criteria are interpreted differently according to context. Under practicality, for example, timing may reflect urgency in incursion response or time awaiting action for import health standard requests. Assessment within the same framework of criteria does, however, provide a consistent format to facilitate comparison of risk management options.

3. Managing a Risk Analysis Project

3.1 Introduction

A risk analysis may be either undertaken by either MAF or an external consultant managed by MAF. Regardless of who undertakes the analysis it is essential to ensure that requirements for consultation[7, 8, 9] and scientific rigour[9] are met by establishing a management framework that is appropriate to the circumstances.

Risk analyses which cover:

- a range of commodities;
- a single commodity derived from a number of countries or regions;
- a pest or disease or a group of pests or diseases; or
- one or more forms of conveyance;

shall be managed through a project. The Project Manager will be accountable for delivering the project to the agreed plan either solely, through the use of the technical resources available within MAF, or in some part through the use of external consultant(s) who may undertake aspects of the risk analysis.

For details on the roles, responsibilities and processes for managing projects for the Ministry of Agriculture and Forestry (MAF) and Biosecurity New Zealand, please refer to the MAF Project Methodology available at the following address on the MAF intranet (http://intranet.maf.govt.nz/intra/projects/methodology/).

The follow section will provide guidance on the application of project management to the development of risk analyses.

3.2 Project Management for Risk Analysis

Project management is the application of knowledge, skills, tools and techniques to project activities to meet the project requirements; that is the art and science of how to go about delivering projects.

Project management provides the means to respond to and manage initiatives that cannot be addressed as readily by the organisation's normal operations (business as usual). Since projects are unique and temporary, project management provides tools to design, develop, and deliver the project's products (deliverables) while providing a defined framework for decision making, performance monitoring and risk minimisation. In simple terms, project management sets the boundaries and rules for the particular project to be managed and monitored against.

7 Biosecurity Council policy statement on interdepartmental consultation. Biosecurity 11, 4-5, May 1999.
8 Biosecurity Authority policy statement on consultation. Biosecurity 18, 3-5, March 2000.
9 Biosecurity Authority policy statement on conducting import risk analyses and applying them in the development of import health standards. Biosecurity 26, 7-10, March 2001.

3.2.1 Project Governance

Project Governance is defined as the organisation's set of structures, systems and processes around projects that assure the effective selection and delivery of the projects.

Project governance, like any other management discipline needs to have basic principles to live by in order to be effective.

The organisation's decision-makers govern projects through three main tasks:

- **Evaluate** the project for strategic importance, value and to establish priority.
- **Decide** if the planning is satisfactory and therefore whether to proceed.
- **Monitor** conformance to policies and performance against what has been planned and intervene as and where appropriate.

There are three decision making roles in a project: Business Owner, Project Sponsor and Project Manager.

3.2.2 The Project Manager

In the context of risk analysis, the Project Manager, along with their normal project management responsibilities, is also accountable for:

- inter-departmental liaison;
- recommending publication of a risk analysis for stakeholder consultation;
- recommending publication of a review of stakeholder submissions;
- publishing the final version of the risk analysis once peer review is completed and approval is granted by the Sponsor;
- analysing and documenting critiques arising from stakeholder submissions and recommending modifications to the risk analysis;
- providing feedback and publishing a review of stakeholder submissions.

3.2.3 Establishing a Project Team

The project team is made up of people who actively work on the project, at some stage, during the lifetime of the project. They are a group of individuals with appropriate and complementary professional, technical or specialist skills who, under the direction of the Project Manager, are responsible for carrying out the work detailed in the project plan. The size of the team will depend on the resources available and the nature of the work being undertaken. Individuals from outside Biosecurity New Zealand may be included in the project team where appropriate. For many of the risk analyses undertaken to support the development of an import health or operational standard it is expected that a representative from the Biosecurity Standards Group will be on the project team.

3.2.4 An External Risk Analysis

Where an external consultant is commissioned by Biosecurity New Zealand, the work undertaken by the consultant will occur within a project managed by a Biosecurity New Zealand Project Manager. The Project Manager will be accountable for the oversight for the work of the consultant. Where the consultant has responsibilities in the development of a risk analysis (consultants may also be employed to draft a risk analysis), each party has the following responsibilities:

3.2.4.1 Project Manager

In addition to the responsibilities outlined in section 3.2.2 the Project Manager will be accountable for:

- the consultant having an appropriate understanding of the scope of their work on the project;
- establishing a risk communication strategy, including the identification of potential stakeholders, in collaboration with the consultant;
- liaising with the consultant to identify potential project risks;
- ensuring adequate technical oversight of the consultants activities in developing the deliverables;
- commissioning a peer review of a draft risk analysis developed by the consultant;
- a review of the consultant's analysis of peer review critiques;
- publishing the final version of the risk analysis once peer review is completed and approval is granted by the Sponsor. A covering letter from the Sponsor must accompany the risk analysis stating that it has been subjected to peer review process commissioned by MAF and that MAF is satisfied with the standard of the analysis and its recommendations.

3.2.4.2 External Consultant

The external consultant will be accountable for:

- liaising with the Project Manager or delegate to establish the scope of the risk analysis;
- liaising with the Project Manager or delegate to identify potential project risks;
- carrying out the risk analysis according to the requirements stated in these procedures;
- submitting the risk analysis to a peer review process commissioned by the Project Manager;
- analysing and documenting critiques arising from peer review and reasons for rejecting or incorporating suggestions or criticisms;
- preparing a response to specific stakeholder's concerns if the Project Manager considers it necessary.

3.3 Summary of the Decision Making Framework

The decision making framework for a risk analysis project details who and how decisions will be made during the project. The "how" part of the decision making framework will be developed through other business processes, but the "who" question can be clarified in these procedures for risk analysis projects.

For risk analysis projects there are four decision makers: The Project Manager; the Project Sponsor; the Business Owner; and the Director Pre-clearance (or designate). The accountabilities of these decision makers can be summarised as follows:

Decision Maker	Accountability
Director Pre-Clearance (or designate)	Approving the risk analysis for consultation and final dissemination.
Business Owner	Approving the project concept and may hold any of the accountabilities normally delegated to the Sponsor.
Project Sponsor	Approving project deliverables including the recommendations to the Director Pre-Clearance (or designate)
Project Manager	Project management decisions related to ensuring the project is delivered to the project plan.

The decision-making roles must be allocated and agreed prior to the project commencing, but may be altered during the project if certain aspects of the project such as scope or profile change. It is possible for the Director Pre-Clearance (or designate) to also be the Business Owner.

3.4 Developing a Communication Strategy

It is essential to establish a communication strategy from the start of a risk analysis to ensure from the outset that stakeholders are provided with an opportunity to provide comment and the appropriate governance systems are in place. The project reporting requirements to ensure adequate governance are discussed further in the MAF Project Methodology.

When dealing with stakeholders it must be recognised that risk communication is an interactive and iterative process involving a two-way dialogue. As a result all legitimate concerns raised are to be considered and timely feedback provided. Since New Zealand is a member of the WTO, non-disease or pest associated costs and/or benefits, such as the financial impact of an imported commodity on a domestic industry as a result of competition, do not constitute legitimate concerns. However, concerns relating to the technical details of the risk analysis including its scope, the list of hazards identified, the data, information, assumptions, references and expert opinion are all legitimate. To ensure that a meaningful dialogue is established, all parties should acknowledge that they have an obligation to provide a reasoned argument that is relevant to the analysis and a right to propose a contrary view.

The risk communication strategy should also identify various opportunities with which to communicate with stakeholders, for example, MAF publications such as *Biosecurity*, MAF's

website, direct mail-outs and public notices in newspapers. It must identify potential stakeholders and aim to be inclusive rather than exclusive.

Once a decision is reached not all stakeholders may agree with it. However, by involving them from the outset, taking their concerns seriously and addressing them appropriately, they may have a greater understanding of why a particular decision has been reached.

3.4.1 Expert peer review

Peer review is a fundamental component of a risk analysis to ensure the analysis is based on the most up to date and credible information available. Each analysis must be submitted to a peer review process involving recognised and relevant experts from New Zealand or overseas. Initially, the analysis may be reviewed by appropriate staff within those government departments with applicable biosecurity responsibilities. Following internal review, external reviewers are to be commissioned by the Project Manager and given specific terms of reference to provide a detailed critique. The Project Manager is accountable for ensuring each critique is reviewed and where appropriate, incorporated into the analysis. If suggestions arising from the critique are not adopted the rationale must be fully explained and documented.

The Project Manager must also ensure that each issue raised by a reviewer is individually and separately documented with an appropriate response. Similar issues raised by others must not be amalgamated into a summary of common themes, although identical comments may not need repeating. Once peer review has been completed the Project Manager must ensure the conclusions are discussed with the Project Sponsor and/or Business Owner before the draft risk analysis is revised and published. Using the criteria listed in table 3.1, the Project Manager selects the number and characteristics of the external reviewers.

Table 3.1: Criteria for Selecting Peer Reviewers

Criterion	Outcome (minimum)
The risk analysis dealt with one or more types of organism that have a significant potential impact on an economic, environmental and/or health issue.	1 reviewer per organism type, with each respective type of organism and their consequences
There were no organisms of potential significant consequence identified within the scope of the risk analysis project, and a suitably skilled person can be identified who has had no involvement in the development of the project to-date.	MAF reviewer possible
There were organisms of potential significant consequence identified within the scope of the risk analysis project.	Reviewer external to MAF only
There were organisms of high consequence identified within the scope of the risk analysis project, for which international expertise that is independent of the outcome of the analysis is not known within New Zealand.	International reviewer

Requirements for the completion of an external peer review include:

- Peer reviewers will be required to confidentially evaluate the technical merits of the document;
- Reviews shall be completed within the time specified by the Project Manager;

- Peer reviewers may consult with non-MAF experts providing the document does not contain confidential business information and the Project Manager agrees to it;
- Peer reviewers should provide a list of any considerations that were not adequately taken into account in the document;
- Peer reviewers should not reveal any of the content or recommendations of the review to other parties except as necessary to conduct an objective review as addressed above.

Peer review may involve a significant time commitment to ensure a risk analysis, particularly if large and/or complex, is properly reviewed. Peer reviewers are chosen on the basis of their status as acknowledged authorities in their fields.

The following terms of reference should be provided to each peer reviewer:

i) Is the logic of the process clear to you from your reading of the analysis? That is, can you readily follow the steps from hazard identification, through the risk assessment to formulation of appropriate measures?

ii) Does the document make clear what are facts and what are assumptions?

iii) Has the literature been cited accurately? Have any important publications been overlooked?

iv) Are the references cited appropriate? That is, are the critical epidemiological observations based on secondary sources where it would have been preferable to consult primary sources?

v) In those sections where risks have been assessed quantitatively:

- Do you understand precisely what has been modelled?
- Have the scenario being modelled, and the modelling approach, been adequately described in the written text?
- Is the scenario being modelled plausible, logical and appropriate?
- Would every iteration of the model give a biologically plausible output?
- Is the structure of the model appropriate?
- Are the data used appropriate?
- Is the model mathematically sound and are the formulae used appropriate?
- Are the distributions used appropriate for the data or information being modelled?
- Are you aware of any data or information that have been overlooked but which might be appropriate in the quantitative assessment?

3.4.1.1 The peer review process

The following process should be followed for the expert peer review of the draft risk analysis.

1. Commissioning a review

- Determine level of internal and external review required.
- Draft terms of reference for reviewers. This could include asking reviewers to review a specific section or the entire document. The template reviewer letter should provide an adequate terms of reference (ToR) for most cases but should be amended as required.
- For external reviewers the ToR should include a mechanism to control the cost of the review e.g.

requiring authorisation before exceeding a dollar value or time spent on the review. If the cost of a particular review is likely to exceed $15,000 then the use of a more formal contract through the Biosecurity New Zealand contract team should be considered. Note however that this may delay the start of the review by several weeks.

- Selecting reviewers. Reviewers should be able to carry out the review within a suitable timeframe. External reviewers should be acknowledged authorities in their field. Previous experience in carrying out reviews for MAF would be an advantage. Creditability of reviewer with stakeholders may also be considered.
- Once reviewers have been selected send them the risk analysis, ToR and fill in the checklist with relevant details of reviewers.

2. Analysis of reviewers comments

- Consider the reviewers comments and decide how to address them. All issues raised by reviewers must be addressed either by adopting the reviewers comments or if rejecting them by a fully explained and documented rationale.
- Amend the risk analysis accordingly.

3.4.2 Consulting on a risk analysis

Once a risk analysis has been peer reviewed and the critiques addressed it ceases to be a draft. Following a recommendation from the Project Manager and approval of the recommendation by the Sponsor, the risk analysis is formally approved by the Director Pre-Clearance (or designate) and becomes an official risk analysis, which is a statement of MAF's expert opinion. Once approved the risk analysis is then published and released for public consultation. The analysis must be made available to potential stakeholders, and its availability should be announced through MAF publications such as *Biosecurity*, MAF's web page, direct mail-outs and public notice advertisements in newspapers, etc. The period for public consultation is usually 6 weeks from the date of publication of the risk analysis.

All submissions received from stakeholders must be analysed and compiled into a review of submissions. As with the comments from peer reviewers, similar issues raised by others must not be amalgamated into a summary of common themes, although identical comments may not need repeating. The Project Manager is accountable for the preparation of a document containing the results of the review and recommended modifications to the risk analysis.

3.4.2.1 The Consultation Process

The following is a process for undertaking consultation on a risk analysis:

1. Commissioning the consultation

- Release the risk analysis for consultation by placing it on the consultation page on the MAF website, placing a notice in Biosecurity magazine, and completing a direct mail out to potentially interested stakeholders. Other methods can be employed if the nature of the risk analysis warrants it, for example a risk analysis for cats and dogs has a wide public audience as a result notices could also sent to vet practices for their notice boards. The risk analysis should remain on the MAF website until the review of submissions has been on the MAF website for six weeks after which both documents are moved to the Risk Analysis section of the website.
- The consultation period should be for a period of 6 weeks.

- Key pieces of information to include in any notice are; in what context the analysis has been undertaken, where the analysis can be obtained, when submissions close, and where submissions should be sent.
- All submissions should be acknowledged in writing or by e-mail.

2. Amend risk analysis or develop bridging document as required

- Review the submissions and identify the issues raised.
- Each issue raised must be addressed, this does not mean each issue must be accepted, but if rejected then a clear explanation as to why it was rejected is required and must be documented. The escalation criteria described in 3.4.4 should be used to identify issues to be discussed with the Project Sponsor.
- Once all submissions have been analysed a review of submission document is produced.
- If any changes to the risk analysis are required, either the risk analysis is amended and re-issued with the changes included or a bridging document is developed which details the changes required to the risk analysis outcomes.

3.4.3 Announcing the outcome of the risk analysis process

Once all stakeholder submissions have been analysed, a document containing the results of the review and recommended modifications to the risk analysis should be prepared. The Project Manager must ensure these results and recommendations are discussed with the Sponsor and/or the Business Owner. Following approval of the recommendations by the Sponsor and final approval of the either amended risk analysis or the risk analysis bridging document by the Director Pre-Clearance (or designate), the final risk analysis document and bridging document (if appropriate) should be published.

The final outcome from the risk analysis process is three main documents:

i) A risk analysis for consultation;

ii) A review of stakeholder submissions and recommendations on revisions to the risk analysis;

iii) Either; a final risk analysis, incorporating the revisions recommended by the review of stakeholder submissions; or a bridging document clearly showing the required changes to the outcomes of the risk analysis. If a bridging document is developed the original risk analysis must have a link included at the beginning of the document providing a clear link between the risk analysis and the bridging document.

3.4.3.1 Notification process

The following is a process for notifying the outcome of the risk analysis process:

Notifying the outcome of the risk analysis process

1. Send a copy of the review of submissions to all those that: made submissions; expressed interested in receiving the review of submissions; and affected government departments. A notice advising the availability of the review of submissions should be put in Biosecurity Magazine (see notice template). A pdf of the risk analysis and the review of submissions should be put on the risk analysis section of the MAF website were they will remain indefinitely. Depending of the nature of the risk analysis other notification steps may also be taken. The project communications strategy should provide guidance on this.

2. Send a copy of the review to the Biosecurity Standards Group of Biosecurity New Zealand.

3. Any issue raised subsequent to the release of the review needs to be assessed as to whether it significantly challenges the results of the risk analysis. A simple acknowledgement of their issue will suffice for those that do not significantly challenge the results of the risk analysis. For those that do, the Project Manager should bring the issue to the attention of the Project Sponsor and decide on a course of action to address the issue.

3.4.4 Escalation Criteria

A communication strategy must also contain a set of criteria to aid in identifying issues that require escalation to more senior staff to inform or to action to ensure appropriate resolution.

The details of the project escalation criteria will be specific to any given project, but the following principles should be used as the basic framework:

Issues to be escalated for information:

- Domestic or international stakeholder(s) accept findings but indicate they have issues with process.
- Domestic stakeholder(s) indicate they are considering raising issues with more senior MAF staff (up to EMT level).
- Domestic stakeholder(s) indicate they are considering raising issues with other Government organisations.

Issues to be escalated for action:

- Domestic stakeholder(s) indicate they are considering taking legal action against findings.
- Domestic stakeholder(s) indicate they are considering raising issues with senior MAF staff (above EMT level) or Government Ministers.

The degree of urgency in reporting the various types of issues and the form in which they are to be reported will either be specified as part of the project plan (if they are project management issues) or agreed with the Sponsor in the communication strategy.

3.5 Developing a Project Plan

The overarching purpose of the project plan is to ensure that the project is aligned for success, clearly defining the roles, responsibilities, processes, and activities which will result in the project producing the deliverables required, on-time, within budget, and to the agreed standard(s). It addresses the strategies, scope, roles, responsibilities, timetable, costs, and risks and issues appropriate to the project's management activities, and identifies the impact of the project on the business.

The following sections provide guidance on the delivery of aspects of the project plan for the purposes of completing risk analyses or organism impact assessments. All other required aspects of project planning should be competed as required and in compliance with existing MAF and Biosecurity New Zealand policies and procedures.

3.5.1 Scoping a Risk Analysis

There are a number of options to choose from when deciding on the scope of a risk analysis. Each has its own advantages and disadvantages. Market access requests, reviewing existing import health standards, ensuring consistency and resource constraints all influence which option is chosen. A risk analysis may be based on a particular commodity, a category of commodities, a particular organism or disease, or group of organisms or diseases that share common epidemiological characteristics, or one or more forms of conveyance. The analysis may apply to a particular exporting country (bilateral) or a trading block, such as the European Union (multilateral) or, in some cases it may not apply to any particular country, in which case it is referred to as a *generic* risk analysis. Regardless of which option is chosen it is important to define the scope of the analysis and document the rationale for choosing a particular one.

The appropriate scientific name should be used when reference is made to an organism or disease agent. Where it is relevant, the nature, source(s), intended use(s) and the likely annual quantity of trade of the commodity should be detailed. A description of the relevant methods of production, manufacturing or processing normally applied, such as cooking, curing, irradiation, filtration and tests for sterility or freedom from contamination, should be included as well as any quality assurance programs, such as HACCP, and how they are verified. While an accurate estimate of the anticipated quantity of trade is desirable, it may not be readily available, particularly where such trade is new. It is important to appreciate that a commodity definition or description does not, in itself, constitute a sanitary or phytosanitary measure. It merely represents the starting point for a risk analysis.

Some commodities could contain organisms that, while not affecting animal or plant health, may have an effect on people, the New Zealand environment or the New Zealand economy. Examples include weed seeds trapped in the commodity or passed in and animal's faeces, and soil contaminated with fungal spores on shoes or containers. If the commodity under consideration is likely to contain such organisms, it is essential that this is noted in the scope and that the appropriate expertise is either appointed to the Project Team or made available to provide advice to the Project Team.

Commodities imported into a country are usually packed into bags, or enclosed into wrapping or boxing in their country of origin, and are loaded as baggage, bulk materials, or in containers in or onto road vehicles, sea vessels or aeroplanes for transport. Packaging material (wooden (dunnage) and non-wooden) is often used to support the goods during transport. All such packaging should be noted in the description of the pathway of entry of the commodity, and justification provided for its inclusion or exclusion from the scope.

The pathway or pathways on entry of the commodities or organisms into New Zealand should also be described in detail. Commodities and organisms can arrive in New Zealand by sea or by air carried naturally by wind or sea currents, by sea-going vessels or by aircraft. When carried by aircraft or by sea-going vessels, commodities may enter New Zealand under the categories listed in Table 3.1.

Table 3.1: Categories of modes of entry for commodities

On or in people	Commodities might be carried in or on a person, including the clothing they are wearing. The Biosecurity Act does not directly encompass people themselves as vehicles for the introduction of unwanted organisms.

Personal baggage (accompanied baggage)	This is baggage accompanying a travelling individual and may contain commodities. It includes carry-on and checked baggage. Note that bags themselves are considered to be commodities and may need to be assessed as risk goods.
Personal effects	These are unaccompanied personal or household goods. They are usually carried in containers but are considered separately from other containerised goods because of the way their inspection is handled.
Vessels	Ships, yachts, and aircraft may all themselves either act as vectors for unwanted organisms or contain food, dunnage or personal affects that, if removed from the vessel, could be considered a commodity.
Air courier cargo	This is courier mail and packages arriving by air. Both wrapping and contents may need to be assessed as risk goods. Air courier cargo is usually carried in containers but is considered separately from other containerised goods because of the way its inspection is handled.
Mail	This is international mail. Both packaging and contents may need to be assessed as risk goods. Mail is usually carried in containers but is considered separately from other containerised goods because of the way its inspection is handled.
Container cargo	These are goods that are packed into containers for transport (excluding mail, air courier cargo and personal effects as above). The contents, packaging, and the containers themselves may need to be assessed as risk goods.
Bulk cargo	These are goods transported in bulk form during transit (excluding mail, air courier cargo and personal effects as above).

The following is a checklist for scoping a risk analysis:

A checklist for scoping a risk analysis

1) Use scientific names when reference is made to an organism or disease agent.

- e.g. sheep (*Ovis aries*), cattle (*Bos taurus* or *Bos indicus*), Nile Perch (*Lates niloticus*), Newcastle disease virus (Family *Paramyxoviridae* genus *Paramyxovirus* Avian PMV 1), Radiata pines (*Pinus radiata*), Limes (*Citrus latifolia*)

2) Describe the nature, source(s) and intended use(s) of the commodity or organism where relevant.

- e.g. frozen chicken (*Gallus gallus*) meat and chicken meat products from the USA for human consumption, live viral vaccines for administration by injection, Lychee (*Litchi chinensis*) fresh fruit from Taiwan for consumption, used cars from Japan.

3) Describe the relevant methods of production, manufacturing, processing or testing that are normally applied.

- e.g. cooking, curing, irradiation, filtration, tests for sterility and freedom from contamination of biological products

4) Describe any quality assurance programs that may apply and how they are verified.

- e.g. production of vaccines or other biologicals, HACCP programs for the production of chicken meat

5) Describe the pathway or pathways being considered for entry of the commodity or organism into New Zealand.

6) Estimate the likely annual volume of trade (may not be readily available).

Some examples of appropriate titles for a risk analysis include:

Bilateral risk analysis

- Import risk analysis: fresh or frozen sheep semen (*Ovis aries*) imported from Australia.
- Import risk analysis: Lychee (*Litchi chinensis*) fresh fruit for consumption from Taiwan.

Multilateral risk analysis

- Import risk analysis: live cattle (*Bos taurus* or *Bos indicus* or crossbred animals derived from these species) imported from the European Union
- Import risk analysis: frozen Nile Perch (*Lates niloticus*) skinless, boneless fillets imported from Uganda, Kenya or Tanzania for human consumption.
- Import risk analysis: Polynesian plum (*Spondias dulcis*) fresh fruit for consumption from Fiji, Cook Islands and Samoa.

Generic risk analysis

- Import risk analysis: Foot and mouth disease (Family Picorniviridae, genus Apthovirus, Foot-and-mouth disease virus A, Asia 1, C, O, SAT 1, SAT 2, SAT 3)
- Import risk analysis: Live viral vaccines for administration by injection
- Import risk analysis: Sera for administration to animals
- Import risk analysis: Diagnostic agents of animal origin for use in a transitional facility
- Import risk analysis: Wood packaging material from all countries
- Import risk analysis: Used vehicles from all countries
- Import risk analysis: *Cordyline* and *Dracaena* fresh cut foliage from all countries

3.5.2 Choosing a qualitative or quantitative approach

No single method of import risk assessment has proven applicable in all situations, and different methods may be appropriate in different circumstances. A qualitative risk assessment is essentially a reasoned and logical discussion of the relevant commodity factors and epidemiology of a hazard where the likelihood of its entry and exposure and the magnitude of its consequences are expressed using non-numerical terms such as high, negligible or non-negligible. It is suitable for the majority of risk assessments and is, in fact, the most common type of assessment undertaken to support routine decision-making. In some circumstances it may be desirable to undertake a quantitative risk assessment, for example, to gain further insights into a particular problem, to identify critical steps or to compare sanitary measures. Quantification involves developing a mathematical model to link various aspects of the epidemiology of an organism or disease, which are expressed numerically. The results, which are also expressed numerically, invariably present significant challenges in interpretation and communication.

Regardless of which method is adopted it is important to appreciate that a risk assessment inevitably includes a degree of subjectivity. The personal opinions and perceptions of the analyst, experts and decision-makers are inescapable realities. Although a quantitative assessment involves numbers, it is not necessarily more objective, nor are the results necessarily more "precise" than a qualitative assessment. Choosing an appropriate model structure, which pathways to include or exclude, the level of aggregation or dis-aggregation, the actual values used for each input variable and the type of distribution applied to them all involve a degree of subjectivity. In addition, because data are lacking, some models incorporate expert opinion, which by its very nature is inevitably subjective.

Since both qualitative and quantitative assessments are inevitably subjective, how can a reasonable level of objectivity be attained? The solution lies, not in the method chosen, but in ensuring that the assessment is transparent. All the information, data, assumptions, uncertainties, methods and results must be comprehensively documented and the discussion and conclusions supported by a reasoned and logical discussion. The assessment should be fully referenced and subjected to peer-review.

3.5.2.1 Semi-quantitative methods

As discussed in the preceding section, all risk assessments inevitably include a degree of subjectivity. Semi-quantitative methods appear to be favoured by those who are concerned about subjectivity. Because many people find numbers seductive and reassuring, some analysts use so-called semi-quantitative methods in the mistaken view that they are somehow more "objective" than strictly qualitative techniques. However, a number of significant problems arise from adopting a semi-quantitative approach in an import risk assessment. It is sometimes employed as a means of combining various qualitative estimates, by assigning numbers to them, to produce a summary measure or to prioritise risks. The numbers may be in the form of probability ranges or scores, which may be weighted before being combined by addition, multiplication etc. The numbers, ranges, weights and methods of combination chosen are usually quite arbitrary and as a result, lack transparency. It is impossible to assign precise numbers unless a quantitative assessment has already been carried out. Semi-quantitative assessments often give a misleading impression of objectivity and precision and may not adequately reflect relativities, which can lead to inconsistent outcomes. Assigning numbers to subjective estimates does not result in a more objective assessment, particularly when the numbers chosen and their method of combination is arbitrary.

These issues may not be such a problem where the aim is to prioritise risks in a non-contentious environment so that decisions can be made, for example, on where to channel scarce resources. However, where the goal is to obtain a realistic estimate of risk, particularly in a contentious environment, such as import risk analysis, semi-quantitative methods offer no advantages over a well researched, transparent, peer reviewed qualitative assessment.

Essentially, semi-quantitative methods introduce an unnecessary level of complexity by apparently imposing a quantitative framework on a qualitative assessment. The best antidote for "too much subjectivity" is transparency, of which a vital ingredient is peer review. An adequately peer-reviewed risk assessment will minimise the impact of subjectivity as it will reflect the collective knowledge and wisdom of recognised specialists.

3.5.2.2 Dealing with incomplete information (uncertainty)

Incomplete information is often referred to as uncertainty in the context of a risk analysis. However, the way in which uncertainty has been described by risk analysts from a range of disciplines has led to a degree of confusion. To understand what is meant it is important to appreciate that risk analysis is essentially a tool aimed at helping to make an informed decision by attempting to predict the future. For example, we might want to predict the height of a person chosen at random. We know from our own observations that there is a great deal of natural variation between individuals. Such variability is an inescapable reality. While we might have a good "feel" for its range and what an average might be, it is only by

measuring several people that we can begin to make some accurate predictions. As more data are collected, more knowledge is acquired, and we can describe the variation in people's heights with increasing certainty, enabling us to be increasingly confident of our predictions. If we measured everybody in the population we would have a perfect understanding of the average height and how much variation exists. Obviously, this is impractical and we need to achieve a balance between acquiring perfect knowledge and obtaining reasonable estimates upon which we can base our predictions with a reasonable level of confidence. Uncertainty then may be thought of as a measure of the incompleteness of one's knowledge or information about an unknown quantity. It is important to remember that even with perfect knowledge, variability still exists.

These ideas can be extended to import risk analysis where, for example, we want to predict the likelihood of an outbreak of foot and mouth disease (FMD) following the importation of goats' cheese from country X. For an outbreak to occur a complex chain of events needs to take place leading from:

i) an outbreak of FMD in country X that results in at least one infected goat shedding FMD virus in its milk,
ii) the virus surviving pasteurisation, the cheese manufacturing process, storage and transportation,
iii) a susceptible animal ingesting discarded cheese in the importing country, becoming infected and passing it on to other animals.

There may be some very good information on the survival of FMD in pasteurised milk, some limited information on the occurrence of FMD in country X and virtually no information on the likelihood of susceptible animals ingesting cheese scraps in the importing country. A prediction in these circumstances will be based on information ranging from poor to excellent. As a result we could conclude that there is significant uncertainty in the estimates for the occurrence of FMD in country X and the exposure of susceptible animals in the importing country. The impact of these uncertainties on the overall estimate of risk needs to be carefully considered. For instance, the impact is likely to be insignificant if pasteurisation is predicted to effectively kill FMD virus. On the other hand, if pasteurisation cannot be relied upon because FMD virus is either heat tolerant or there is significant variability in its effectiveness, the impact of these uncertainties becomes much more important.

Where there is significant uncertainty in the estimated risk, a precautionary approach to managing risk may be adopted. However, the measures selected must nevertheless be based on a risk assessment that takes account of the available scientific information. In these circumstances the measures should be reviewed as soon as additional information becomes available[10] and be consistent with other measures where equivalent uncertainties exist. It is not acceptable to simply conclude that, because there is significant uncertainty, measures will be selected on the basis of a precautionary approach. The rationale for selecting measures must be made apparent.

Biological pathways considered in the entry and exposure assessments must be ascertainable. Since it is very difficult or perhaps impossible to prove that a particular pathway does not exist, there will always be a degree of uncertainty. In some cases a pathway may be hypothetical rather than ascertainable. It is not appropriate to consider such pathways in a risk assessment.

10 Article 5.7 of the SPS Agreement states that "a Member may provisionally adopt sanitary …. measures" and that "Members shall seek to obtain additional information …. within a reasonable period of time." Since the plural noun "Members" is used in reference to seeking additional information a co-operative arrangement is implied between the importing and exporting country. That is the onus is not just on the importing country to seek additional information.

3.5.3 Developing Risk Criteria

Risk Criteria is defined in the Australia/New Zealand Standard AS/NZS 4360:2004 as "*threshold or other decision rule by which the significance of risk is assessed to determine whether risk treatment actions are recommended*". This standard goes on to say:

> "Decisions concerning whether risk treatment is required may be based on operational, technical, financial, legal, social, humanitarian or other criteria. These often depend on an organisation's internal policies, goals and objectives and the interests of stakeholders. Criteria may be affected by the perceptions of stakeholders and by legal or regulatory requirements. It is important that appropriate criteria be determined at the outset."

Within the Biosecurity New Zealand risk analysis framework for determining appropriate measures (Chapter 4), risk attributes are considered as being either "negligible" or "non-negligible". Where possible descriptors should be used to describe the comparative levels of the critical risk attributes to aid in the communication of the nature of the risk to the decision maker and stakeholders. Apart from the exception provided below, the risk criteria to be used are provided in table 3.2.

Table 3.2: Descriptors for critical attributes of risk

Risk Attributes	
Negligible	Not worth considering; insignificant
Non-negligible	Worth considering; significant
Risk Descriptors (not all may be used)	
Very Low	Close to insignificant
Low	Less than average, coming below the normal level
Medium	Around the normal or average level
High	Extending above the normal or average level
Very High	Well above the normal or average level

The exception occurs when assessing the level of consequences of a potential hazard in risk assessment (Section 4.3).

To inform processes external to risk assessment, namely prioritising processes in measures review and the development of response plans, hazards that could potentially result in a consequence of sufficient magnitude to warrant consideration for measure review or the development of response plans need to be identified. These hazards are deemed *high consequence* hazards if they meet the following criteria:

> A *high consequence* hazard is considered likely to cause an unwanted impact to people, the New Zealand environment[11], or the New Zealand economy of sufficient magnitude that should it become established in New Zealand either eradication would be attempted or other active response options (e.g., contain/exclude or control) would be implemented if eradication was deemed inappropriate.

11 The New Zealand environment includes ecosystems and their constituent parts, including people and their communities; and all natural and physical resources; and amenity values; and the aesthetic, cultural, economic, and social conditions that affect or are affected by any matter referred to above.

3.5.4 Ensuring Adequate Project Transparency

To facilitate the understanding of a risk analysis and to ensure that the reasons for the conclusions reached and recommendations made are obvious, it is essential that it is transparent. The analysis must be well documented and supported with references to the scientific literature and other sources of information, including expert opinion. It must provide a reasoned and logical discussion that supports the conclusions and recommendations. There must be comprehensive documentation of all data, information, assumptions, methods, results, and uncertainties. Transparency ensures:

- fairness and rationality
- consistency in decision making
- ease of understanding by all the interested parties
- assumptions are documented
- uncertainties are dealt with appropriately
- reasons for conclusions and recommendations are obvious
- stakeholders are provided with clear reasons for the imposition of measures.

3.5.5 Ensuring the analysis is relevant and as simple as possible

To facilitate risk communication it is essential to ensure that the risk analysis focuses on information directly relevant to the logic chain of the analysis. Each organism or disease should be discussed only to the extent necessary to enable the reader to gain an appreciation of likelihood of entry, establishment or spread of hazard(s) and of their associated potential consequences. If, for example, it is concluded that the likelihood of a hazard entering New Zealand is negligible, there is no need to undertake an exposure, establishment and consequence assessment and explore risk management options. It is not necessary to offer detailed description of clinical syndromes, pathology, treatments etc., unless these have a direct bearing on the likelihood of detecting infested commodities or organisms, or managing disease or organism risks.

For some commodities, as soon as a risk assessment is completed for a particular hazard and measure(s) proposed, for example some form of processing such as cooking or kiln drying, there may be no need to undertake a full risk assessment for the other potential hazards. In these circumstances an assessment of the efficacy of the proposed measure(s) on the other potential hazards might be all that is required.

3.6 Monitoring and Review of Risk Analyses

The risk analysis should be based on the best available information that is in accord with current scientific thinking and be amenable to updating when additional information becomes available. As researchers develop improved diagnostic tests, or formulate new insights into the epidemiology of specific pests or diseases, conclusions of risk assessments, or recommendations for risk management may no longer be completely appropriate, and should be revised. As risk is always proportional to the volume of commodity traded, risk assessments may need to be revised if the volume of trade is greater or less than projected in

the original assessment. The same scientific rigour that applied to the original risk analysis should apply to its revision.

Under the *International Plant Protection Convention* the principle of "modification" states: "As conditions change, and as new facts become available, phytosanitary measures shall be modified promptly, either by inclusion of prohibitions, restrictions or requirements necessary for their success, or by removal of those found to be unnecessary"[12]. Thus, the implementation of particular measures should not be considered to be permanent. After application, the success of the measures in achieving their aim should be determined by monitoring during use. This is often achieved by inspection of the commodity on arrival, noting any interceptions or any entries of the hazard organisms to the risk analysis area or any related hazard events within the risk analysis area. The information supporting the risk analysis should be periodically reviewed to ensure that any new information that becomes available does not invalidate the decision(s) taken.

Sources of such information should be monitored and new hazard/pathway associations recorded as they occur. The *World Organisation for Animal Health* publishes regular reports of changes in international disease status, as do many National Plant Phytosanitary Organisations for plant pests under the *International Plant Protection Convention*, and this information should be used to revise risk analyses, as appropriate. Other information sources include: internal database systems; various domestic or international email notification services (e.g. EPPO Reporting service, USDA pest alert); and appropriate scientific journals. New hazard associations or organism distributions, or changes in pathway characteristics (e.g. volume) should be assessed for potential risk against current measures to ensure existing measures are appropriate.

3.7 Project Close-Out Reporting

The main purpose of the project close-out report is to state the reason why the project is being closed and report on the performance against the various deliverables of the project. This is usually because the outputs have been delivered, the closing date has been reached and/or the budget has been expended, but may also be due to a change in policy or priorities, a loss of funding, or a deadline has been reached.

It is also an opportunity to describe the high- and low- lights of the project, any innovations used or developed by the project, and any lessons learned that may be of value to other projects with regard to people, process and deliverables.

The close-out report should also make a number of recommendations. One of the recommendations should be for the Sponsor or Business Owner (as appropriate) to agree that the project can be deemed closed; that the project has fulfilled all of the requirements as documented in the relevant Business Case and Project Management Plan; or, the Sponsor or Business Owner is satisfied that all outstanding items have been satisfactorily addressed or there is some other reason to close the project (e.g. unavailability of appropriate or adequate resourcing).

Further details and templates for project close-out reporting are provided as part of the Ministry of Agriculture and Forestry project management system.

12 ISPM Pub. No. 1: Principles of plant quarantine as related to international trade

4. The Risk Analysis Framework for Determining Measures

The Biosecurity New Zealand framework should be used for each risk analysis. As discussed in Section 1.6 it consists of:

i) Managing the risk analysis

ii) Hazard identification

iii) Risk assessment

iv) Risk management options

v) Risk communication and documentation

As "*Managing the risk analysis*" has been covered in Chapter 3, "*Risk communication*" covered in Section 3.4, and "*documentation*" will be covered in Chapter 5, these will not be considered further in any detail here. The following chapter will therefore look at the *Hazard identification*, *Risk assessment*, *Risk management options* steps, more commonly referred to as risk analysis.

4.1 Information Supporting a Risk Analysis

Information gathering and recording are activities that are usually carried out recursively throughout the risk analysis. Only information sufficient to reach a decision should to be gathered for each particular step, although during earlier stages of a risk analysis information may be collated for later stages of the analysis. As the analysis progresses, information gaps may be identified requiring further enquiries or research. Where information is insufficient or inconclusive expert judgement should be used if appropriate. Assumptions and uncertainties underpinning such judgements should be clearly stated at all stages of the risk analysis.

4.2 Reasons for Initiating a Risk Analysis

A risk analysis may be initiated for one of three reasons:

4.2.1 A Risk Analysis for a particular Organism or Disease

The need for a risk analysis on a specific recognized pest or disease may arise in situations such as:

- an established infestation or an outbreak of a new organism or disease is discovered within an exporting country or area;
- a new organism or disease is intercepted on an imported commodity;
- a new organism or disease risk is identified by scientific research;
- an organism or disease is introduced into an area;
- an organism or disease is reported to be more damaging in an area other than in its area of origin;
- a organism or disease is repeatedly intercepted;

- a organism or disease is proposed to be imported for research or other purpose;
- an organism is identified as a vector for other recognized unwanted organism or diseases;
- the risk associated with a recognised unwanted organism or disease is unclear.

In such cases, the hazard is known and the fact can be recorded in preparation for risk assessment. Where the risk analysis is specifically aimed at determining if measures should be developed for the pest or disease, the risk analysis process may progress immediately to the second stage of the risk analysis process (risk assessment).

4.2.2 A Risk Analysis for a Pathway

The need for a risk analysis on a specific pathway may arise in situations such as:

- international trade is proposed with a commodity not previously imported into New Zealand or a commodity from a new area of origin;
- a new organism is to be imported for selection and scientific research, and could potentially be hosts to biosecurity hazards;
- a pathway other than commodity import is identified (natural spread, packing material, mail, garbage, compost, passenger baggage etc.);
- a change in susceptibility or resistance of a host organism to an associated organism or disease is identified.

In these situations, the pathway is not itself the hazard; rather, the potential hazard is the organism or disease that may be carried by the pathway. The risk analysis should therefore proceed through the hazard identification stage.

4.2.3 A Risk Analysis for a Review or Revision of Measures or Policy

A need for a new or revised risk analysis may arise from situations such as:

- a national review of biosecurity regulations, requirements or operations;
- elaboration of an official control programme (e.g. certification scheme) to avoid unacceptable economic impact of specified unwanted organisms;
- evaluation of a regulatory proposal of another country or international organisation;
- possible introduction of a new system, process, procedures or new information that could influence a previous decision (e.g. a new treatment or loss of a treatment; new diagnostic methods);
- an international dispute on sanitary or phytosanitary measures;
- the biosecurity situation in New Zealand changes or political boundaries have changed.

In most of these situations the pest or disease is recognized, i.e. the biosecurity hazard is known and the fact can be recorded in preparation for risk assessment stage. Otherwise, the biosecurity hazard should be identified or confirmed.

4.3 Hazard Identification

Hazard identification is an essential step that must be conducted prior to a risk assessment where the hazard is not itself defined in the scope of the risk analysis (e.g. a pest risk assessment). To effectively manage the risks associated with imported risk goods, unwanted organisms or diseases which could be introduced by the risk goods into New Zealand and are capable of, or potentially capable of, causing unwanted harm must be identified. Such unwanted organisms and diseases are referred to as hazards by the *World Organisation of Animal Health*, and as "regulated pests" under the *International Plant Protection Convention*. For the purposes of these procedures the more common term of "hazards" will be used.

A hazard is any organism or disease that has the potential to produce adverse consequences. Under section 22 of the Biosecurity Act (1993)[13], a Chief Technical Officer must have regard to the following matters before recommending that an import health standard be issued:

> The nature and possible effect on people, the New Zealand environment, and the New Zealand economy of any organisms that the goods specified in an import health standard may bring into New Zealand.

The environment can be further defined as including ecosystems and their constituent parts, including people and their communities; and all natural and physical resources; and amenity values; and the aesthetic, cultural, economic, and social conditions that affect or are affected by any matter referred to above[13].

Each organism or disease should be dealt with separately with a reasoned, logical and referenced discussion of its relevant epidemiology including an assessment of its likely presence in the exporting country. A conclusion is then reached as to whether the risk good or conveyance under consideration is a potential vehicle for the introduction of the organism or disease into New Zealand. If it is, the organism or disease is classified as a potential hazard for further consideration in a risk assessment.

A risk analysis may be concluded if the hazard identification step fails to identify potential hazards associated with an imported risk good or conveyance. If an importing country applies the appropriate sanitary standards recommended by the *World Organisation of Animal Health*, or phytosanitary standards recommended under the *International Plant Protection Convention*, for a hazard organism or disease, there is also no need to conduct a risk analysis.

4.3.1 Assembling a list of potential hazards

A list of organisms and diseases likely to be associated with the pathway (i.e. associated with the commodity) should be assembled. The list may include organisms or diseases for which the biosecurity hazard is not clear. The list may be generated by any combination of:

- scientific and other literature searches;
- overseas and New Zealand experience of pathway/commodity and organism associations;

13 See Appendix 1 section 2.3.1 for further details

- national and international databases on interceptions/incursions;
- expert consultation;
- results from targeted survey (e.g. container, or other Border Monitoring Group or international surveys);
- requests for information from other countries or regions.

NOTE: When requesting information from other countries or region, requests should be as specific as possible and limited to information essential to the analysis. Occasionally countries may not respond to our requests for information and the risk analysis will have to proceed regardless. In these circumstances care will be taken to acknowledge any added uncertainty arising from the lack of country-derived information.

It is important to also consider organisms or diseases that might be associated with material that is contaminating the risk good, if that contaminating material can not be easily separated from the goods on import.

Before performing a new risk analysis, a check should be made as to whether the organism, disease, risk good or pathway has already been subjected to a risk analysis or some aspect of a risk analysis, whether nationally or internationally. The validity of any existing analysis should be checked as circumstances and information may have changed. Its relevance to the risk analysis area should be confirmed.

4.3.2 Generic criteria for determining potential hazards

When considering whether an identified organisms or disease should be included in the hazard list for a particular risk analysis, the following questions should be considered:

- Is the organism or disease associated with the commodity or conveyance?

  If the organism or disease will not be associated with the commodity or conveyance under consideration, it should not be consider a hazard. For example, gastro-intestinal parasites need not be considered in a risk analysis for semen or embryos as it is biologically implausible that these commodities would be a potential vehicle for such organisms. The methods of production, manufacturing or processing may also exclude certain categories of organisms. Highly processed commodities, such as live virus vaccines or hormonal products derived from sera are not likely to be contaminated with certain bacteria or viruses because of their method of production. Provided details of these production methods and a verifiable quality control program, that includes testing, are included as part of a commodity description, these organisms would not need to be considered individually in a risk analysis. Hitchhiker organisms can be included in this list if they have been recorded as being or could be considered likely to be associated with the commodity or conveyance.

- Is the organism or disease absent from New Zealand but likely to be present in the exporting country?

  An evaluation of an exporting country's relevant service (e.g. Veterinary Service for animal hazards or a National Plant Protection Organization for plant based hazards), surveillance and control programs and zoning and regionalization systems are important factors to consider when assessing the likelihood of hazards being present and associated with the risk good in the exporting country. They enable the exporting country to substantiate claims of organism or disease status and the importing country to establish and maintain confidence in such claims.

  If a country claims that it is free of a particular hazard, supporting evidence must be documented. In such cases the appropriate measure to be applied may be certification from the Veterinary Authority or National Plant Protection Organization in the exporting country that it is free of the hazard.

- Is the organism or disease present in New Zealand and likely to be present in the exporting country, and meets one of the following criteria?

- The organisms are vectors of pathogens or parasites, but whose populations in New Zealand are free of the pathogen or parasite of concern.

- The organisms have strains that do not occur in New Zealand, though the overall species does occur in New Zealand.

  A "strain" refers to any group of organisms considered to be of the same species but with different shared characteristics, which makes the group distinct to the currently occurring population at a sub-specific level. Measures to exclude strains may be necessary where the strains display different characteristics that may cause them to have greater or different consequences. This is justifiable under the World Trade Organization Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) and is an implicit requirement under the Biosecurity Act which arises through: (i) a Chief Technical Officer's obligation when recommending an import health standard to have regard to the effects of "organisms" (i.e. it doesn't refer to "species") (section 22(5)(b) BSA); and (ii) New Zealand's international obligations (s22(5)(c) BSA).

- The organisms differ genetically from those that occur in New Zealand in a way that may present a potential for greater consequences in New Zealand, either from the organism itself or through interactions with existing organisms in New Zealand.

  Examples of genetic differences potentially resulting in greater consequences would primarily related to strain differences already mentioned, but could also include the consequences of increasing genetic diversity in an otherwise monoclonal or low variability population. For example *Dothistroma pini*, a foliage disease of *Pinus* species, is represented by only one mating type in New Zealand. The reduced genetic variability, and lack of opportunity for genetic recombination, provides a relatively high level of predictability in the epidemiology of the disease in New Zealand. This predictability enables industry to more effectively manage the impacts of the disease on plantation forestry.

- The organisms or diseases are already in New Zealand however the nature of the imports would significantly increase the existing hazard.

  If the organism in its current habitat in New Zealand does not usually come into contact with people, and the infested imported goods (e.g. spiders on fresh produce) provide an exposure to people that is much greater than what normally occurs, then measures equivalent to those applied in New Zealand to mitigate the risk can be justified. For example, populations of red-back spiders (*Latrodectus hasselti*) were known to be present in New Zealand in areas where contact with people would be unlikely to occur (e.g. around Lake Te Anau). However, their arrival on bunches of imported grapes would greatly increase the exposure to people, and MAF therefore requires that adequate treatment of such commodities is carried out to mitigate this hazard.

- The organisms or diseases are already in New Zealand however their presence is geographically bounded.

  Such measures may be justifiable if the presence of the organism in New Zealand is geographically bounded and importation is taking the organism to areas in New Zealand where it is not known to occur. However, measures should not be greater than those taken to restrict the movement of the organism within New Zealand, as per our international obligations.

- The organisms or diseases have host associations different to those currently present in New Zealand.

  Measures against such organisms may be justifiable where there are clear differences in host associations between the one found in New Zealand and that in the country of origin. For example, MAF currently takes action against the fungus *Rhizoctonia solani* when imported on pine products, although the fungus is present in New Zealand. Experts have identified 12 different 'types' of *R. solani* based on host associations, only one of which is associated with *Pinus* spp. There are no records of *R. solani* on Pine species in New Zealand, and MAF consequently treats this organism as a potential hazard.

- The organisms or diseases have only minimal information available and as such should be considered a hazard at this stage, as the more detailed risk assessment process will determine the level of likely risk.

- The organisms or diseases have free zones or zones of low prevalence in New Zealand that are established under a national or regional pest management strategy or small-scale program and where the movement of host products into the zone is under statutory control.

- The organisms or diseases are listed on the unwanted organisms register as a notifiable organism.

Where categories of organisms are excluded, a description of the category and the rationale for their exclusion should be included as part of the hazard identification process. Diseases of unknown aetiology can be included in the hazard list if the causal agent of a particular set of symptoms has not as yet been fully identified and they have been shown to produce consistent symptoms and to be transmissible.

4.3.3 Presentation of hazard identification

Information gathering is particularly important at the hazard identification stage in order to clarify:

- the identity of the hazard;
- any hazard leading to a potential unwanted consequence.

In addition, other information on the organism may include:

- its geographical distribution;
- hosts and/or habitats;
- association with the commodity.

The source of information must be referenced correctly. The latest taxonomy and nomenclature should be used. An example of a hazard identification for a specific organism is provided in Plate 4.1. For the purposes of demonstration the risk analysis that the example in Plate 4.1 is based on can be assumed to be a generic import risk analysis for domestic horses (*Equus caballus*).

Plate 4.1: An example of hazard identification.

1 African horse sickness

1.1 Hazard identification

1.1.1 Aetiologic agent: Family *Reoviridae,* Genus *Orbivirus,* African horse sickness viruses 1 to 10

1.1.2 OIE: List A

1.1.3 New Zealand's status: African horse sickness (AHS) has never been reported in New Zealand and is classified as an exotic disease.(1)

1.1.4 Epidemiology

African horse sickness (AHS) is an infectious non-contagious disease of horses and other Solipeds (Order *Perissodactyla*) caused by an *Orbivirus* and transmitted by *Culicoides* midges (Lagreid, 1996). There are nine known serotypes all of which may cause significant mortality in horses (Coetzer and Eramus, 1994). It is endemic in tropical East and West Africa, from where it regularly spreads to southern, and occasionally, northern Africa ((Coetzer and Eramus, 1994; Anonymous, 1995). AHS occurs seasonally and is influenced by climatic conditions favouring the breeding of *Culicoides* midges (Anonymous, 1997; Mellor and Wellby, 1998. Most horses are infected between sunset and sunrise when *Culicoides* midges are most active ((Coetzer and Eramus, 1994).)

There are four classical forms of AHS: pulmonary, cardiac, mixed and horse sickness fever. The pulmonary form has a short incubation period, ranging from 3 to 5 days, and a marked and progressive respiratory involvement leading to death in more than 95% of cases within 4 to 5 days. The incubation period for the cardiac form varies from 7 to 14 days, followed by clinical disease lasting for 3 to 8 days with death in 50% to 70% of cases. The mixed form is characterised by a combination of respiratory and cardiac involvement with an incubation period and mortality rate roughly halfway between the pulmonary and cardiac forms. Horse sickness fever is the mildest form and is frequently overlooked in natural outbreaks. The incubation period varies from 5 to 14 days and is followed by a low grade fluctuating fever lasting for 5 to 8 days. All affected animals recover. This form of the disease is usually observed in immune animals infected with a heterologous virus type or in resistant species, such as the donkey and zebra. Horses are the most susceptible equine species, followed by mules, while most infections in donkeys and zebras are subclinical (Lagreid, 1996; Anonymous, 1996). In view of the high mortality rate in horses, this species is regarded as an accidental or indicator host (Coetzer and Eramus, 1994).

The virus is present in all body fluids and tissues from the onset of fever until recovery. Viraemia in horses is of variable duration, typically lasting for 4-8 days, but no longer than 21 days, while in donkeys it may last up to 28 days (Anonymous, 1995). Horses that recover from AHS do not remain carriers. Survivors develop a strong immunity to the particular serotype with which they were infected. While this may confer some cross-protection to infection with other serotypes, a strong challenge may overcome it (Coetzer and Eramus, 1994).

Two types of vaccine are most commonly used: a polyvalent or monovalent live vaccine and an inactivated monovalent vaccine (Anonymous, 1996). While both types of vaccine provide protection against clinical disease, vaccinated animals may still develop a viraemia sufficiently high enough to infect vectors. Problems remain with some live vaccines reverting to virulence although the opportunity to escape the host would be limited as the viraemia associated with a live vaccine is likely to be of a similar duration to that occurring in a natural infection. Subunit vaccines which are being developed offer the most effective means of inducing protective immunity. They are not subject to reversion or vector transmission (Lagreid, 1996).

1.1.5 Conclusion

While domestic horses that recover from infection do not remain carriers, horses that are either naturally infected or vaccinated with a live vaccine may be viraemic for up to 21 days and therefore potential vehicles for AHS virus. As a result AHS virus is classified as a potential hazard.

A summary list of potential hazards such as that provided in Table 4.1 may be created to be included in the executive summary or as an Appendix to the risk analysis.

Table 4.1: An example of a template of a list of potential hazards. The rationale for classifying each hazard according to the criteria and the conclusion reached must be supported by a referenced discussion as above. (y = yes, n = no, *n/a* = not applicable).

Common name	Scientific name	In NZ?	Vector of a hazard	More virulent strains on goods overseas	Genetic difference may cause greater consequence	In NZ but association with goods increases hazard	In NZ but geographically bounded	In NZ but has different host associations	No or little information on organism	Under official control or notifiable	Potential hazard
Foot & mouth disease	Family *Picorniviridae*, genus *Apthovirus*, FMD virus A, Asia 1, C, O, SAT 1, SAT 2, SAT 3	N	N	*n/a*	*n/a*	*n/a*	*n/a*	*n/a*	N	*n/a*	Y
African horse sickness	Family *Reoviridae* Genus *Orbivirus* African horse sickness viruses 1 to 10	N	N	*n/a*	*n/a*	*n/a*	*n/a*	*n/a*	N	*n/a*	Y
Bovine tuberculosis	*Mycobacterium bovis*	Y	N	N	N	N	N	N	N	Y	Y
Newcastle disease	Family *Paramyxoviridae* genus *Paramyxovirus* Avian PMV 1	N	N	*n/a*	*n/a*	*n/a*	*n/a*	*n/a*	N	*n/a*	Y
Enzootic bovine leucosis	Family *Retroviridae* genus "*blv-htlv retroviruses*" type species bovine leukemia virus	Y	N	N	N	N	N	N	N	N	N
Infectious bovine rhinotracheitis	Family Herpesviridae Subfamily *Alphherpesvirinae* Genus *Varicellovirus* bovine herpesvirus 1 (BoHV-1)	Y	N	y	N	N	N	N	N	N	Y
Johne's disease	*Mycobacterium paratuberculosis*	Y	N	N	N	N	N	N	N	N	N
Biting midges	*Culicoides spp*	N	N	*n/a*	*n/a*	*n/a*	*n/a*	*n/a*	N	*n/a*	Y
Salmonellosis	*Salmonella enterica* subsp. *Enterica*" serovar Typhimurium DT 104	Y	N	N	N	N	N	N	N	Y	Y
-	*Zucchini yellow mosaic virus*	N	N	*n/a*	*n/a*	*n/a*	*n/a*	*n/a*	N	*n/a*	Y
Cotton aphid	*Aphis gossypii*	Y	Y	N	N	N	N	N	N	N	N
Leaf spot	*Fusarium oxysporum*	Y	N	Y	N	N	N	N	N	N	Y
Red-back spider	*Latrodectus hasselti*	Y	N	N	N	Y	Y	N	N	N	Y
Rhizoctonia leaf blight	*Rhizoctonia solani*	Y	N	N	N	N	N	Y	N	N	Y
Needle blight	*Dothistroma pini*	Y	N	N	Y	N	N	N	N	N	Y

4.3.4 Hazard Scoping

The hazard scoping step looks at the list of hazards together with other aspects of the project that may already be determined, and attempts where possible to establish a mechanism to reduce the extent of effort required to undertake the risk assessment stage of the project. Hazard scoping also determines the type of risk assessment that will be applicable to the project and the hazards.

4.3.4.1 Mechanisms for grouping hazards

The following table (Table 4.2) provides a number of methods that may be used to group hazards and avoid unnecessary duplication of effort in the assessment stage of the project. What is both consistent and critical to each of the methods is that organisms within each group of hazards share a set of biological traits that provide a common risk profile appropriate to the grouping. If a common risk profile can not be established with any confidence between the identified hazards, grouping of hazards would not be appropriate. The rationale for grouping the hazards should be documented along with any assumptions supporting the grouping.

Table 4.2: Potential methods for grouping hazards

Group type	Description
Available Measures	If it has been determined in the scoping of the project that only a few measures options are available to the analysis, the critical characteristics of these measures in terms of applicability to a particular set of biological traits of the target hazard can form the basis of the groupings, e.g. if area freedom and visual inspection and sterilising heat treatment are the only measures options available, hazards could be grouped as follows: a) Not in export area; b) Can be detected on inspection; c) Neither of the first two options.
Use of a Higher Classification	In instances where there is insufficient information about organisms or groups of organisms to allow an adequate assessment of risks to be undertaken, the organism or group of organisms can be grouped together with a representative organism or group of organisms with sufficient information. It must be expected that the representative organism would have similar risk attributes to the organisms with insufficient known information.

4.3.4.2 Determining which type of risk assessment is applicable

Once the risk analysis has been scoped and potential hazards identified the type of risk assessment that is applicable can be determined. The *Agreement on the Application of Sanitary and Phytosanitary Measures*[14] defines two types of risk assessments, a disease or pest risk assessment and a food safety risk assessment. In some situations both types of risk assessment may be applicable. Table 4.3 provides a guide to the type of risk assessment required, the responsible government department and applicable legislation.

Since the Biosecurity Act (1993) is only concerned with the risks associated with hazard-causing organisms[15], the risks associated with additives, contaminant or toxins need to be considered under different legislation. For animal feeds the relevant legislation is the

14 See Appendix 2 section 2.4.1 for further details.
15 See Appendix 2 section 2.2 for further details.

Agricultural Compounds and Veterinary Medicines Act (1997)[16], while for food intended for human consumption the applicable legislation is the Food Act (1981) and the Food Regulations (1984)[17].

Table 4.3: Which type of risk assessment is applicable? (BNZ) Biosecurity New Zealand; (NZFSA) New Zealand Food Safety Authority; (MoH) Ministry of Health; (ACVMA) Agricultural Compounds and Veterinary Medicines Act (1997); (BSA) Biosecurity Act (1993); (FA) Food Act (1981); (HTA) Human Tissues Act (1964); (HART) Human Assisted Reproductive Technology Act (2004).

Commodity	Type of risk assessment, responsible department and applicable legislation	
	Disease or pest risk assessment	**Food safety or human health risk assessment**
1. Animals or products of animal origin		
Live animals for breeding	BNZ (BSA)	
Live animals for slaughter	BNZ (BSA)	NZFSA (BSA, FA)
Genetic material: in-vitro and in-vivo derived embryos, semen, brood-combs of bees and hatching eggs	BNZ (BSA)	
Animal products for human consumption	BNZ (BSA)	NZFSA (BSA, FA)
Animal products for animal feeding	BNZ (BSA, ACVMA)	
Animal products for pharmaceutical or surgical use	BNZ (BSA)	
Animal products for agricultural or industrial use	BNZ (BSA)	
Biological products: for example, includes sera, inactivated or live vaccines and microbial genetic material	BNZ (BSA)	
Pathological material (non-human)	BNZ (BSA)	
Biological products and pathological material of human origin.		MoH (HTA, HART)
2. Plant or products of plant origin		
Feedstuffs for animal consumption e.g. grains, meals derived from grains	BNZ (BSA)	NZFSA (ACVMA)
Plant products for human consumption	BNZ (BSA)	NZFSA (ACVMA)
Live plants or plant parts for cultivation	BNZ (BSA)	
Plant products not for consumption	BNZ (BSA)	
3. Inanimate objects or non-descript organic material		
Water, soil, earth and organic matter	BNZ (BSA)	
Inanimate objects e.g. steel, plastic, tires	BNZ (BSA)	

4.3.5 Summary of Hazard Identification

Each organism should be dealt with separately with a reasoned, logical and referenced discussion of its relevant epidemiology including an assessment of its likely presence in the exporting country. A conclusion is then reached as to whether the commodity under consideration is a potential vehicle for introduction of the organism/disease into the importing country. If it is, the organism is classified as a hazard for further consideration in the risk analysis. Although less desirable than individual examination, where due to large numbers, organisms are to be considered in groups, the same process should be followed for each group. Depending on factors such as the nature of the commodity, the degree of processing, or method of storage and transport some organisms may be excluded from further consideration.

16 See Appendix 2 section 2.3.2 for further details.
17 See Appendix1 section 2.2.3 for further details.

4.4 Risk Assessment

A risk assessment evaluates the likelihood and the biological, environmental, human health, and economic consequences of the entry, establishment and exposure of a potential hazard to New Zealand. The aim is to identify hazards which present an unacceptable level of risk, for which risk management measures are required. A risk assessment consists of four inter-related steps:

v) Assessment of likelihood of entry

vi) Assessment of likelihood of exposure and establishment

vii) Assessment of consequences

viii) Risk estimation

These steps will be considered in more detail in the following sections. In each case a generic method, applicable to all types of risk analysis, is followed by guidance on factors to consider. The list of factors is not comprehensive and not all factors will be applicable in all cases.

A decision will need to be made on a case by case basis, whether it is more appropriate to complete the consequence assessment before assessing the likelihood of entry, exposure and establishment. In cases such as a pest risk analysis for an internationally recognised pest with clear adverse human, plant or animal health, environmental or socioeconomic consequences, it will not be necessary to assess the consequences in detail, a summary will suffice. It will generally be appropriate to provide this before undertaking an analysis of the likelihood of entry, exposure and establishment.

In the case of an import risk analysis, the commodity under consideration, which may act as a vehicle for a potential hazard, must be evaluated in the form that it is intended to be used, processed or sold when imported into New Zealand. In all cases care should be taken to ensure the assessment only considers risks and information relevant to the scope of the project.

4.4.1 Entry assessment

The aim of this step is to assess the likelihood of movement of a potential hazard from its country of origin into a risk analysis area via an imported commodity, pathway or conveyance. An entry assessment is equivalent to a release assessment in *World Organisation of Animal Health* terminology, and assessment of the probability of introduction in *International Plant Protection Convention* terminology (see Section 1.6).

Each potential hazard or group of hazards should be dealt with separately with a reasoned, logical and referenced discussion of its relevant epidemiology and/or biology to:

i) describe the biological mechanisms necessary for a commodity or pathway to become infected, infested or contaminated,

Note: A scenario tree provides a useful conceptual framework to assist in identifying and describing biological pathways. Figure provides an example for African horse sickness.

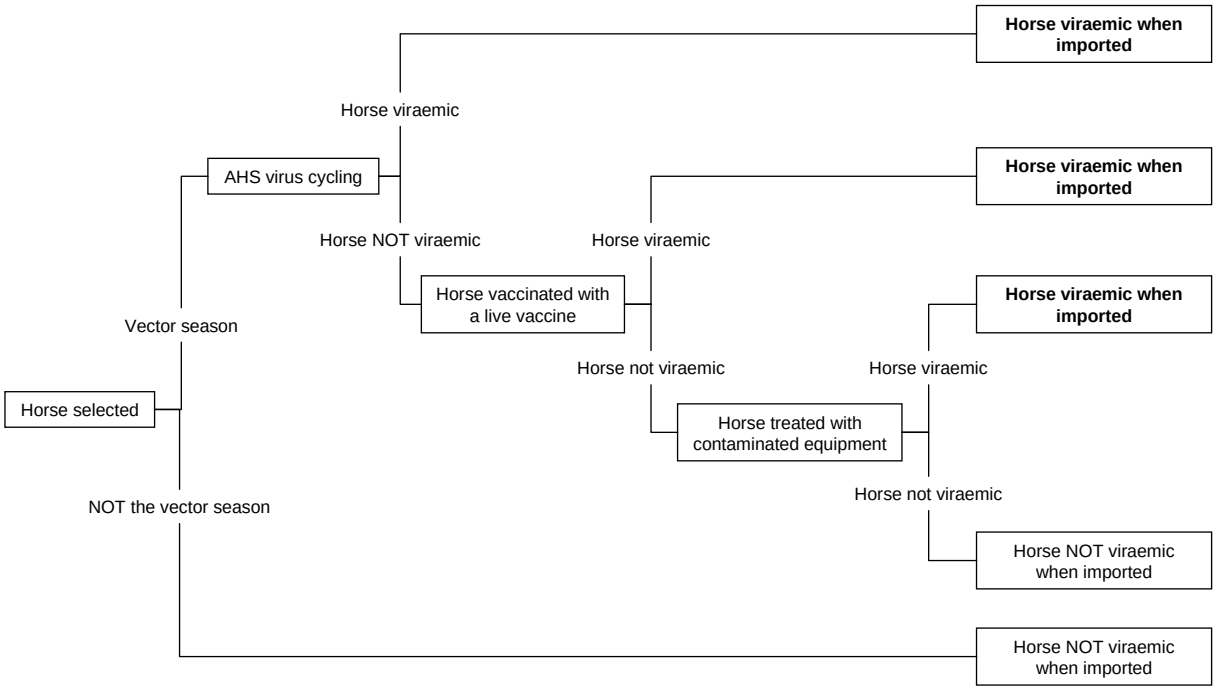
ii) estimate the likelihood of a commodity or pathway being infected, infested or contaminated when imported into New Zealand i.e. the likelihood of the potential hazard surviving transport and storage

In the case of a single species pest risk assessment this step will also involve pathway identification. Each of the pathways or commodities with which the potential hazard may be associated within the scope of the assessment, from its origin to its establishment in New Zealand, will need to be assessed. Pathways may be identified in relation to the geographical distribution and host range of the hazard. Interception data may provide evidence of the ability of a potential hazard to be associated with a pathway and to survive in transport or storage.

A scenario tree outlining the biological pathways necessary for the entry of the organism or disease under consideration should be developed (see Figure 4.1 for an example). For a pathway-based assessment the scenario tree may be common for all the identified hazards and can be provided in the introduction to the analysis. For organism-based assessments that include a number of different pathways, a scenario tree may need to be developed for each individual pathway.

A conclusion should be stated on the likelihood of entry of each potential hazard or in the case of a pest risk analysis, along each potential pathway. The risk analysis may be concluded at this point if the likelihood of the potential hazard being able to enter into New Zealand is negligible.

Figure 4.1: A scenario tree for an entry assessment outlining the biological pathways necessary for a horse to become infected and harbour with African horse sickness virus when imported.



4.4.1.1 Possible factors to consider during entry assessment

The following are provided as a guide to what factors could be considered during an entry assessment:

a) Biological factors:

- susceptibility of a commodity or pathway to infection or contamination by the potential hazard;
- means of transmission of the potential hazard;
  - horizontal transmission
    - direct (contact, airborne spread, ingestion, coitus)
    - indirect (mechanical and biological vectors, intermediate hosts)
  - vertical transmission (from an infected female to a foetus or egg)
- infectivity, virulence, stability or reproductive strategy of the potential hazard;
- demographics of the potential hazard;
- outcome of infection or contamination (sterile immunity, incubatory or convalescent carriers, latent infection);
- in the case of diseases, routes of infection (oral, respiratory, percutaneous etc) and predilection sites of the potential hazard.

b) Country of origin factors:

- incidence and prevalence of hazard in the country of origin (annually or seasonally);
- evaluation of the exporting country's pest and disease management systems, including surveillance;
- seasonal timing;
- existence of hazard -free areas and areas of low hazard prevalence in the exporting country.

c) Commodity/pathway factors:

- ease of contamination;
- effect of relevant processes (e.g. refrigeration) and production methods in the country of origin, country of destination, or in transport or storage;
- volume and frequency of movement of commodity to be imported along the pathway;
- speed and conditions of transport and duration of the life cycle of the hazard in relation to time in transport and storage;
- vulnerability of the life-stages during transport or storage.

For the sake of durability of the risk analysis, the entry assessment should ignore any hazard management measures such as vaccination, testing, treatment and quarantine in the country

of origin or within New Zealand, as these may change over time. Similarly cultural and commercial procedures applied at the place of origin should not be considered as part of the entry assessment. However, all such measures should inform the assessment of risk management options. Plate 4.2 provides an example of a release assessment for African horse sickness virus.

Plate 4.2: An example of a release assessment for African horse sickness virus.

Risk assessment

Entry assessment

Since infections occur seasonally in the endemic areas of Africa (Coetzer and Eramus, 1994; Anonymous, 1997; Mellor and Welby, 1998) the likelihood of a horse incubating AHS or being viraemic when imported increases during summer and autumn. In South Africa, for instance, AHS occurs every summer in the northern provinces, with the first cases occurring in February. The disease spreads southwards over the next few months, with the epidemic stopping abruptly in late April or early May after the first frosts (Coetzer and Eramus, 1994). There may be several months during the drier or cooler times of the year when vectors are inactive and horses are unlikely to become infected. Provided such periods can be sufficiently well defined, and an allowance made for the maximum duration of viraemia in horses that become infected late in the season, there may be a window of opportunity when the likelihood of a horse incubating AHS or being viraemic when imported is negligible.

Domestic horses are most likely to be transported to New Zealand by air. Travel times are likely to be short, perhaps less than 24 hours. In such circumstances it is likely that a viraemic horse, particularly one that has been vaccinated or suffering from horse sickness fever, characterised by a low grade fluctuating fever, or in the pre-clinical incubatory phase of AHS, would be imported into New Zealand.

Conclusion

If a horse is exported to New Zealand during the winter and spring months from the endemic areas in Africa there is a negligible likelihood of it carrying AHS virus. For other times of the year the likelihood of a horse harbouring AHS virus is non-negligible.

4.4.2 Exposure and Establishment Assessment

The aim of this step is to assess the likelihood of the potential hazard or group of hazards, having entered a risk analysis area, becoming established in it, and/or having the potential to cause an adverse consequence. A potential hazard may cause an adverse consequence without necessarily being established, for example, spiders on grapes can adversely affect vulnerable consumers. Each potential hazard, group of hazards, or, in the case of a pest risk analysis, each pathway, should be dealt with separately with a reasoned, logical and referenced discussion of its relevant epidemiology and/or biology to:

i) describe the biological mechanisms necessary for the potential hazard to become established;

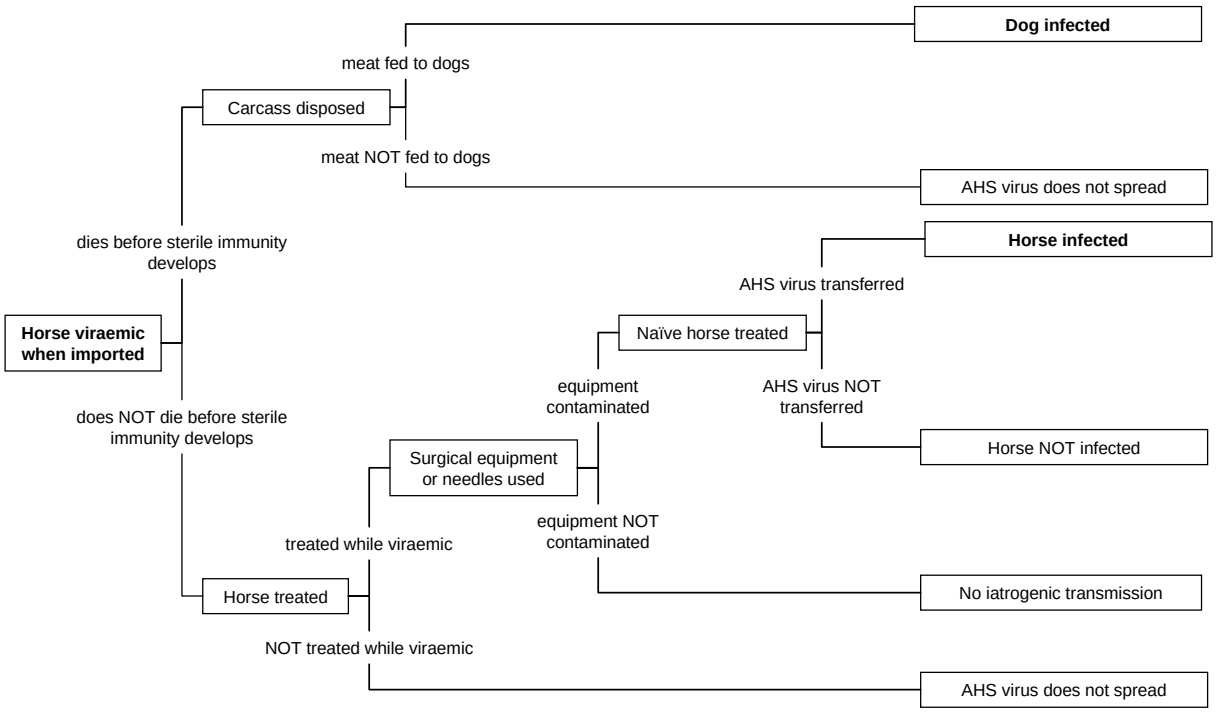
ii) describe the mechanism for the exposure of the environment or other receptors in New Zealand to the potential hazard;

iii) estimate the likelihood of establishment and/or exposure occurring.

A scenario tree outlining the biological pathways necessary for the exposure and establishment of the organism or disease under consideration should be developed (see Figure 4.3 for an example). For a pathway-based assessment this exposure and establishment scenario tree may be common for all the identified hazards and can be provided in the

introduction to the analysis. For organism-based assessments that include a number of different pathways, a scenario tree may need to be developed for each individual pathway.

Figure 4.3: A scenario tree for the exposure assessment outlining the biological pathways necessary for susceptible animals to become infected with African horse sickness virus in New Zealand



It is difficult to predict how an organism or disease will behave in a new environment, and the environmental characteristics within which an organism or disease lives in its natural ranges may not equate to its environmental tolerance in new areas of establishment. Case histories concerning comparable hazards may be considered and expert judgement may be required to facilitate the risk assessment.

A conclusion should be stated on the likelihood of exposure and establishment of each potential hazard, group of hazards or pathway. The risk analysis may be concluded at this point if the likelihood of establishment and exposure in New Zealand is negligible.

4.4.2.1 Possible factors to consider during an exposure and establishment assessment

The following are provided as a guide to what factors could be considered during an exposure and establishment assessment:

a) Biological factors:

- means of transmission of the potential hazard from the commodity or pathway to a suitable host or environment;
  - horizontal transmission
    - direct (contact, airborne spread, ingestion, coitus, water splash)
    - indirect (mechanical and biological vectors, intermediate hosts)
  - vertical transmission

- in the case of diseases, route of infection (oral, respiratory, percutaneous etc) and outcome of infection (sterile immunity, incubatory or convalescent carriers, latent infection);
- infectivity, virulence or reproductive strategy of the potential hazard. Characteristics, which enable the potential hazard to reproduce effectively in the new environment, such as parthenogenesis/self-crossing, duration of the life cycle, number of generations per year, resting stage etc., should be identified;
- adaptability and stability of the potential hazard;

  Identify whether the potential hazard is polymorphic and the degree to which it has demonstrated the ability to adapt to conditions like those in the risk analysis area, for instance by becoming established elsewhere outside its natural range. Genotypic and phenotypic variability facilitates a hazard's ability to withstand environmental fluctuations, to adapt to a wider range of habitats, and to overcome host resistance. Similarly organisms with generalised habitat preferences, unspecialised diets and behaviours, and non-migratory habit are more likely to be able to adapt to a new environment.
- demographics of the potential hazard;
- minimum population needed for establishment - If possible, the threshold population that is required for establishment should be estimated;
- susceptibility of the environment likely to be exposed to the potential hazard, to adverse impacts such as infection/infestation, predation, competition or hybridization.

b) Risk Analysis Area factors

- presence of potential hosts including intermediate or alternate hosts, vectors or habitats and how abundant or widely distributed they may be;
- geographical and environmental characteristics including rainfall, soil and temperature;

  Climatic modelling systems may be used to compare climatic data on the known distribution of a potential hazard with that in the risk analysis area. It is necessary to bear in mind that the environmental characteristics within which an organism lives in its natural ranges may not equate to its environmental tolerance – it may be able to live within significantly broader habitat parameters. It should be noted that the environment is likely to have different effects on the potential hazard, its host and its vector. This needs to be recognised in determining whether the interaction between these organisms in the area of origin is maintained in the risk analysis area to the benefit or detriment of the hazard. The likelihood of establishment in a protected environment, e.g. in glasshouses, should also be considered.
- presence of potential competitors or predators which could reduce the likelihood of establishment.

c) Commodity/pathway factors

- intended use of the commodity (e.g. for planting, processing or consumption);
- unintended use of the commodity (e.g. wood packaging used for fencing);
- quantity of commodity to be imported on a pathway or pathways;
- proximity of entry, transit and destination points to suitable hosts or habitats;
- likelihood of repeated introductions maintaining a permanent non-breeding population of the potential hazard;

- waste disposal practices- risks from by-products and waste;
- time of year at which import or entry takes place.

Control programmes for other organisms which may hinder the establishment of the potential hazard should be considered at the risk management stage of the analysis. Pests for which control is not feasible should be considered to present a greater risk than those for which treatment is easily accomplished. Plate 4.3 provides an example of an establishment and exposure assessment for African horse sickness.

Plate 4.3: An example of an establishment and exposure assessment for African horse sickness.

Exposure assessment

AHS virus is probably maintained in an endemic cycle between *Culicoides* midges, principally *C. imicola*, and an as yet unidentified mammalian reservoir host (Anonymous, 1997a; Mellor and Welby, 1998). However, serological evidence indicates that zebras may be the most likely reservoir (Lagreid, 1996; Barnard, 1993). Although the mosquitoes, *Aedes aegypti*, *Culex pipiens* and *Anopheles stephensi*, biting flies and the dog tick, *Rhipicephalus sanguineus*, have been demonstrated to transmit AHS virus experimentally, *C. imicola* is the only recognised natural vector (Coetzer and Eramus, 1994; Anonymous 1995; Radostits et al, 1974). Although *C. imicola* occurs across Europe and the Mediterranean, AHS has failed to become established outside Africa despite several outbreaks in the Middle East, Spain and Portugal. These outbreaks were associated with the movement of either infected hosts or vectors (Lagreid, 1996). Although it is not understood why AHS did not establish in these areas (Lubroth, 1992), likely reasons include the absence of a suitable reservoir host and large scale vaccination programs.

AHS can be readily transmitted by the parenteral injection of infected blood, particularly by the intravenous route (Coetzer and Eramus, 1994, Anonymous, 2000).

In addition to Solipeds, the vertebrate host range is potentially quite large with antibodies being recorded in camels, goats, sheep, cattle, buffalo, elephants and dogs (Lubroth, 1992). Apart from dogs, which may contract a fatal form of the disease after ingestion of infected horsemeat, the other species appear to be resistant to disease (Laegrid, 1996). As *Culicoides* midges do not usually feed on dogs, dogs probably play no role in the spread of AHS virus. Pigs, cats and monkeys are refractory to infection (Coetzer and Eramus, 1996). Humans are apparently not susceptible to field strains of the virus, although some vaccine strains can cause encephalitis and retinitis following transnasal infections (Anonymous, 1996).

Even if an incubating carrier or a viraemic animal was to be imported into New Zealand, AHS would not become established because *Culicoides* midges, recognised as the only natural vectors, do not occur in this country. Furthermore, it is more than likely that the unidentified reservoir host is restricted to Africa as AHS has never become established elsewhere, despite the presence of competent vectors and susceptible animals in Europe and the Mediterranean.

It is possible that semen collected from a viraemic donor might result in a limited outbreak, which would, however, be restricted to inseminated mares. Such a scenario is extremely unlikely as a stallion would normally be imported some time before the breeding season to allow it to settle in most likely more than the maximum period of viraemia. There is also a chance that AHS virus could be spread by iatrogenic transmission if direct blood transfer occurred during the viraemic period by practices such as needle sharing. However, given the value of imported animals and the ready supply of cheap disposable needles and syringes in New Zealand, such a risk would be very unlikely.

Conclusion

While there is a negligible likelihood of AHS becoming established in New Zealand, the likelihood of short term, limited spread from an imported horse harbouring AHS virus is non-negligible.

4.4.3 Consequence assessment

The aim of this step is to assess the potential consequences associated with the entry, exposure and establishment of the potential hazard or group of hazards, and to estimate the likelihood of such consequences occurring. In many cases it will include an assessment of

the likelihood of spread of the potential hazard within the risk analysis area. This can be used to estimate how rapidly a hazard's potential economic, societal and/or environmental impacts may be expressed. It also has significance if the potential hazard is liable to enter and establish in an area of low potential consequence and then spread to an area of high potential consequence. In addition it may be important in assessing risk management options when considering the feasibility of containment or eradication of an introduced hazard.

Detailed analysis of the estimated consequences is not necessary if there is sufficient evidence, or it is widely agreed, that the introduction of a hazard will have unacceptable consequences. In such cases, risk assessment will primarily focus on the likelihood of entry, establishment and exposure. It will, however, be necessary to examine impact factors in greater detail when the level of unwanted consequences is in question, or when the level of unwanted consequences is needed to evaluate the strength of measures used for risk management or in assessing the cost-benefit of exclusion or control.

The Biosecurity Act (1993)[18] requires that the nature and possible effect on people, the New Zealand environment, and the New Zealand economy be considered in developing risk management measures. It is important to appreciate that these matters can only be taken into account to the extent that they are affected by a potential hazard. As a result those effects not related to the potential hazard, for example the impact of cheaper goods on a particular industry or the economy in general, cannot be considered. A causal process must be identified linking the hazard to the potential impact.

The BSA's definition of the environment is very broad and includes a number of criteria, which may not be relevant to any individual risk analysis. Table 4.4 provides an indication of the relevance of the various criteria and how they may be dealt with.

Table 4.4: Environmental criteria from the Biosecurity Act (1993)

Environmental criterion	Comment
a) Ecosystems and their constituent parts, including people and their communities.	This applies to hazards that may have an adverse effect on domestic and indigenous organisms and habitats, as well as people. Consequences for human health should be specifically identified here. Impacts on habitats, such as fragmentation, change in community composition, and change in relationships between components may also be important. For instance, displacement of aquatic vegetation can be brought about by the consumption of plant material by herbivorous species, by the uprooting of macrophytes through digging for food or nesting sites, and by roiling and organic enrichment which increase turbidity and thus reduce light penetration and photosynthesis and the degradation of water quality.
b) All natural and physical resources:	
• Organisms of all kinds	• This applies to hazards that may have an adverse effect on domestic and indigenous organisms. Impacts may occur at the genetic, individual, population, community or ecosystem levels. Potential impacts on indigenous organisms include competition with organisms occupying the same ecological niche, predation, disease, hybridization, parasite or vector of parasite, fragmentation effects on food supply, shelter, breeding sites etc. Indigenous organisms of particular concern include those that occur only in New Zealand, threatened species; keystone species in particular indigenous habitats e.g. Kereru in Podocarp forests, manuka in regenerating forests; and international migratory species. Domestic species include commercially or culturally important species.
• The air, water, and soil in or on which organisms may live;	• This applies to hazards such as toxic algae, weeds or burrowing animals.
• Landscape and land forms;	• This applies to hazards such as weeds or herbivores, which can cause a change in vegetation cover. Impacts on nationally important landscapes in protected areas are of particular concern.

18 Section 22 part 5; of the Biosecurity Act (1993). Further information is provided in Appendix 2 section 2.2.

• Geological features; • Structures of all kinds; • Systems of interacting living organisms and their environment.	• This applies to hazards such as weeds or burrowing animals where they change the face of such features. • This applies to hazards such as termites that may cause structural damage to wooden buildings, including houses. • This applies to hazards that may have an adverse effect on whole ecosystem processes, such as the water cycle. For example wetland weeds can change evaporation rates and consequent flow regimes.
c) Amenity values.	This applies to hazards that may have an adverse effect on domestic and indigenous organisms or habitats and which may impact on peoples' perceptions of the pleasantness of a place and recreational opportunities. For example, the pleasure derived from visiting a wilderness area may diminish as the result of an avian disease that leads to a decline in native birds populations. It could also apply in situations where the habits of a proportion of the population are changed, for instance, when the supply of a socially important food is limited because of a pest or disease. A recent example of an organism with the potential to cause significant consequences to amenity values in New Zealand is *Didymosphenia geminata* (Didymo).
d) Aesthetic, cultural, economic and social conditions that affect or are affected by any matters (a) to (c).	These are relevant as some hazards may have an adverse effect on domestic production industries (increased control costs, loss of productivity, the demise of an industry due to loss of trade and flow on social and economic effects) and native animal and plant species (aesthetic and cultural effects due to their demise). Impacts on Maori cultural, spiritual, environmental and economic values will also need to be considered.

Each potential hazard or group of hazards should be dealt with separately with a reasoned, logical and referenced discussion to:

i) identify the likely spread within the risk analysis area;

ii) identify the potential biological, environmental, economic and human health consequences associated with the entry, establishment, and exposure of the potential hazard;

Note: A causal relationship must exist between exposure to a potential hazard and an adverse affect.

iii) estimate the likelihood of these potential consequences.

A conclusion of the consequences of the entry, establishment, and exposure of the potential hazards should be given. The areas of New Zealand where potential consequences may occur should be stated, as appropriate. Hazards for which the potential consequences are very high (high consequence hazards) should be flagged as such to assist in prioritising other work such as incursion response preparedness (see Section 3.5.3).

The risk assessment may be concluded at this point if potential consequences are not identified or the likelihood of the potential consequences is negligible.

4.4.3.1 Possible factors to consider during consequence assessment

The following are provided as a guide to what factors could be considered during an establishment and exposure assessment:

a) Direct consequences

- production and environmental consequences;
  - Effects of disease, including morbidity and mortality, sterile immunity, incubatory or convalescent carriers, latent infection;
  - predation, competition;
  - hybridisation;

- production losses;
- animal welfare.

- human health consequences
  - morbidity and mortality, sterile immunity, incubatory or convalescent carriers, latent infection);
  - toxicity, allergenicity.

b) Indirect consequences

- economic considerations;
  - control and eradication costs;
  - surveillance costs;
  - reduced tourism and loss of social amenity;
  - costs of environmental restoration;
  - additional health care costs;
  - potential trade losses (embargoes, sanctions, market opportunities).
- Environmental considerations;
  - amenity values;
  - effects on other species for instance those which utilise the species directly affected;
  - effects on ecological community structure;
  - effects on ecosystem processes and the life-supporting capacity of the air, water or soil;
  - undesired effects of control measures;
  - effects on human use (e.g. water quality, fishing);
  - effects on structures of all kinds (e.g. destruction by termites of wooden buildings);
  - social, cultural and aesthetic conditions.

c) Time and place factors

- most consequences will be expressed over a period of time, and it will be necessary to estimate potential impacts, particularly economic consequences over a period of time;
- the consequences may change over time;
- there may be a lag between the establishment of a hazard and the expression of an impact;
- presence of natural/man made barriers to spread;
- the potential for movement with commodities or conveyances;
- potential vectors of the hazard (passive or active) in the risk management area;
- natural factors that facilitate dispersal e.g. water and wind.

d) Analytical techniques

There are analytical techniques which can be used in consultation with experts in economics to make a more detailed analysis of the potential economic effects. Note however that non-commercial and environmental consequences are often not adequately measured in terms of prices in established product or service markets. Furthermore a lack of knowledge about potential consequences and the time required for consequences to be realised can make consequence assessment difficult and introduces a degree of uncertainty. In such cases it is likely to be necessary to use qualitative information about the consequences. Assumptions and uncertainties must be clearly documented and the use of expert judgement identified. This is necessary for transparency and may also be useful for identifying and prioritising research needs.

The assessment of the likelihood and consequences of environmental impacts often involves greater uncertainty than the assessment of impacts on cultivated or managed plants/animals. This is due to the lack of information, additional complexity associated with ecosystems and variability associated with unwanted organisms or diseases, hosts or habitats and the lack of

baseline data. In these cases it is again necessary to document the areas of uncertainty and the degree of uncertainty in the assessment, and to indicate where expert judgement has been used. Plate 4.4 provides an example of a consequence assessment for African horse sickness virus, while Table 4.5 provides an example of a summary of a consequence assessment.

Plate 4.4: An example of a consequence assessment for African horse sickness.

Although the potential trade implications and costs of control following the introduction of AHS virus in New Zealand are likely to be negligible, the likelihood that those animals that become infected would be significantly affected is high.

Consequence assessment

Horses and dogs are the only animals likely to be affected by AHS virus in New Zealand. It is not a zoonotic disease and would not become established in this country. Since there is likely to be only a very short time span following the importation of a viraemic animal, during which there would be limited opportunities for spread through iatrogenic transmission, ingestion of horse meat and coitus or artificial insemination, the number of animals likely to become infected would be very small. However, the consequences for the affected animal(s) are likely to be severe.

There are unlikely to be any significant trade implications associated with a case of AHS as it has never occurred outside Africa and the Middle East, neither its natural vector, *Culicoides imicola* nor any *Culicoides* spp in New Zealand and it would be directly associated with a recently imported animal. The costs of an investigation and any short-term control costs are likely to be minimal.

Conclusion

Although the potential trade implications and costs of control following the introduction of AHS virus in New Zealand are likely to be negligible, the likelihood that those animals that become infected would be significantly affected is high.

References

Table 4.5: An example of a summary of a consequence assessment for African horse sickness

Consequence	Significance	Likelihood
Biological		
Horses	High	Non-Negligable (medium)
Dogs	High	Non-Negligable (medium)
Other animals	Negligible	Negligible
Humans	Negligible	Negligible
Environmental	Negligible	Negligible
Economic	Negligible	Negligible

4.4.4 Risk estimation

The aim of this step is to summarise the conclusions arising from the entry, exposure and establishment, and consequence assessments, to estimate the likelihood of the potential hazard entering the risk analysis area and resulting in adverse consequences. Each potential hazard, or, in the case of a pest risk analysis, pathway, should be dealt with individually. It is not sufficient to conclude that there is a mere possibility of entry, establishment or spread or that there may be potential consequences. An evaluation of the likelihood of each of these factors must be undertaken.

If the estimated risk is not negligible the potential hazard is classified as an actual hazard and risk management measures may be required (while the level of risk may be non-negligible it

may still be considered acceptable). It should also be noted that there may be exceptional cases in which the consequences of entry, establishment and exposure would be so great that risk management measures may be considered necessary, even if the likelihood of entry and establishment was initially considered negligible. In such cases a full justification for a non-negligible risk estimate is required.

Plate 4.5 provides an example of a risk estimate for African horse sickness virus.

Plate 4.5: An example of a risk estimate for African horse sickness virus.

Risk Estimation

Although AHS virus would not become established in New Zealand, the likelihood that a horse imported from an endemic area will be viraemic leading to a limited opportunity for spread to other horses in New Zealand is low. The consequences of infection are likely to be severe for infected animals, particularly if affected by the pulmonary, cardiac or mixed form of the disease. As a result the risk estimate for AHS virus is non-negligible and it is classified as a hazard.

4.4.5 Targeted consultation/peer review of the risk assessment and estimation

It will not normally be necessary to undertake formal external consultation at this stage as stakeholders will be consulted on these sections along with all other parts of the risk analysis at the conclusion of the external peer review (see Section 3.4.2). However targeted peer review (internal and/or external) may be helpful in the following situations:

- When the potential mitigation measures are likely to be contentious and/or costly;
- When there is a high level of uncertainty associated with any of the assessment stages.

The objective of 'consultation' at this stage is to check that the risk assessment process is transparent and rigorous and that the list of actual hazards, or in the case of a pest risk analysis, pathways, requiring risk mitigation measures is justifiable.

4.4.6 Assessment of Uncertainty

The purpose of this section of the risk analysis process is to summarise the uncertainties and assumptions identified during the preceding hazard identification and risk assessment stages. An analysis of these uncertainties and assumptions can then be completed to identify which are critical to the outcomes of the risk analysis. Critical uncertainties or assumptions can then be considered for further research with the aim of reducing the uncertainty or removing the assumption.

As mentioned in Section 3.5.2.2, where there is significant uncertainty in the estimated risk, a precautionary approach to managing risk may be adopted. In these circumstances the measures should be reviewed as soon as additional information becomes available[19] and be consistent with other measures where equivalent uncertainties exist.

19 Article 5.7 of the SPS Agreement states that "a Member may provisionally adopt sanitary …. measures" and that "Members shall seek to obtain additional information …. within a reasonable period of time." Since the plural noun "Members" is used in reference to seeking additional information a co-operative arrangement is implied between the importing and exporting country. That is the onus is not just on the importing country to seek additional information.

4.5 Risk Management

Risk management in the context of risk analysis is the process of deciding measures to effectively manage the risks posed by the hazard(s) associated with the commodity or organisms under consideration. It is not acceptable to identify a range of measures that might reduce the risks. There must be a reasoned relationship between the measures chosen and the risk assessment so that the results of the risk assessment support the measure(s)[20].

Since zero-risk is not a reasonable option, the guiding principle for risk management should be to manage risk to achieve the required level of protection that can be justified and is feasible within the limits of available options and resources. Risk management (in the analytical sense) is the process of identifying ways to react to a risk, evaluating the efficacy of these actions, and identifying the most appropriate options.

The uncertainty noted in the assessments of economic consequences and probability of introduction should also be considered and included in the consideration of a risk management options. Where there is significant uncertainty, a precautionary approach may be adopted. However, the measures selected must nevertheless be based on a risk assessment that takes account of the available scientific information. In these circumstances the measures should be reviewed as soon as additional information becomes available. It is not acceptable to simply conclude that, because there is significant uncertainty, measures will be selected on the basis of a precautionary approach. The rationale for selecting measures must be made apparent.

Each hazard or group of hazards should be dealt with separately using the following framework:

i) Risk evaluation

- If the risk estimate, determined in the risk assessment, is non-negligible, measures can be justified.

ii) Option evaluation

a) Identify possible options, including measures identified by international standard setting bodies, where they are available.

- To assist in the identifying appropriate option(s) an objective, which states what these option(s) should aim to achieve in order to effectively manage the risks, should be formulated. The objective needs to be quite specific, for example, "*to effectively manage the risks of AHS, measures should ensure that horses are either not incubating the disease or viraemic when imported"*. Statements such as "*measures to ensure infected animals are not imported are warranted*" must be avoided.
- It is not acceptable to simply identify a range of options. There must be a rational relationship between the option(s) and the risk assessment.

b) Evaluate the likelihood of the entry, exposure, establishment or spread of the hazard according to the option(s) that might be applied.

c) Select an appropriate option or combination of options that will achieve a likelihood of entry, exposure, establishment or spread that reduces the risk to an

20 Handbook on Import Risk Analysis for Animals and Animal Products Volume 1: Introduction to Qualitative Risk Analysis. OIE. 2004.

acceptable level. The following guidelines must be taken into account when selecting option(s):

- ensure that the option(s) are based on scientific principles.
- ensure that measures identified by international standard setting bodies are considered. If there is a scientific justification that an international measure does not effectively manage the risks, measures that result in a higher level of protection may be applied. Alternatively less stringent measures than those recommended in international standards may be applied where there is sufficient justification that the risks can be effectively managed.
- ensure that the option(s) are applied only to the extent necessary to protect human, plant or animal life or health, or the environment.
- ensure that negative trade effects are minimised.
- ensure that the option(s) do not result in a disguised restriction on trade.
- ensure that the option(s) are not applied arbitrarily e.g. ISPM 1: *Principle of "non-discrimination"* - If the pest under consideration is established in the risk analysis area but of limited distribution and under official control, the measures in relation to import should not be more stringent than those applied within the risk analysis area.
- ensure that the option(s) do not result in discrimination between exporting countries where similar conditions prevail.
- ensure that the option(s) are feasible by considering the technical, operational and economic factors affecting their implementation.

iii) Monitoring and review

a) measures are audited to ensure that they are achieving the results intended, for example through inspections and random checks.

An example of risk management for African horse sickness appears in Plate 4.6 and for *Bactrocera kirki* (fruit fly) in Plate 4.7.

Plate 4.6: An example of risk management for African horse sickness virus.

1.3 Risk management

1.3.1 Risk evaluation

Since the risk estimate for AHS virus is non-negligible, sanitary measure(s) will need to be employed to effectively manage the risks to reduce them to a negligible level.

1.3.2 Option evaluation

1.3.2.1 Objective

To effectively manage the risks of AHS virus, sanitary measure(s) need to ensure that horses are not carrying the virus (i.e. not incubating the disease and not viraemic) when given a biosecurity clearance in New Zealand.

1.3.2.2 Options available

As the currently available commercial vaccines are unlikely to prevent viraemia, the only means available to ensure that horses are not carrying the virus when given a biosecurity clearance in New Zealand, is to ensure they are either resident in a free country or free zone, or protect them from insect vectors for a period equal to the maximum duration of viraemia plus the incubation period. Since the incubation period may be up to 14 days and viraemia may last up to 21 days (Lagreid, 1996, Coetzer and Erabus, 1994) horses would need to be protected from insect vectors for up to 35 days. Since the duration of viraemia following vaccination with a live vaccine is likely to be similar to that resulting from a natural challenge, animals would need to be vaccinated no less than 35 days prior to being given a biosecurity clearance.

Articles 2.1.11.2 and 2.1.11.3 of the *Code* (Anonymous, 2000) detail the accepted standards for defining a free country or free zone while Article 2.1.11.6 specifies the conditions for importing domestic horses from a free country or free zone. The

requirements specified in these articles are consistent with the objective outlined in Section 1.3.2.1. As a result they provide appropriate measures to mitigate against the risks associated with AHS virus for horses derived from free countries or free zones.

Article 2.1.11.8 specifies the conditions for the importation of domestic horses from an infected country or an infected zone. The requirements specified in these articles are consistent with the objectives outlined in Section 1.3.2.1, although a negative test for AHS in unvaccinated animals that are protected from vectors is not warranted. A seropositive test in such circumstances indicates past infection, not current infectivity. Apart from the requirement to test unvaccinated animals this article provides appropriate measures to mitigate against the risks associated with AHS virus for horses imported from infected countries or infected zones.

1.3.3 Recommended sanitary measures

1.3.1.1 horses must either:

i) originate from an AHS free country or free zone as specified by Article 2.1.11.2 or article 2.1.11.3 of the *Code* (Anonymous, 2000) and satisfy the requirements of Article 2.1.11.6 for the importation of domestic horses from an AHS free country or free zone,

or

ii) if from a country or zone considered to be infected with AHS, be protected from insect vectors for 35 days prior to being given a biosecurity clearance in New Zealand. A live vaccine may be used, however it must be administered at least 35 days prior to a biosecurity clearance being given in New Zealand.

Plate 4.7: An example of risk management for *Bactrocera kirki* (fruit fly).

Risk management

Risk evaluation

Since the risk estimate for *Bactrocera kirki* (fruit fly) is high and therefore non-negligible, measure(s) will need to be employed to effectively manage the risks to reduce the risk to an acceptable level.

Option evaluation

Objective

To effectively manage the risks of *Bactrocera kirki* (fruit fly), phytosanitary measure(s) need to ensure, to a level of confidence equivalent to probit level 9, that none of the units in any given consignment of eggplant fresh fruit are infested with *Bactrocera kirki* (fruit fly) when given a biosecurity clearance into New Zealand.

Options available

Area Freedom: A contamination level of probit 9 or less of the units in any given consignment of eggplant fresh fruit with *Bactrocera kirki* (fruit fly) will be achieved if the consignment of eggplant fresh fruit originates from an area determined to be free of *Bactrocera kirki* (fruit fly). Area freedom status should be determined in a manner compliant with that stipulated in the International Standards for Phytosanitary Measures; Requirements for the Establishment of Pest Free Areas, IPPC, FAO, Publication 4, 1996.

Heat Treatment: A contamination level of probit 9 or less of the units in any given consignment of eggplant fresh fruit with *Bactrocera kirki* (fruit fly) will be achieved if all fruit within each consignment are subjected to a heat treatment that raises all parts of the eggplant fruit from ambient temperature to a temperature of at least 47.2^{o}C and held for a minimum of 20 minutes.

Recommended phytosanitary measures

Eggplants fresh fruit must either:

i) originate from an area free of *Bactrocera kirki* (fruit fly), as stipulated in the International Standards for Phytosanitary Measures; Requirements for the Establishment of Pest Free Areas, IPPC, FAO, Publication 4, 1996.

or

ii) if from a country or zone considered to be infected with *Bactrocera kirki* (fruit fly), prior to export undergo a treatment that raises all parts of the eggplant fruit from ambient temperature to a temperature of at least 47.2^{o}C and held for a minimum of 20 minutes.

4.5.1 Option Evaluation – Identifying Possible Options[21]

The measures listed below are examples of those that are most commonly applied to traded commodities. They are applied to pathways, usually consignments of a host, from a specific origin. The measures should be as precise as possible as to consignment type and origins as not to act as barriers to trade by limiting the import of products where this is not justified. Combinations of two or more measures may be needed in order to reduce the risk to an acceptable level. The available measures can be classified into broad categories that relate to the pest status of the pathway in the country of origin. These include measures:

- applied to the consignment;
- applied to prevent or reduce original infestation of the consignment;
- to ensure the area or place of production of the consignment is free from the hazard;
- concerning the prohibition of commodities.

Other options may arise in the risk analysis area (restrictions on the use of a commodity), control measures, introduction of a biological control agent, eradication, and containment. Such options should also be evaluated and will apply in particular if the hazard is already present but not widely distributed in the risk analysis area.

4.5.1.1 Options for consignments

Measures may include any combinations of the following:

- inspection or testing for freedom from a hazard or to a specified hazard tolerance; sample size should be adequate to give an acceptable probability of detecting the hazard;
- prohibition of parts of the host of the hazard;
- a pre-entry or post-entry quarantine system - this system could be considered to be the most intensive form of inspection or testing where suitable facilities and resources are available, and may be the only option for certain hazards not detectable on entry;
- specified conditions of preparation of the consignment (e.g. handling to prevent infestation or reinfestation);
- specified treatment of the consignment - such treatments are applied post harvest or production and could include chemical, thermal, irradiation or other physical methods;
- restrictions on end use, distribution and periods of entry of the commodity.

21 Section 4.5.1 substantially includes text modified from section 3.4 of ISPM 11: Pest risk analysis for quarantine pests, including analysis of environmental risk and living modified organisms. FAO 2004.

4.5.1.2 Options preventing or reducing infestation in the commodity prior to harvest or production

Measures may include:

- treatment of the pre-manufactured commodity or the place of production;
- restriction of the composition of a consignment so that it is composed of parts that are less susceptible to infestation;
- producing the commodity under specially protected conditions (containment, isolation);
- production of the commodity at a certain age or a specified time of year;
- production in an officially monitored certification scheme.

4.5.1.3 Options ensuring that the area, place or site of production is free from the hazard

Measures may include:

a) organism or disease-free area or country;

- phytosanitary requirements for pest-free area status are described in ISPM Pub. No. 4: Requirements for the establishment of pest free areas

b) hazard-free place of production or hazard-free production site;

- phytosanitary requirements are described in ISPM Pub. No. 10: Requirements for the establishment of pest free places of production and pest-free production sites

c) inspection of pre-harvest or pre-production commodity to confirm hazard freedom.

4.5.1.4 Options for other types of pathways

For many types of pathways, the measures considered above to detect the hazard on the consignment or to prevent infestation of the consignment, may also be used or adapted. For certain types of pathways, the following factors should be considered:

- Natural spread of an organism includes movement of the organism by flight, wind dispersal, transport by vectors such as insects or birds and natural migration. If the organism is entering the risk analysis area by natural spread, or is likely to enter in the immediate future, phytosanitary measures may have little effect. Control measures applied in the area of origin could be considered. Similarly, containment or eradication, supported by suppression and surveillance, in the risk analysis area after entry of the organism could be considered.
- Measures for human travellers and their baggage could include targeted inspections, publicity and fines or incentives. In a few cases, treatments may be possible.
- Contaminated machinery or modes of transport (ships, trains, planes, road transport) could be subjected to cleaning or disinfestation.

4.5.1.5 Options within the importing country

Certain measures applied within New Zealand may also be used. These could include careful surveillance to try and detect the entry of the hazard as early as possible, eradication programmes to eliminate any foci of infestation, public education programmes to limit the extent of any consequences, and/or containment action to limit spread. While these measures are unlikely to be included in an import health standard, the existence of such measures may affect the type of nature of measures included in an import health standard.

4.5.1.6 Prohibition of commodities

If no satisfactory measure to reduce risk to an acceptable level can be found, an option may be to prohibit importation of the relevant commodities. This should be viewed as a measure of last resort and should be considered in light of the anticipated efficacy, especially in instances where the incentives for illegal import may be significant.

4.5.1.7 Certification and other compliance measures

Risk management includes the consideration of appropriate compliance procedures. The most important of these is export certification[22]. The issuance by governments or national authorities of certificates[23] provides official assurance that a consignment is meets a specified pre-clearance requirement. It thus confirms that the specified pre-clearance risk management options have been followed. Other compliance measures may be used subject to bilateral or multilateral agreement.

4.5.2 Conclusion of risk management

The result of the risk management procedure will be either that no measures are identified which are considered appropriate, or the selection of one or more management options that have been found to lower the risk associated with the hazard(s) to an acceptable level. These management options form the basis of regulations or requirements specified with an import health standard. The application and maintenance of such regulations is subject to certain obligations that may be relevant to risk analysis, in the case of contracting parties to the various international agreements (see Appendix 1).

4.6 Assessment of Residual Risk

Residual risk can be described as the risk remaining after measures have been implemented. Assuming:

22 For example see ISPM Pub. No. 7: *Export certification system*. FAO. 1997
23 For example see ISPM Pub. No. 12: *Guidelines for Phytosanitary Certificates*. FAO. 2002

a) the measures have been implemented in a manner that ensures they reduce the level of risk posed by the hazard(s) to a degree anticipated by the risk analysis; and

b) the level of risk posed by the hazard(s) was determined accurately in the risk assessment;

the remaining risk while being acceptable may still result in what could be interpreted as failures in risk management.

An example of such a "failure" would be the interception of 8 live insects within a consignment of fruit, when the objective of the applied measure was to reduce the infestation rate to below 10 live insects per consignment. The residual risk in this instance would be 10 or less live insects detected per consignment making 8 live insects an acceptable level of infestation.

The residual risk information then becomes the basis for developing a monitoring protocol that may, for instance, interpret interception data to determine if risk thresholds are being exceeded. The residual risk information also ensures the risk management decision maker understands the nature of the risk remaining should the measures achieve their objectives.

1. Residual Assessment

1.1 Objective of measure(s)

To effectively manage the risks of *Aspidiotus destructor* (coconut scale), phytosanitary measure(s) would need to ensure that with 95% confidence not more than 0.5% of the units in any given consignment of eggplant fresh fruit are infested with the scale when given a biosecurity clearance into New Zealand.

1.2 Expected performance of measure(s)

A contamination level of less than 0.5% of the units in any given consignment of eggplant fresh fruit with *Aspidiotus destructor* (coconut scale) will be achieved with 95% confidence if a 600 sample randomly collected from a homogenous lot of eggplant fresh fruit is visually inspected and no live *Aspidiotus destructor* (coconut scale) life stages are found.

Should monitoring activities then determine that the risk threshold has been exceeded for any particular hazard or group of hazards; either the risk analysis can be reviewed to determine what aspects of the risk(s) or management option(s) have altered or were assessed incorrectly, or the implementation audited to ensure adequate compliance.

5. Documentation and Record Keeping

The principle of transparency of the SPS Agreement (1994) requires that contracting parties should, on request, make available the rationale for sanitary or phytosanitary requirements. As a prerequisite, the underlying risk analysis should be sufficiently documented. Complete and careful documentation is also a prerequisite to implementing an effective and efficient review process for the risk analysis.

When documenting a particular analysis, the entire process from project initiation to the close-out reporting should be sufficiently documented so that the sources of information and rationale for management decision can be clearly demonstrated.

5.1 References, Editorial Guidelines and Terminology

The following aspects of the documentation process are specified here to ensure a degree of consistency is maintained within the risk analysis work program. The *MAF Style Guide* should be consulted to ensure all other aspects of documentation are also compliant with MAF requirements.

5.1.1 Referencing

Critical epidemiological observations that are the key to the analytical process should be attributed to primary sources. Where a number of references are cited in support of a particular point, the analyst should ensure that they are all based on independent studies. That is, the analyst should not cite several references that are all based on the same, single primary source.

5.1.2 Citing references

The accuracy of references is the responsibility of the author, and they must be verified against the original article. Ensure that all articles cited in the text are included in the bibliography and vice versa. Where possible, avoid using abstracts or web sites as references. Do not use unpublished observations, personal communications, or articles in press unless they exist in written form and are placed on an appropriate file in MAF. They should all be cited as personal communications.

5.1.3 Editorial guidelines

MAF Corporate Style Guide should be used for all citations and references included in the risk analysis document(s). The following editorial guidelines must also be followed:

i) Numbers

When a number is followed by a unit of measurement, it must be printed as a numeral. Otherwise, numbers greater than ten are generally printed as numerals, whereas words may be used for small numbers, at the beginning of a sentence, or when clarity requires it. A decimal point must always be preceded by a numeral, e.g., "0.5", not ".5".

ii) Quantities

All measurements should be reported in S.I. units or their decimal multiples, unless it is normal practice in a discipline to use derivatives, e.g., the international unit and the curie. Temperatures should be given in degrees Celsius. Attention is drawn to New Zealand Standard 6501, which contains the recommended S.I. units.

iii) Dates

Dates should take the form "25 May 2000" in the text but they can be abbreviated in tables and figures. Use the 24 hour clock for times of day.

iv) Abbreviations

Abbreviations should not be used if they are in any way ambiguous. They should only be used where they are in common use in English, standard SI form, or commonly accepted in a discipline. Non-standard abbreviations should be listed in a "Glossary of Abbreviations", and their meaning must be clearly evident or explained when they are first introduced. For international units, "IU" should be used; "U" should be used for enzyme activity. Units of length, weight and volume should be given in lower case (e.g. kg, mg/l). Abbreviations for chemical elements, SI units, contractions and suspensions in common use (including country names such as USA, UK and NZ, but excluding "e.g." and "i.e.") are not followed by stops; other suspensions generally are (e.g. pers. comm.). Latin terms and their abbreviations that are now in common use in the scientific literature such as "ad libitum" "in vivo", "in vitro", "e.g.", "i.e." and "et al" are not italicised. Probability values are given in the form "p=0.003" (lower case, no spaces, to 2 or 3 decimal places only) and standard deviations, standard errors, standard errors of means and least significant differences given as SD, SE, SEM and LSD, respectively.

v) Nomenclature

Manuscripts should conform to internationally recognised codes of nomenclature (e.g. The *International Code of Zoological Nomenclature, International Code of Nomenclature of Bacteria,* and the *International Code of Botanical Nomenclature*). All biotica should be identified by their scientific names when the English term is first used, with the exception of common domestic animals. Generic and specific names should be italicised. Names of organisms should be given in full when used in the title and when first used in the text; after first use, generic names should be abbreviated as far as possible without causing confusion.

5.1.4 Terminology

Unless stated otherwise in the glossary included in these procedures (Chapter 6) or in any generic MAF glossary policy document, the terminology outlined by the relevant standard setting bodies, the *Terrestrial Animal Health Code* for animal health and *ISPM No. 5: Glossary* for plant health must be used. The coining of new terms should be avoided. Each risk analysis should have a glossary of terms at the beginning of the document, including at the very least, the definitions for the four terms that result in most confusion: risk, risk analysis, risk assessment and risk management.

Care must be exercised when using various terms to estimate or describe risk. As discussed in Section 2.1, various WTO Panels and Appellate Bodies have emphasised the importance of the correct use of terms such as likelihood and potential. Most biosecurity risk assessments are concerned with evaluating the *likelihood* of entry, establishment or exposure of an organism or disease, as well as the associated *potential* biological and economic consequences. It is not sufficient to conclude that there is a possibility of entry, establishment or exposure. Instead the likelihood, which may be expressed qualitatively or quantitatively, must be evaluated. Similarly, as the ordinary meaning of "potential" relates to possibility, the likelihood of possible consequences must be evaluated. For this reason it is important to use appropriate terms when describing a risk (Table 5.1).

Table 5.1: Terminology for describing likelihood.

Term	The Concise Oxford Dictionary definition
When expressing likelihood:	
a) Terms to avoid	
Chance	When used in a singular context it indicates a possibility
Could	Past of can, where can means to be potentially capable of
Might	Expressing a possibility based on a condition not fulfilled
Potential	When used as a noun means possibility
Possibility	a thing that may exist or happen
Possible	that is likely to happen; whatever is likely
b) Acceptable terms	
Chances	in its plural form chance indicates a probability
Likelihood	probability; the state or fact of being likely
Likely	probable; such as well might happen or be true; to be reasonably expected
Probability	the likelihood of something happening; mathematically it is defined as the extent to which an event is likely to occur, measured by the ratio of the favourable cases to the whole number of cases possible.
Probable	May be expected to happen or prove true; likely
Would	To express probability (I guess she would be over 50 by now); past of Will: expressing a wish, ability, capacity, probability or expectation

Terms used as adjectives to qualify likelihood estimates:	
Average	The usual amount, extent, rate
Extremely	Outermost, furthest from the centre; situated at either end; utmost; the highest or most extreme degree of anything
High	Extending above the normal or average level
Highly	In a high degree
Insignificant	Unimportant; trifling
Low	Less than average, coming below the normal level
Negligible	Not worth considering; insignificant
Significant	Noteworthy; important; consequential
Remote	Slight, faint

5.2 Records Management

Sound records management practices are not only required to fulfil New Zealand's domestic legislative requirements and meet international obligations, but also to provide a readily accessible information recall system that can act as an information resource for future and ongoing work and ensure that issues identified during the development of a risk analysis are recorded and directed to the appropriate business group for action or consideration.

MAF has a number of policies and standards for record keeping and document management that have been developed from relevant New Zealand legislation, including the Copyright Act 1994 e.g. MAF data and Document Management Policy, MAF Record keeping Policy, MAF Record Retention and Disposal Policy. Staff should also be aware of acceptable practice under these policies and such policies must be taken in to consideration when developing record management practices within the risk analysis group.

5.2.1 Process for records management

The procedural recommendations for this project covers records management associated with the production of import risk analyses after the notification of the final risk analysis. The three main parts of this process serve to ensure that:

1. Hazard information databases are updated appropriately;

2. Literature records referred to by the risk analysis are complete;

3. All related files or files developed during the project are complete;

4. Other groups or process owners are informed of risk analysis outputs relevant to their work area.

5.2.2 Updating hazard information in databases

Ensure the hazard information database(s) are updated as appropriate with the relevant hazard information developed during the risk analysis project.

5.2.3 Updating referenced literature records

Full-text references and citations should be stored in accordance with current MAF policies. As a guide references and citations should be held as a single unit until the project has been completed. After project completion references and citations relevant to particular organisms and diseases and of potential use in other projects should be stored for easy retrieval by future projects.

5.2.4 Ensure related files are complete

All documents related to a project should be easily recalled as a unit. Ensure that all documents relating to the risk analysis project are filed in either the electronic or the hardcopy files established at the initiation of the project. Such project-related records or documents include project planning documents, emails and other correspondence, references, submissions, drafts and final risk analysis documents. In the MAF electronic document management system all documents should be flagged with the project name.

Ensure that the following are updated as appropriate both during the project and on completion of the project:

- *Check List*, detailing progress of a single project and kept in the project file;
- *Contractors and Reviewers Folder*, containing a record of external reviewers and contractors used for risk analysis projects;
- *Risk Analysis Tracking Log,* the electronic file that is used to monitor progress of all projects across the risk analysis group.

The completed risk analysis document(s) should be published on the MAF website as *pdf* files and remain on the website indefinitely or until revised. The MAF Information Bureau should be notified for inclusion in their library catalogue. A hardcopy of risk analysis documents should be placed in the risk analysis group library collection for easy access by Biosecurity New Zealand staff.

The availability of risk analysis documents, including the Review of Submissions document, should be advertised, such as in the *Biosecurity* magazine and on the MAF website. Organisations and individuals that made a submission to the project should be notified individually as detailed in Chapter 3.

5.2.5 ***Ensure notifications are completed***

The following groups with MAF should be notified as appropriate on the outcomes of the risk analysis project:

- *BNZ Science Strategy Group*, on potential science research or information needs identified during the project;

- *BNZ Biosecurity Standards Group*, on the outcomes of the risk analysis relevant to the development of operational or regulatory standards;
- *BNZ Post-Clearance Directorate*, on the outcomes of the risk analysis relevant to the management of surveillance, incursion response or pest management activities.
- *BNZ Border Monitoring Group*, on the outcomes of the risk analysis relevant to the monitoring of border activities.

There may also be other groups within MAF that, depending on the scope of the risk analysis project, may also need to be notified of the outcome or aspects of the outcomes of the project. These other groups include the *Biosecurity New Zealand Exports Team*, the *New Zealand Food Safety Authority*, and the various policy and strategy groups with Biosecurity New Zealand and MAF.

6. Glossary

The following terms have been adopted for use in risk analysis in MAF or have either been adapted from existing international standards or have come from an existing international standard and have been adopted as the official risk analysis definition.

Area	An officially defined country, part of a country or all or part of several countries, as identified by the competent authorities. (SPS agreement 1994[24])
Biosecurity	The exclusion, eradication or effective management of risks posed by pests and diseases to the economy, environment and human health." (Biosecurity Strategy 2003[25])
BNZ	Biosecurity New Zealand
BSA	Biosecurity Act 1993
Commodity	A good being moved for trade or other purposes. Packaging, containers, and craft used to facilitate transport of commodities are excluded unless they are the intended good.
Consequences	The adverse effects or harm as a result of entry and establishment of a hazard, which cause the quality of human health or the environment to be impaired in the short or longer term (DOE, 1995[26]).
CTO	Chief Technical Officer under the Biosecurity Act 1993
Disease	A finite abnormality of structure or function with an identifiable pathological or clinicopathological basis, and with a recognizable syndrome of clinical signs. Its cause may not be known, or may be from infection with a known organism. (Blood & Studdert 1990[27])
Ecosystem	A dynamic complex of plant, animal and micro-organism communities and their non-living environment interacting as a functional unit (Convention on Biological Diversity 1992[28])
Entry (of a organism or disease)	Movement of an organism or disease into a risk analysis area.
Environment	(Biosecurity Act 1993) Includes: (e) Ecosystems and their constituent parts, including people and their communities; and (f) All natural and physical resources; and (g) Amenity values; and (h) The aesthetic, cultural, economic, and social conditions that affect or are affected by any matter referred to in paragraphs (a) to (c) of this definition
Establishment	Perpetuation, for the foreseeable future, of an organism or disease within an area after entry
Exposure	The condition of being vulnerable to adverse effects
FAO	Food and Agriculture Organization, United Nations.

24 Agreement on the Application of Sanitary and Phytosanitary Measures, 1994. World Trade Organization, Geneva.
25 The Biosecurity Strategy for New Zealand. 2003. http://www.biosecurity.govt.nz/bio-strategy/
26 DOE, 1995
27 Blood & Studdert 1990
28 Convention on Biological Diversity 1992

Hazard	Any disease or organism that has the potential to produce adverse consequences
Hitchhiker Organism	An organism that is carried by or with a commodity and is not a pest of the commodity.
IHR	International Health Regulations, World Health Organization.
Import Health Standard (IHS)	A document issued under section 22 of the Biosecurity Act 1993 by the Director General of MAF, specifying the requirements to be met for the effective management of risks associated with the importation of risk goods before those goods may be imported, moved from a biosecurity control area or a transitional facility, or given a biosecurity clearance Note: An import health standard is also an "import permit" as defined under the IPPC
Import risk analysis	A process to identify appropriate risk-mitigating options for the development of import health standards. These risk analyses can focus on an organism or disease, a good or commodity, a pathway, or a method or mode of conveyance such as shipping, passengers or packaging.
Inanimate object	An object or material not of plant or animal origin on which organisms or diseases can be conveyed. For example, containers, bricks, plastics, and metal
IPPC	International Plant Protection Convention (1997), FAO
MAF	New Zealand Ministry of Agriculture and Forestry
Measure	A measure may include all relevant laws, decrees, regulations, requirements and procedures including, *inter alia*, end product criteria; processes and production methods; testing, inspection, certification and approval procedures; quarantine treatments including relevant requirements associated with the transport of risk goods, or with the materials necessary for their survival during transport; provisions on relevant statistical methods, sampling procedures and methods of risk assessment; and packaging and labelling requirements directly related to biosecurity
MoH	New Zealand Ministry of Health
Natural and physical resources	(Biosecurity Act 1993) Means: (i) Organisms of all kinds; and (j) The air, water, and soil in or on which any organism lives or may live; and (k) Landscape and land form; and (l) Geological features; and (m) Structures of all kinds; and (n) Systems of interacting living organisms and their environment
Notifiable Organism	An organism that has been declared under the Biosecurity Act (1993) to be a notifiable organism for New Zealand or a region or regions of New Zealand.
NZFSA	New Zealand Food Safety Authority
OIE	World Organisation for Animal Health

Organic material	(Biosecurity Act 1993) Subject to subsection (2) of this section, means any material that is or contains: (a) Material derived from an organism; or (b) An excretion or secretion of an organism, (whether or not it also contains material derived from a human being or contains the secretions of a human being) Subsection 2: No goods are an organic material by virtue only of being or containing cardboard, coal, paper, petroleum oil, or a substance derived from coal or petroleum oil.
Organism	(Biosecurity Act 1993) (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.
Organism consequence assessment	A process to measure the level and nature of the consequences of an organism or disease that has established in New Zealand. An organism consequence assessment is most often used to inform response and/or pest management programs within New Zealand.
Pathway	Any means that allows the entry or spread of a potential hazard
Pest	Any species, strain or biotype of plant, animal or pathogenic agent, injurious to plants or animals (or their products) or human health or the environment. Note: the definition given for "pest" here is different from that used in the Biosecurity Act 1993 "an organism specified as a pest in a pest management strategy". The Biosecurity Act 1993 deals more with "risks" and "risk goods"
Pest risk assessment	A process to measure the level and nature of biosecurity risk posed by an organism. A pest risk assessment can be used to inform biosecurity surveillance activities or identify pests of high risk to New Zealand.
Residual Risk	The risk remaining after risk management requirements have been implemented.
Risk	The likelihood of the occurrence and the likely magnitude of the consequences of an adverse event.
Risk analysis	The process composed of hazard identification, risk assessment, risk management and risk communication.
Risk analysis area	The area in relation to which a risk analysis is conducted.
Risk assessment	The evaluation of the likelihood, and the biological and economic consequences, of entry, establishment, or exposure of an organism or disease.
Risk good	(Biosecurity Act 1993) Means any organism, organic material, or other thing, or substance, that (by reason of its nature, origin, or other relevant factors) it is reasonable to suspect constitutes, harbours, or contains an organism that may: (a) Cause unwanted harm to natural and physical resources or human health in New Zealand; or (b) Interfere with the diagnosis, management, or treatment, in New Zealand, of pests or unwanted organisms

Risk management	The process of identifying, selecting and implementing measures that can be applied to reduce the level of risk.
Risk threshold	The upper limit of acceptable residual risk
Route of introduction	The recognized entry categories by which an organism could be introduced into a defined country, part of a country or all or part of several countries.
Spread	Expansion of the geographical distribution of a potential hazard within an area
SPS Agreement 1995	World Trade Organization Agreement on the Application of Sanitary and Phytosanitary Measures (1995)
Unwanted organism	(Biosecurity Act 1993) Means any organism that a chief technical officer believes is capable or potentially capable of causing unwanted harm to any natural and physical resources or human health; and (a) Includes: (i) Any new organism if the Authority has declined approval to import that organism; and (ii) Any organism specified in the Second Schedule of the Hazardous Substances and New Organisms Act 1996; but (b) Does not include any organism approved for importation under the Hazardous Substances and New Organisms Act 1996, unless: (i) The organism is an organism which has escaped from a containment facility; or (ii) A chief technical officer, after consulting the Authority and taking into account any comments made by the Authority concerning the organism, believes that the organism is capable or potentially capable of causing unwanted harm to any natural and physical resources or human health.

Appendix 1: Domestic and International Obligations

The following appendix provides information on the obligations afforded by New Zealand's domestic and international legislative framework for the provision of risk analysis and risk management activities in biosecurity

AP1.1 A Summary of the Legal Burden of Proof

The following summary has been extracted from a report produced as part of a project to determine the "legislative burden of proof" (LBOP) for import health standards and their related risk analyses. The project defined the LBOP as the level of risk analysis required of MAF under both domestic and international law to provide robust assessment of the risk posed by imported goods and covering the potential to inadvertently import pests and diseases with those goods. The report summarised the domestic statutory and case law and international law which determines this LBOP. The LBOP relevant to the development of risk analyses (as apposed to the development of import health standards) is presented here.

This project found that MAF must do the following with regard to undertaking risk analyses in support of the development of import health standards.

I MAF must:

- **have regard** to the following mandatory matters:
  - the likelihood that goods being assessed will bring organisms into New Zealand;
  - the nature and possible effect on people, environment and economy of those organisms;
  - New Zealand's international obligations, including: the SPS Agreement; the Convention on Biological Diversity; and the International Health Regulations;
- **consult appropriately** by treating it as more than mere notification, approaching it with an open mind, and waiting till the consultation process has finished before making a decision;
- act in accordance with **natural justice;**
- ensure that SPS measures **comply with the SPS agreement** by being **transparent, consistent, scientifically based** and **least trade restrictive;**
- allow its **SPS measures to be determined by New Zealand's "appropriate level of protection"**, not the other way around;
- **publish SPS measures** for international availability and internationally advertise occasions when it is considering bringing in new measures that differ from international standards;
- **maintain an enquiry point** for international enquiries about the contents of risk analyses;
- ensure that SPS measures **comply with the Convention on Biological Diversity** by ensuring that as far as possible and appropriate that measures prevent the introduction of, control or eradicate those alien species which threaten ecosystems, habitats or species;
- ensure that SPS measures **comply with the International Health Regulations** by:
  - considering the need for deratting, disinfection, disinsection or decontamination of goods

- considering the need to control the discharge from ships of sewage, refuse and ballast water
- considering the need to **supervise unpacking of cargo**
- complying with **standing recommendations** of the World Health Organization.

II MAF must not do the following:

- make **errors of fact;**
- make decisions that are ***ultra vires*** ("beyond the power") with regard to the empowering legislation;
- act against the **legitimate expectation** of parties to treat similar cases in a similar manner, while recognising that policy is allowed to evolve over time;
- involve people in decisions who have a **bias** (such as a financial or other personal interest in the outcome, or a personal prejudice against a party or a party's case, or having predetermined the issue before all the relevant information is available);
- make decisions that are **unreasonable** by, for example, there being no rational basis upon which to draw certain conclusions upon which a decision depends;
- adopt **different levels of sanitary protection** for the same risk resulting in discrimination or a disguised restriction on international trade.

III While not technically required, MAF should **record** all details of the risk analysis and decision-making process. Though MAF is technically able to rely on retrospective affidavits to document what happened within the decision making process there is no guarantee that the court will accept these affidavits in their entirety

IV There is no legal requirement for MAF to do the following (though there may often be technical or other reasons to do some of these things):

- **reach agreement** with all submitters or delay a decision until all matters that the submitter considers are outstanding have been resolved;
- provide a **detailed response** to all submitters;
- Always, in every case, **identify and assess all organisms** associated with a commodity to be imported;
- **attain perfect or absolute consistency** across all SPS measures;
- **Prove to a WTO dispute settlement body that a blanket SPS measure is consistent with the SPS Agreement**, unless a complainant country is able to raise a prima facie case that it is not consistent;
- **Publish risk analyses for an international audience** (though there should be an enquiry point to provide these on request).

V Any person seeking to challenge MAF decisions around import health standards in the domestic courts does not have a statutory right of appeal. Such a challenge would need to be through an application to the High Court for judicial review on the grounds of: (i) illegality; (ii) unfairness; or (iii) unreasonableness. Only under the ground of unreasonableness can the court question the merits of a decision and even then under very limited circumstances. Otherwise the court is limited to ensuring the decision-making process was valid.

AP1.2 Domestic Legislation

The following is a summary of the domestic legislation relevant to undertaking risk analyses for the development of import health standards.

1.2.1 Biosecurity Act (1993)

The Biosecurity Act (1993) (BSA) is *"an Act to restate and reform the law relating to the exclusion, eradication, and effective management of pests and unwanted organisms"*. The purpose of Part III of the Biosecurity Act (1993) is *"to provide for the effective management of risks associated with the importation of risk goods"*. MAF is the Ministry responsible for the administration of the BSA and its Director-General is responsible for, amongst other things, issuing import health standards (IHS), which specify the requirements to be met before risk goods may be imported.

Risk goods are defined in the BSA as any organism[29], organic material[1], or other thing, or substance, that (by reason of its nature, origin, or other relevant factors) it is reasonable to suspect constitutes, harbours, or contains an organism that may:

i) Cause unwanted harm to natural and physical resources[29] or human health in New Zealand; or

ii) Interfere with the diagnosis, management, or treatment, in New Zealand, of pests[29] or unwanted organisms[29]

All goods imported into New Zealand must be given a biosecurity clearance by an inspector who must be satisfied that the goods are either not risk goods or, if they are, that they comply with the requirements specified in an IHS and are accompanied by appropriate documentation. If the risk good is an organism the inspector must be satisfied that it does not display any signs or symptoms of harbouring unwanted organisms. An unwanted organism is any organism that a Chief Technical Officer (CTO) believes is capable or potentially capable of causing unwanted harm to any natural and physical resources or human health.

The BSA is not concerned with the deliberate importation of new organisms[29]. The relevant legislation, implemented by the Environmental Risk Management Authority (ERMA), is the Hazardous Substances and New Organisms Act (1996) (HSNO). Its purpose is to protect the environment, and the health and safety of people and communities, by preventing or managing the adverse effects of hazardous substances and new organisms. ERMA assesses and grants approvals for new organisms. Once an approval is granted an IHS, issued under the BSA, must be developed before new organisms can be imported.

MAF Biosecurity's policy is that the all new and revised IHSs must be based on a risk analysis. There are no obligations in the BSA to issue an IHS. If the measures that could be applied when importing risk goods are insufficient to effectively manage the risks, an IHS will not be issued.

29 These terms are defined in Appendix 2.

The BSA specifies that a CTO must have regard to the following matters before recommending that an IHS be issued:

i) The likelihood that the (risk) goods specified in an IHS may bring organisms into New Zealand:

ii) The nature and possible effect on people, the New Zealand environment, and the New Zealand economy of any organisms that the goods specified in an IHS may bring into New Zealand:

iii) New Zealand's international obligations:

iv) Other matters that the CTO considers relevant to the purpose of Part III of the BSA.

It is important to appreciate the extent to which a CTO may take these matters into account, particularly those relating to the economy and the environment. Under BSA the environment includes amenity values and aesthetic, cultural, economic, and social conditions. However, the CTO can only take such matters into account to the extent that they are affected by "any organisms". As a result the CTO may not consider those affects not related to an organism, for example the impact of cheaper goods on a particular industry or the economy generally.

The BSA requires a CTO to consult with stakeholders, including other government departments, before issuing an IHS unless it needs to be issued or amended urgently. Normally the consultation would involve a risk analysis in the first instance followed by an IHS.

1.2.2 Agricultural Compounds and Veterinary Medicines Act (1997)

The Agricultural Compounds and Veterinary Medicines Act (1997) regulates the importation, manufacture, sale and use of agricultural compounds. One of its main purposes is to prevent or manage the risks[30] associated with the use of agricultural compounds to trade, animal welfare and agricultural security[31]. The definition of an agricultural compound is very broad and, in relation to animals, includes any substance or biological compound used in the management of animals, for example for the purpose of treating, maintaining the productivity or fulfilling special nutritional requirements. It includes any veterinary medicine and is broad enough to include feedstuffs such as grains and meals. Nothing in this Act affects the requirements of BSA in relation to any agricultural compound. As a result an IHS must be developed for those agricultural compounds that constitute risk goods under the BSA.

30 *Risk* includes any costs or potential costs

31 "Agricultural security" means the exclusion, eradication, and effective management of--

1) Pests:
   a) Includes any unwanted living organism including micro-organisms, pest agents, and any 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) that may affect plants, animals, or raw primary produce; and
   b) Includes any entity declared to be a pest for the purposes of this Act
   c) Does not include—
      i) Any human being or living organism which affects only human beings; and
      ii) Any living organism declared not to be a pest for the purposes of this Act
2) Unwanted organisms under the Biosecurity Act 1993

1.2.3 Food Act (1981) and Food Regulations (1984)

The Food Act (1981) requires that food prepared, packed or sold within New Zealand be fit for human consumption. In addition imported food must not be contaminated with pesticides or animal remedies greater than those specified in the *Codex Alimentarius*. Food Standards, deemed to be regulations, may be issued by the Minister. They aim to protect public health with a desire to avoid unnecessary restrictions on trade, maintain consistency with international food standards and fulfil international obligations. The standards may apply to a food's composition (contaminants, residues, additives or other substances) and microbiological status. A food may be declared to be a prescribed food for the purpose of importation in order to ensure the food satisfies certain requirements to minimise the risk of illness. Prescribed foods are listed in the Mandatory Food Standard (1999) and must be issued with a clearance before they are imported. Consultation with interested persons must be undertaken before a food standard is issued. Certain foods may be prohibited from importation.

The Food Regulations (1984) prescribe labelling requirements; establish standards defining what constitutes various foods such as fresh, chilled or frozen meat, fresh or chilled fish, cheese and eggs, standards for additives and the protection and safety of food. They prohibit the importation of low acid canned food, cheese, clams, oysters, scallops, mussels, prawns, shrimps or frogs legs unless these foods comply with the relevant provisions of the Food Act and Food Regulations.

1.2.4 Human Assisted Reproductive Technology Act (2004)

The Human Assisted Reproductive Technology Act (2004) (HART) covers the importation of gametes and embryos. HART allows people to import their own gametes (sperm and eggs) for use in their own fertility treatment. HART does not currently allow the importation of donated sperm from another country to NZ for use in fertility treatment. The Advisory Committee on Assisted Reproductive Technologies (ACART), which has recently been established, will be developing guidelines and consulting on this issue and until that has occurred this practice is not allowed. HART prohibits the importation of gametes and embryos which have been formed by a prohibited action under the Act (e.g. reproductive cloning).

1.2.5 Human Tissue Act (1964)

The current Human Tissue Act (1964) (HTA) does not place restrictions on the import or export of human bodies, body parts, organs or tissue. The only restrictions are those that are imposed by the airlines (around packaging etc). Currently human tissue may be imported for a number of reasons, including: teaching/education, research, audit, and transplantation. The use of imported whole organs for transplantation (only from Australia at the moment) is covered by the Australia New Zealand Intensive Care Association guidelines. The HSNO Act provides scrutiny of the importation of genetically modified cells.

AP1.3 International Agreements and Standards

The following is a summary of international agreements and standards relevant to undertaking risk analyses for the development of import health standards.

1.3.1 WTO SPS Agreement (1995)

1.3.1.1 Basic rights and obligations

As a member of the World Trade Organization, New Zealand has certain rights and obligations. Under the Agreement on the Application of Sanitary and Phytosanitary Measures (the so-called "SPS Agreement" (1995)) member countries can employ measures[32] to protect human, animal or plant life or health provided that these measures are not applied arbitrarily, do not result in discrimination between members where similar condition prevail or constitute a disguised restriction on trade. Members are obliged to apply these measures only to the extent necessary and to base them on scientific principles, in particular risk assessment techniques developed by relevant international organisations. In addition measures should be based on international standards where they exist. However, if there is a scientific justification that these standards do not achieve an appropriate level of protection, measures that provide a higher level of protection may be applied. The relevant international standards for animal health and zoonoses are the *Terrestrial Animal Health Code*[33] and *Aquatic Animal Health Code*, for food safety issues it is the *Codex Alimentarius Commission*, while for plant health it is *ISPM No. 2 – Guidelines for Pest Risk Analysis* and *ISPM No. 11 Pest Risk Analysis for Quarantine Pests, Including Analysis of Environmental Risks and Living Modified Organisms*.

1.3.1.2 Risk assessment

The SPS Agreement (1995) effectively defines two types of risk assessments, disease or pest risk assessments and food safety risk assessments.

i) Disease or pest risk assessments cover:

a) animal or plant health risks arising from pests or diseases, or

b) human health risks from diseases carried by animals, plants or their products, or

c) human health risks arising from pests

32 Any measure applied:

(a) to protect animal or plant life or health within the territory of an importing country from risks arising from the entry, establishment or spread of pests, diseases, disease-carrying organisms or disease-causing organisms;

(b) to protect human or animal life or health within the territory of an importing country from risks arising from additives, contaminants, toxins or disease-causing organisms in foods, beverages or feedstuffs;

(c) to protect human life or health within the territory of an importing country from risks arising from diseases carried by animals, plants or products thereof, or from the entry, establishment or spread of pests; or

(d) to prevent or limit other damage within the territory of an importing country from the entry, establishment or spread of pest.

These measures include all relevant laws, decrees, regulations, requirements and procedures including, *inter alia*, end product criteria; processes and production methods; testing, inspection, certification and approval procedures; quarantine treatments including relevant requirements associated with the transport of animals or plants, or with the materials necessary for their survival during transport; provisions on relevant statistical methods, sampling procedures and methods of risk assessment; and packaging and labelling requirements directly related to food safety.

33 OIE. *Terrestrial Animal Health Code*, Office International des Epizooties, 2001

These risk assessments evaluate the likelihood of entry, establishment or spread of a disease or pest within the territory of an importing country according to the sanitary or phytosanitary measures which might be applied, and of the associated potential biological and economic consequences (SPS Agreement (1995)). There are three steps involved for these types of assessments (WTO (1998a)[34]; WTO (1998b)[35]). They must:

- identify the pests or diseases whose entry, establishment or spread a Member wants to prevent within its territory, as well as the potential biological and economic consequences associated with the entry, establishment or spread of these pests or diseases;
- evaluate the likelihood of entry, establishment or spread of these pests or diseases, as well as the associated potential biological and economic consequences; and
- evaluate the likelihood of entry, establishment or spread of these pests or diseases according to the SPS measures that might be applied

ii) Food safety risk assessments cover:

a) human or animal health risks arising from foods, beverages or feedstuffs

This type of risk assessment evaluates the potential for adverse effects on human or animal health from the presence of disease causing organisms, additives, contaminants or toxins in foods, beverages or feedstuffs (SPS Agreement (1995))

1.3.1.3 Factors to take into account in a risk assessment

For both types of assessments the following factors must be taken into account (SPS Agreement (1995)):

- available scientific evidence;
- relevant processes and production methods;
- relevant inspection, sampling and testing methods;
- prevalence of specific diseases or pests;
- existence of pest- or disease-free areas and areas of low pest or disease prevalence;
- the existence of eradication or control programs;
- relevant ecological and environmental conditions;
- quarantine or other treatment.

1.3.1.4 Economic factors to consider in a risk assessment

When undertaking a disease or pest risk assessment the relevant economic factors to consider are (SPS Agreement (1995)):

- the potential damage in terms of loss of production or sales in the event of the entry, establishment or spread of a pest or disease;
- the costs of control or eradication;
- the relative cost-effectiveness of alternative approaches to limiting risks.

34 WTO. Report of the Appellate Body. Australia – Measures Affecting Importation of Salmon. WT/DS18/AB/R (AB-1998-5), 1998a
35 WTO. Report of the Panel. Australia – Measures Affecting Importation of Salmon. WT/DS18/R (98-2258), 1998b

1.3.1.5 Levels of risk to be considered

While a disease or pest risk assessment requires an evaluation of the *likelihood* of entry, establishment or spread of a pest or disease, and of the associated potential biological and economic consequences, a food safety risk assessment requires only the evaluation of the *potential* for adverse effects. Since the ordinary meaning of "potential" relates to possibility, not probability or likelihood, there appears to be a significant difference between the two types of risk assessment. However, it is important to bear in mind that the SPS Agreement requires that all risk assessments, whether they are pest or disease risk assessments or food safety risk assessments, should take into account techniques developed by the *International Plant Protection Convention* (IPPC), *World Organisation for Animal Health* (OIE) or *Codex Alimentarius* (Codex) (SPS Agreement (1995)). All of these organisations have developed standards that require that risk be expressed in terms of probability or likelihood, not possibility (OIE (2000); Codex (1997a)[36], Codex (1997b)[37]). As a result it is not sufficient to conclude that there is a possibility of a risk arising. An evaluation of the likelihood of the risk, which may be expressed qualitatively or quantitatively, must be undertaken.

Regardless of which type of assessment is undertaken, the risk evaluated must be ascertainable. Since it is very difficult or perhaps impossible to prove that a risk does not exist, there will always be a degree of uncertainty. In many cases such a risk may be theoretical rather than ascertainable. Theoretical risks are not the types of risks to be considered in a risk assessment (WTO (1998a)[38]).

1.3.1.6 Evaluating disease or pest risks individually

A risk assessment must *identify* risk on a disease-specific basis, that is, it has to identify the risk for any given disease of concern separately, not simply address the overall risk related to the combination of all diseases of concern. However, some of the elements of a risk assessment related to one disease might be used as part of the assessment for another disease, so that disease-by-disease assessments may overlap. As a result, as soon as there is a disease specific assessment for one disease of concern, on which the sanitary measure as a whole can be based, there might be no more need to assess the risks related to the other diseases of concern (WTO (1998b)[39]).

1.3.1.7 Evaluating disease or pest risks according to the measures that might be applied

The SPS Agreement requires that a disease or pest risk assessment must evaluate the likelihood of entry, establishment or spread of disease *according to the SPS measures which might be applied* (SPS Agreement (1995); WTO (1998a)[38]; WTO (1998b)[39]). Although a similar evaluation of measures that might be applied to food safety is not mentioned, Codex does require an evaluation "in light of the results of risk assessment". As a result, regardless of the type of risk assessment, it is not acceptable to simply identify a range of measures that might reduce the risks. There must be a rational relationship between the measures and the risk assessment so that the results of the risk assessment support the measures. Each measure

36 Codex. Codex Alimentarius Commission: Procedural Manual. Tenth edition. Rome. 1997a
37 Codex. Report of the twenty-second session of the joint FAO/WHO Codex Alimentarius Commission. Geneva. Ref. No. ALINORM 97/37, 1997b
38 WTO. Report of the Appellate Body. Australia – Measures Affecting Importation of Salmon. WT/DS18/AB/R (AB-1998-5), 1998a
39 WTO. Report of the Panel. Australia – Measures Affecting Importation of Salmon. WT/DS18/R (98-2258), 1998b

must be evaluated either singly or in combination to determine its relative effectiveness in reducing the overall disease risk (WTO (1998a)[40]).

1.3.1.8 Striving for objectivity in a risk assessment

While a risk assessment inevitably includes subjective elements there are a number of factors within the SPS Agreement, including "risk assessment techniques developed by the relevant international organisations", "available scientific evidence", "scientific principles" and "sufficient scientific evidence", which should be used when evaluating likelihood. The level of objectivity must be such that a reasonable confidence in the evaluation, particularly in the nominated levels of risk, is achieved (WTO (2000)[41]).

1.3.1.9 Dealing with insufficient information (uncertainty)

Sanitary or phytosanitary measures should not be more trade-restrictive than required to achieve the appropriate level of protection[42], taking into account technical and economic feasibility. Where scientific evidence is insufficient, measures may be provisionally adopted on the basis of available pertinent information. However, additional information should be sought to allow a more objective risk assessment within a reasonable period of time (SPS Agreement (1995)). While the so-called "Precautionary Principle"[43] has not been written into the SPS Agreement, it finds reflection in Article 5.7. Its status in international law is the subject of debate and considered by some to be more an approach than a principle. Nevertheless, the "Precautionary Principle" does not over-ride the requirements of the SPS Agreement that sanitary or phytosanitary measures must be based on a risk assessment that takes account of available scientific evidence (WTO (1998c)[44]).

1.3.1.10 Notification

WTO member countries are required to notify other member countries when they propose to introduce a new measure or make changes to an existing measure, particularly where the measure is not substantially the same as an international standard, guideline or recommendation. Except in urgent circumstances, sufficient time should be allowed for comments to be taken into account, amendments to be introduced and exporters to adapt. Where circumstances are urgent member countries are still required to notify with a brief indication of the objective and the rationale of the measure, including the nature of the urgency, and allow other members to comment and take them into account (SPS Agreement (1995)).

40 WTO. Report of the Appellate Body. Australia – Measures Affecting Importation of Salmon. WT/DS18/AB/R (AB-1998-5), 1998a
41 WTO. Report of the Panel. Australia – Measures Affecting Importation of Salmon – Recourse to Article 21.5 by Canada. WT/DS18/RW (00-0542), 2000
42 The level of protection deemed appropriate by the Member establishing a sanitary or phytosanitary measure to protect human, animal or plant life or health within its territory. NOTE: Many Members otherwise refer to this concept as the "acceptable level of risk".
43 Principle 15 of the Rio Declaration on Environment and Development (1992) is often referred to as the *Precautionary Principle*. It states that "in order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation".
44 WTO. Report of the Appellate Body. EC Measures Concerning Meat and Meat Products (Hormones). WT/DS26/AB/R (AB-1997-4), 1998c

1.3.2 International Terrestrial Animal and Aquatic Animal Health Codes

The *Terrestrial Animal Health Code* and *Aquatic Animal Health Code* of the *World Organisation for Animal Health* (OIE) are the standards referred to in the SPS Agreement that apply to animal health and zoonoses (OIE (2000a)[45]; OIE (2000b)[46]). These *Codes*[47] aim to ensure the sanitary safety of international trade in animals (mammals, birds, bees and aquatic species) and animal products so as to avoid the transfer of disease-agents that are pathogenic for animals or humans. There is a separate chapter for each disease covered by these *Codes* detailing applicable sanitary measures. Each chapter lists the commodities that the OIE considers capable of transmitting the disease through international trade. Where a particular commodity is not listed it means that the OIE has not yet been able to develop a recommendation. This inconsistency creates a challenge for those managing the risks posed by trade. In situations where the OIE has not formulated recommendations and in those where stricter sanitary conditions may be warranted, a risk analysis needs to be carried out to determine the need for, and type of, sanitary measures that are appropriate. If OIE measures are applied there may be no need to conduct a risk analysis, at least as far as international obligations are concerned.

Import risk analysis is covered in Section 1.4 of the *Aquatic Animal Health Code* and Section 1.3 of the *Terrestrial Animal Health Code*. As both texts are closely similar, the following discussing focuses on the *Terrestrial Animal Health Code* only. Section 1.3 of that document (hereafter referred to as the *Code*) provides recommendations and guidelines for import risk analysis. It is divided into five sections: general considerations, guidelines for risk analysis, evaluation of veterinary services, zoning and regionalisation, and surveillance and monitoring of animal health.

According to the *Code* the principal aim of import risk analysis is to provide *importing countries* with an objective and defensible method of assessing the disease risks associated with the importation of *animals*, animal products, animal genetic material, feedstuffs, *biological products* and *pathological material*. The analysis should be transparent. This is necessary so that the *exporting country* is provided with clear reasons for the imposition of import conditions or refusal to import.

The *Code* identifies four components of a risk analysis: hazard identification, risk assessment, risk management and risk communication and provides a list of terms and corresponding definitions.

1.3.2.1 Hazard identification

Hazard identification involves identifying pathogenic agents that could potentially produce adverse consequences associated with the importation of a commodity[48]. To classify an agent as a hazard the following criteria need to be fulfilled:

45 OIE. *Terrestrial Animal Health Code: mammals, birds and bees*. 10th edition. Office International des Epizooties, Paris, 2001a

46 OIE. *Aquatic Animal Health Code*. 3rd edition. Office International des Epizooties, Paris, 2001b

47 The full text of Section 1.4, Import Risk Analysis, of the Terrestrial Animal Health Code is in appendix 4. Section 1.4 of the Aquatic Animal Health Code is being re-drafted to harmonise it with the Animal Health Code. Since it is expected to be essentially the same as the Animal Health Code it is not re-produced here.

48 Commodity means animals, products of animal origin intended for human consumption, for animal feeding, for pharmaceutical or surgical use or for agricultural or industrial use, semen, embryos/ova, biological products and pathological material.

- the agent must be appropriate to the species being imported, or from which the commodity is derived;
- it may be present in the exporting country[49];
- if present in the importing country it must be a notifiable disease[50] or subject to control or eradication.

A risk assessment may be concluded if the hazard identification step fails to identify potential hazards associated with an imported commodity. If an importing country applies the appropriate sanitary standards recommended in the *Code* there is no need to conduct a risk assessment.

1.3.2.2 Risk assessment

Risk assessment is the process of evaluating the likelihood and biological and economic consequences of entry, establishment or spread of a pathogenic agent within the territory of an importing country. It consists of four inter-related steps:

i) *Release assessment*, which consists of estimating the likelihood of an imported commodity being infected or contaminated with a hazard and describing the biological pathway(s) necessary for that hazard to be introduced into a particular environment.

ii) *Exposure assessment*, which consists of describing the biological pathway(s) necessary for exposure of animals and humans in the importing country to the hazards and estimating the likelihood of those exposure(s) occurring.

iii) *Consequence assessment*, which consists of describing the relationship between exposures to a hazard, the potential consequences of those exposures and their likelihood.

iv) *Risk estimation*, which consists of integrating the results from the release assessment, exposure assessment, and consequence assessment to produce summary measures of the risks associated with the identified hazards.

1.3.2.3 Risk management

Risk management is the process of deciding upon and implementing measures to achieve the importing country's appropriate level of protection, whilst at the same time ensuring that negative effects on trade are minimised. The objective is to manage risk appropriately to ensure that a balance is achieved between a country's desire to minimise the likelihood or frequency of disease incursions and their consequences and its desire to import goods and fulfil its obligations under international trade agreements. Four components are identified:

i) *Risk evaluation*, where the estimated risk is compared with the importing country's appropriate level of protection.

ii) *Option evaluation*, where measures are identified, evaluated and selected to effectively manage the risks in line with the importing country's appropriate level of protection.

49 The evaluation of the Veterinary Services, surveillance and control programmes and zoning and regionalisation systems are important inputs for assessing the likelihood of hazards being present in the animal population of the exporting country.

50 Notifiable disease means a disease listed by the Veterinary Authority, and that, as soon as detected or suspected, must be brought to the attention of the Veterinary Authority

iii) *Implementation*,

iv) *Monitoring and review*, where measures are audited to ensure that they are achieving the results intended.

1.3.2.4 Risk communication

Risk communication is the process by which information and opinions regarding hazards and risks are gathered from potentially affected and interested parties during a risk analysis, and by which the results of the risk assessment and proposed risk management measures are communicated to the decision-makers and interested parties in the *importing* and *exporting countries*. It is a multidimensional and iterative process and should ideally begin at the start of the risk analysis process and continue throughout.

1.3.3 International Plant Protection Convention

Standards developed under the *International Plant Protection Convention* (IPPC), namely *ISPM No. 2 Guidelines for Pest Risk Analysis*[51], *ISPM No. 11 Pest Risk Analysis for Quarantine Pests, Including Analysis of Environmental Risks and Living Modified Organisms*[52], and *ISPM No. 21 Pest risk analysis for regulated non-quarantine pests*[53], provide details for the conduct of pest risk analysis (PRA) to determine if pests are quarantine pests. These standards describe the integrated processes to be used for risk assessment as well as the selection of risk management options. They also include details regarding the analysis of risks of plant pests to the environment and biological diversity, including those risks affecting uncultivated/unmanaged plants, wild flora, habitats and ecosystems contained in the PRA area.

Under these standards the objectives of a PRA are, for a specified area, to identify pests and/or pathways of quarantine concern to plant health and evaluate their risk, to identify endangered areas, and, if appropriate, to identify risk management options. Pest risk analysis (PRA) for quarantine pests follows a process defined by three stages:

Stage 1 (initiating the process) involves identifying the pest(s) and pathways that are of quarantine concern and should be considered for risk analysis in relation to the identified PRA area.

Stage 2 (risk assessment) begins with the categorization of individual pests to determine whether the criteria for a quarantine pest are satisfied. Risk assessment continues with an evaluation of the probability of pest entry, establishment, and spread, and of their potential economic consequences (including environmental consequences).

Stage 3 (risk management) involves identifying management options for reducing the risks identified at stage 2. These are evaluated for efficacy, feasibility and impact in order to select those that are appropriate.

51 **ISPM No 2.** *Guidelines for Pest Risk Analysis* (ISPM No. 2). FAO 1996
52 **ISPM No 11.** *Pest Risk Analysis for Quarantine Pests, Including Analysis of Environmental Risks and Living Modified Organisms* (ISPM No. 11). FAO 2004
53 **ISPM No 21**. *Pest risk analysis for regulated non-quarantine pests* (ISPM No. 21). FAO 2004

1.3.3.1 Stage 1: Initiating the PRA Process

There are generally two initiation points for a pest risk analysis:

i) the identification of a pathway, usually an imported commodity, that may allow the introduction and/or spread of quarantine pests

ii) the identification of a pest that may qualify as a quarantine pest.

Either can involve pests already present in the PRA area but not widely distributed and being officially controlled, as well as pests absent from the PRA area, since both are covered by the quarantine pest definition.

At the end of Stage 1, pests have been identified as potential quarantine pests, individually or in association with a pathway.

1.3.3.2 Stage 2: Pest Risk Assessment

Stage 1 has identified a pest, or list of pests (in the case of initiation by a pathway), to be subjected to risk assessment. Stage 2 considers these pests individually. It examines, for each, whether the criteria for quarantine pest status are satisfied:

> "a pest of potential economic importance to the area[54] endangered[55] thereby and not yet present there, or present but not widely distributed and being officially controlled"

In doing so, the PRA considers all aspects of each pest and in particular actual information about its geographical distribution, biology and economic importance. Expert judgement is then used to assess the establishment, spread and economic importance potential in the PRA area. Finally, the potential for introduction into the PRA area is characterized. In characterizing the risk, the amount of information available will vary with each pest and the sophistication of the assessment will vary with available tools. For example, one country may have elaborate pest databases and geographical information systems; another may depend on books, printed soil maps, and climate maps. In some cases, virtually no information may be available, or research may be needed to obtain it. Assessments will be limited by the amount of information available on the biology of a particular pest. Countries where the pest is present may provide available information for the country conducting the PRA, on request.

If the pest satisfies the definition of a quarantine pest, expert judgement should be used to review the information collected during Stage 2 to decide whether the pest has sufficient economic importance and introduction potential, i.e. sufficient risk, for phytosanitary measures to be justified. If so, proceed to Stage 3; if not, the PRA for the pest stops at this point.

54 In this context, "area" should be understood to mean: "an officially defined country, part of a country, or all or part of several countries".
55 An "endangered area" should be understood to mean: "an area where ecological factors favour the establishment of a pest whose presence in the area will result in economically important loss".

1.3.3.3 Stage 3: Risk management

Pest risk management to protect the endangered areas should be proportional to the risk identified in the pest risk assessment. In most respects it can be based on the information gathered in the pest risk assessment. Phytosanitary measures should be applied to the minimum area necessary for the effective protection of the endangered area.

Appropriate measures should be chosen based on their effectiveness in reducing the probability of introduction of the pest. The choice should be based on the following considerations, which include several of the *Principles of plant quarantine as related to international trade* (ISPM No. 1[56]):

- *Phytosanitary measures shown to be cost-effective and feasible* - The benefit from the use of phytosanitary measures is that the pest will not be introduced and the PRA area will, consequently, not be subjected to the potential economic consequences. The cost-benefit analysis for each of the minimum measures found to provide acceptable security may be estimated. Those measures with an acceptable benefit-to-cost ratio should be considered.
- *Principle of "minimal impact"* - Measures should not be more trade restrictive than necessary. Measures should be applied to the minimum area necessary for the effective protection of the endangered area.
- *Reassessment of previous requirements* - No additional measures should be imposed if existing measures are effective.
- *Principle of "equivalence"* - If different phytosanitary measures with the same effect are identified, they should be accepted as alternatives.
- *Principle of "non-discrimination"* - If the pest under consideration is established in the PRA area but of limited distribution and under official control, the phytosanitary measures in relation to import should not be more stringent than those applied within the PRA area. Likewise, phytosanitary measures should not discriminate between exporting countries of the same phytosanitary status.

At the end of Stage 3, the appropriate phytosanitary measures concerning the pest or pathway have been decided. Completion of Stage 3 is essential; it is in particular not justified to complete only Stages 1 and 2 and then take phytosanitary measures without proper assessment of risk management options. After implementation of the phytosanitary measures, their effectiveness should be monitored and the risk management options should be reviewed, if necessary.

1.3.4 Codex Alimentarius

The SPS Agreement nominates the standards, guidelines, codes of practice and recommendations of the *Codex Alimentarius* (hereafter referred to as the *Codex*) relating to food additives, veterinary drugs and pesticide residues, contaminants, methods of analysis and sampling, and hygienic practice as the relevant organisation for food safety. The *Codex* defines food as any substance, whether processed, semi-processed or raw, which is intended for human consumption. Food hygiene comprises conditions and measures necessary for the

56 **ISPM No 1.** *Principles of Plant Quarantine as Related to International Trade* (ISPM No. 1). FAO 1995

production, processing, storage and distribution of food designed to ensure a safe, sound, wholesome product fit for human consumption (*Codex*, 1997a[57]).

The purpose of the *Codex* is to protect the health of consumers against food-borne hazards, whether they are physical, chemical or biological, and to facilitate international trade (*Codex*, 1997a[57]; FAO, 1999[58]). General principles have been developed for food import and export inspection and certification. Codes of practice provide guidance on the production of food to protect the health of consumers. There are two codes of practice and one draft code relevant to international trade:

i) *Recommended International Code of Practice - General Principles of Food Hygiene* that applies to all foods from primary production through to final consumption, highlighting the key hygiene controls required at each stage (Codex, 1997b[59]). It recommends a Hazard Analysis and Critical Control Point (HACCP) based approach wherever possible. This *preventive* system offers more control than end product testing, because the effectiveness of microbiological examination in assessing the safety of food is limited. The *Codex* recommends that the implementation of HACCP should be guided by scientific evidence of risks to human health.

ii) *Code of Ethics for International Trade in Food* which encourages food traders to adopt voluntarily ethical practices as an important way of protecting consumers' health and promoting fair practices in the food trade (FAO, 1999[58]). A principal objective of the *Code of Ethics* is to stop exporting countries and exporters from dumping poor-quality or unsafe food on to international markets.

iii) *Draft Code of Practice for Good Animal Feeding* which applies to feed[60] manufacturing and to the use of all feeds, other than those consumed while grazing free range (FAO, 1998[61]). The objectives of the code are to encourage adherence to Good Manufacturing Practice (GMP) during the procurement, handling, storage, processing (however minimal), and distribution of feed for food producing animals and to facilitate international trade in animal feedstuffs and animal food products.

The *Codex* Commission is developing guidelines and recommendations for Food Import Control Systems to assist in the management of food safety hazards while minimising trade disruptions (Codex, 2000[62]). Amongst other things the guidelines cover the roles and functions of authorities involved, frequency of testing and inspection, points of control, equivalence of control systems between countries, verification and certification.

Risk analysis is the fundamental methodology underlying the development of food safety standards by the *Codex* Commission. It is composed of three separate but integrated

57 **Codex.** Codex Alimentarius Commission: Procedural Manual. Tenth edition. Rome. 1997a.
58 **FAO.** Understanding the Codex Alimentarius. Food and Agriculture Organization of the United Nations. Rome, 1999
59 **Codex.** Recommended International Code of Practice – General Principles of Food Hygiene. CAC/RCP 1-1969, Rev, 3, 1997b
60 Feed means any substance whether processed, semi-processed or raw, which is intended for consumption by animals from which food for human consumption is derived.
61 **FAO.** Draft Code of Practice for Good Animal Feeding, Annex 2, Animal feeding and food safety (FAO Food and nutrition paper – 69). Rome, 1998
62 **Codex.** Codex Committee on Food Import and Export Inspection and Certification Systems. Eighth Session. Adelaide, Australia, 21-25 February 2000

elements, namely risk assessment, risk management and risk communication[63] (Codex, 1997a[64]; Codex, 1997b[65]):

1.3.4.1 Risk assessment

Risk assessment is a scientifically based process consisting of the following steps:

i) *Hazard identification*, which is the identification of biological, chemical, and physical agents capable of causing adverse health effects and which may be present in a particular food or group of foods.

ii) *Hazard characterisation*, which is the qualitative and/or quantitative evaluation of the nature of the adverse health effects, associated with biological, chemical and physical agents that may be present in food. For chemical agents, a dose-response assessment should be performed. For biological or physical agents, a dose-response assessment[66] should be performed if the data are obtainable.

iii) *Exposure assessment*, which is the qualitative and/or quantitative evaluation of the likely intake of biological, chemical, and physical agents via food as well as exposures from other sources if relevant.

iv) *Risk characterisation*, which is the qualitative and/or quantitative estimation, including attendant uncertainties, of the probability of occurrence and severity of known or potential adverse health effects in a given population based on hazard identification, hazard characterisation and exposure assessment.

1.3.4.2 Risk management

Risk management is the process of weighing policy alternatives in the light of the results of risk assessment and, if required, selecting and implementing appropriate control options, including regulatory measures.

1.3.4.3 Risk communication

Risk communication is the interactive exchange of information and opinions concerning risk among risk assessors, risk managers, consumers and other interested parties.

1.3.5 Convention on Biological Diversity (1992)

The objectives of the Convention on Biological Diversity (1992) are the conservation and sustainable use of biological diversity and the fair and equitable sharing of benefits arising out of the use of genetic resources. Article 8(h) of the Convention states that 'each contracting party shall, as far as possible and as appropriate prevent the introduction of, control or eradicate those alien species which threaten ecosystems, habitats or species'.

63These Definitions were adopted by the 22nd Session of the Commission (1997)(4) on an interim basis: they are subject to modification in the light of developments in the science of risk analysis and as a result of efforts to harmonise similar definitions across various disciplines
64 **Codex.** Codex Alimentarius Commission: Procedural Manual. Tenth edition. Rome. 1997a.
65 **Codex.** Recommended International Code of Practice – General Principles of Food Hygiene. CAC/RCP 1-1969, Rev, 3, 1997b
66 ***Dose-response assessment:*** The determination of the relationship between the magnitude of exposure (dose) to a chemical, biological or physical agent and the severity and/or frequency of associated adverse health effects (response).

It does not specify how Parties to the Convention should implement this requirement, but the sixth Conference of the Parties (COP 6) adopted[67] 15 guiding principles for the prevention, introduction and mitigation of impacts of invasive alien species. Guiding principle 7: Border control and quarantine measures, requires States to implement border controls and quarantine measures for alien species that are or could become invasive to ensure that intentional introductions of alien species are subject to appropriate authorization and unintentional or unauthorized introductions of alien species are minimized. These measures should be based on a risk analysis of the threats posed by alien species and their potential pathways of entry.

The SPS allows Members to take sanitary and phytosanitary measures necessary for the protection of human, animal or plant life and health provided that they are based on scientific principles and are not applied in a manner which would constitute a disguised restriction on international trade. The SPS definition of 'animal' includes fish and wild fauna and 'plant' includes forests and wild flora'. It thus makes provision for measures such as those required by the CBD which go beyond the scope of the established international agreements.

The preamble to the Convention on Biological Diversity also provides for application of the precautionary principle: 'where there is a threat of significant reduction or loss of biological diversity, lack of full scientific certainty should not be used as a reason for postponing measures to avoid or minimize such a threat'. Guiding principle 1 (COP6) advises that given the unpredictability of the pathways and impacts on biological diversity of invasive alien species, efforts to identify and prevent unintentional introductions as well as decisions concerning intentional introductions should be based on the precautionary approach, in particular with reference to risk analysis.

1.3.6 International Health Regulations (2005)

The new International Health Regulations (IHR) were adopted by the Fifty-Eighth World Health Assembly on 23 May 2005. At the time of writing New Zealand still has an opportunity to lodge reservations against certain aspects of the regulations. If New Zealand does not lodge any reservations it will be bound by the regulations as adopted by the World Health Assembly.

The new regulations are designed to prevent, protect against, control and provide a public health response to the international spread of disease such as the recent outbreaks of SARS in 2003 and avian influenza in 2004-2005. They aim to do this in ways that are commensurate with and restricted to public health risks, and which avoid unnecessary interference with international traffic and trade. The IHR also establish a single code of procedures and practices for routine public health measures at international airports and ports and some ground crossings.

A great deal of the provisions in the regulations deal with issues that are not directly relevant to MAF's risk analysis procedures, such as: the movement of people; the movement and sanitary conditions of craft; and the sanitary requirements for ports and other points of entry.

Other provisions deal with the movement of cargo, mail, containers and goods generally and so do create obligations for MAF when carrying out risk analysis.

67 One representative entered a formal objection during the process leading to the adoption of this decision and underlined that he did not believe the Conference of the Parties could legitimately adopt a motion or a text with a formal objection in place. A few representatives expressed reservations regarding the procedure leading to the adoption of the decision.

The IHR do not prescribe risk assessment in the same way as the SPS agreement. However they do contain certain general requirements that will have implications for risk assessment by whichever part of the government is deemed to be the "competent authority". MAF currently assumes the role of competent authority much of the time and – when acting in this capacity – is bound by the IHR.

Article 22 (1) (c) requires competent authorities to:

> "(c) be responsible for the supervision of any deratting, disinfection, disinsection or decontamination of baggage, cargo, containers, conveyances, goods, postal parcels and human remains or sanitary measures for persons, as appropriate under these Regulations;"

To the extent that this provision applies to baggage, cargo, containers, goods and postal parcels it requires MAF – as the competent authority - to assess the public health risk posed by such incoming material and the consequent need for deratting, disinfection, disinsection or decontamination.

Also relevant are Articles 22 (1) (f) and (g), which require competent authorities to:

> "(f) take all practicable measures consistent with these regulations to monitor and control the discharge by ships of sewage, refuse, ballast water and other potentially disease-causing matter which might contaminate the waters of a port, river, canal, strait, lake or other international waterway;"

> "(g) be responsible for supervision of service providers for services concerning travellers, baggage, cargo, containers, conveyances, goods, postal parcels and human remains at points of entry, including the conduct of inspections and medical examinations as necessary;"

Article 22 (1) (f) imposes obligations on MAF to assess the risk posed to public health from ship discharges and consider how to monitor and control these discharges. Article 22 (1)(g) requires MAF to assess the need for inspections of goods crossing the border.

MAF must also assess and avoid the collateral effects of any border biosecurity measures on people, goods and the environment. As stated by Article 22 (3):

> "(3) Disinsection, deratting, disinfection, decontamination and other sanitary procedures shall be carried out so as to avoid injury and as far as possible discomfort to persons, or damage to the environment in a way which impacts on public health, or damage to baggage, cargo, containers, conveyances, goods and postal parcels."

Additional obligations to carry out risk assessment may result if the World Health Organization declares a public health emergency of international concern under Article 12.

Such emergencies become relevant under Article 22 (1) (a) of the regulations which requires "competent authorities" within states parties such as New Zealand to:

"(a) be responsible for monitoring conveyances, containers, cargo, goods and baggage and postal parcels departing and arriving from **affected areas**, to ensure that they are maintained in such a condition that they are free of sources of infection or contamination, including vectors and reservoirs;" [emphasis added]

Thus MAF must assess the risk posed by goods originating from an "affected area" and ensure that they are free of the contamination of concern. This may require capacity to make urgent re-assessments of risk and diverge from the regular import health standard measures which were drafted prior to the emergency.

Further obligations may result if the World Health Organization makes standing recommendations under Article 16 for the routine or periodic inspection, treatment or destruction of goods from affected areas that may be associated with organisms of public health concern.

At the time of writing this report there are no standing recommendations however it will be important for MAF to ensure that all risk analyses take account of any such recommendations that exist.

The International Health Regulations allow that compliance with standing recommendations is not mandatory because Article 16 states that:

"Such measures **may** be applied by State Parties…" [emphasis added]

The Ministry of Health will be the lead agency informing a whole of government view as to the desirability of implementing, modifying or exceeding any standing recommendations issued by World Health Organization. However, MAF should seek to comply with standing recommendations at all times, unless in conjunction with the Ministry of Health it is determined that there is some special reason peculiar to New Zealand that would justify an exception.

Appendix 2: Check List for Risk Analysis Projects

File : _____

CHECKSHEET

PROJECT DOCUMENTS

Project Name	**Date initiated**

Document Name	**Author**	**Date completed/signed**
Project Brief		
Project Plan		
Project Communication Plan		
Deliverable (1) e.g. Draft for review		
Deliverable (2)		
Close-out Report		

Comments:

PROJECT PARTICIPANTS

Name	**Project Designation**
	Director Pre-Clearance (or designate)
	Business Owner
	Project Sponsor
	Project Manager
	Steering Group/Project Team/Consultant

INTERNAL PEER REVIEW

1. Risk Assessment only

Reviewer(s) name	**Date**	**Date comments received**	**Changes required?**	**Date complete**

Comments:

2. Risk Management

Reviewer(s) name	**Date**	**Date comments received**	**Changes required?**	**Date complete**

Comments:

DRAFT FOR EXTERNAL REVIEW APPROVED

Approved by (name):	Project designation	Date approved:

EXTERNAL TECHNICAL REVIEW

1. Risk Assessment only

Reviewer(s) name	Date	Date comments received	Changes required?	Date complete

Comments:

2. Risk Management measures proposed

Reviewer(s) name	Date	Date comments received	Changes required?	Date complete

Comments:

COPY FOR CONSULTATION APPROVED

Approved by (name):	Project designation	Date approved:

RELEASE FOR CONSULTATION WITH GOVERNMENT DEPARTMENTS

Sent for consultation to (name)	Date	Date comments received	Changes required?	Date complete

Comments:

NOTIFICATION OF GENERAL RELEASE

Notification type & place	Date of notification

Comments:

PUBLIC DISTRIBUTION FOR CONSULTATION

Sent to:	Date

Comments:

SUBMISSIONS

Original deadline for submissions: _____
Extended to: _____
For reason: _____

Submissions received from	Date

Comments:

REVIEW OF SUBMISSIONS

Approved by (name):	Project designation	Date approved:

Sent to:	Date

Comments:

FINAL COPY APPROVED

Approved by (name):	Project designation	Date approved:

COVERING LETTER FROM SPONSOR (for risk analysis prepared by consultants)

Approved by (name):	Project designation	Date approved:

Notes on Checklist:

- Complete the checklist as the tasks are completed as the checklist may be referenced in your absence.
- Complete comments as indicated to provide an annotated commentary for later reference when completing the close-out report.

Appendix 3: Process Diagrams for the Risk Analysis Framework

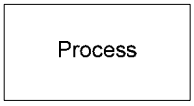
The following process diagrams describe the risk analysis process and how it will interact with different groups within and external to the Ministry of Agriculture and Forestry. Table AP3 and Figure AP3 provide information to aid in the interpretation of the diagrams.

Table AP3: Lane header descriptions for the process diagrams

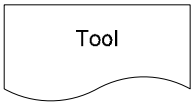
Lane Header	Definition
External	All those involved in the project either through consultation (e.g. stakeholders) (see Section 3.3.2) or peer review (e.g. experts) (see Section 3.3.1) that are external to MAF.
IHS Prioritising Committee	The import health standard application prioritization panel that prioritises import health standard development using the Integrated Risk Management Framework (see Chapter 2)
BSG Processes	Business processes managed by the Biosecurity Standards Group
Post-clearance Processes	Business processes managed by the Post-Clearance directorate
RA Managers	The group and team managers within the risk analysis group
RA Project Manager	The Manager of the risk analysis project (see Section 3.2.2)
RA Project Sponsor	The Sponsor of the risk analysis project (see Section 3.2.2)
Director Pre-Clearance	The Director of Pre-Clearance (Biosecurity New Zealand) or designate
RA Processes	Business processes managed by the Risk Analysis Group
Tools	Documents providing guidance or templates for steps in the process

Figure AP3: Key to symbols used in the process diagrams

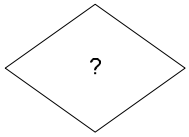
Links the beginning or end of the process to the previous or next page.



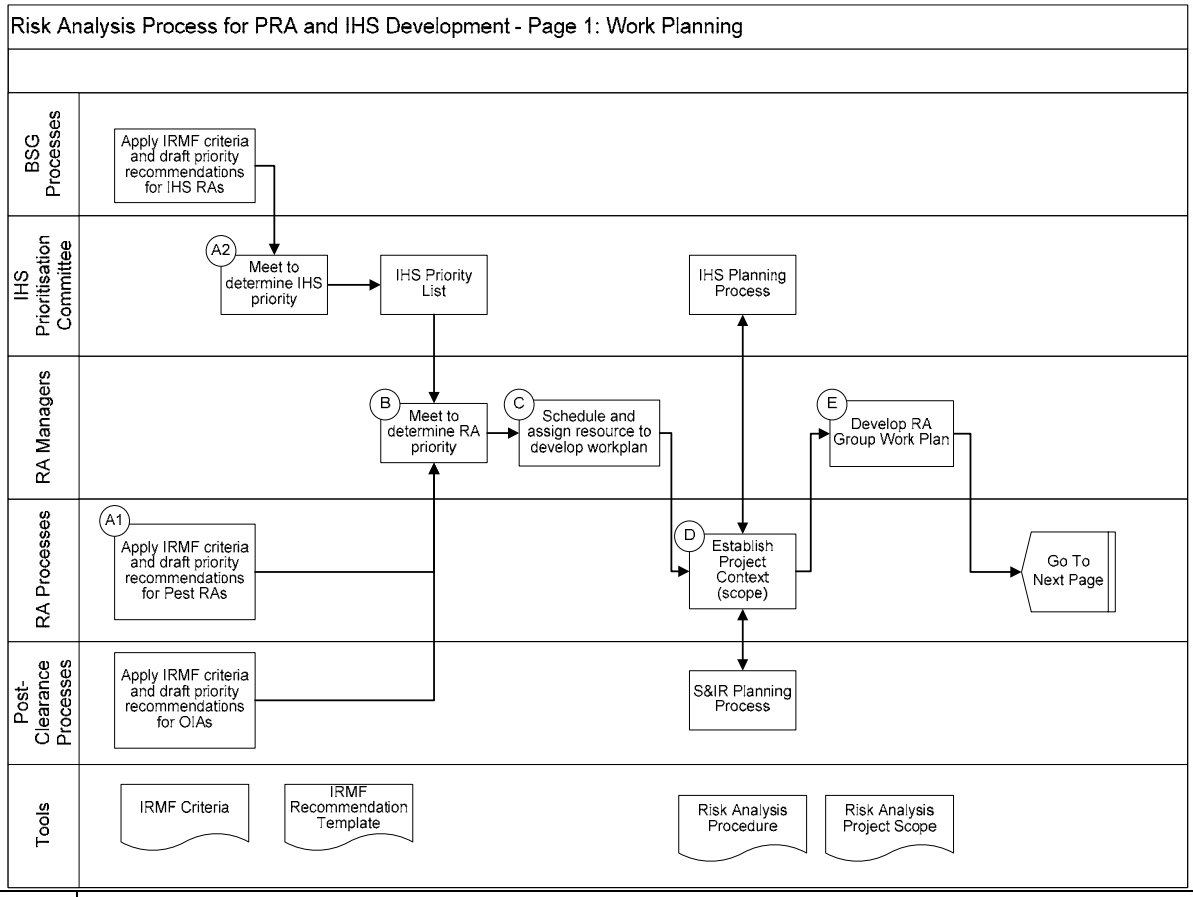
Contains a short description of a process or activity.



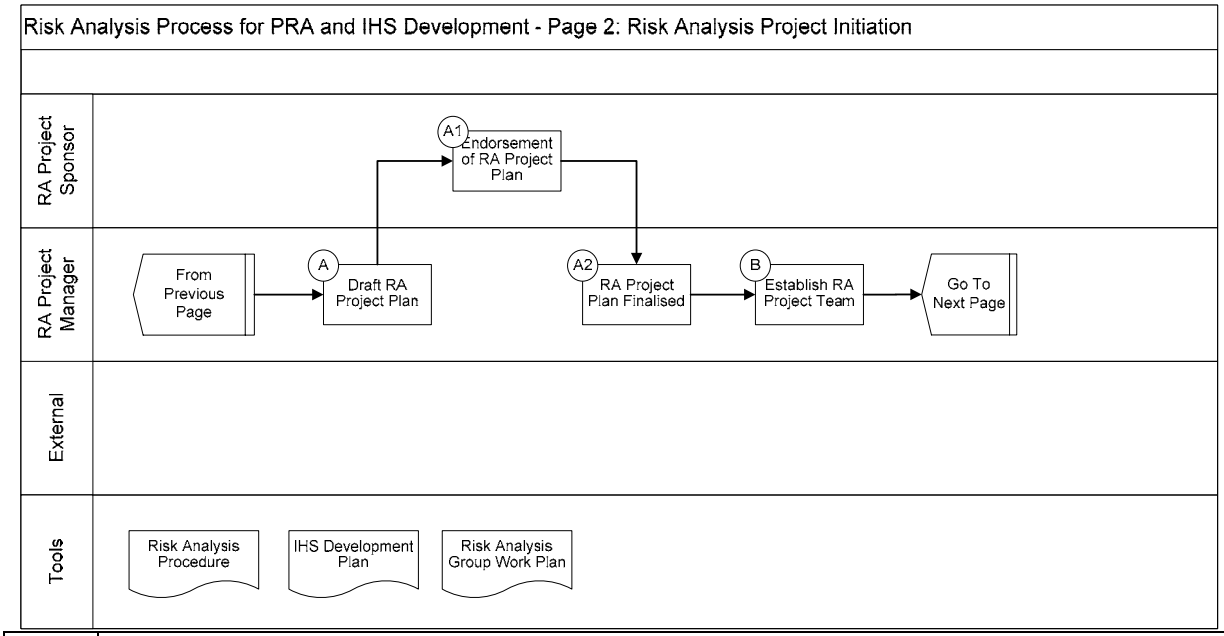
Represents a tool e.g. a template or a procedure.



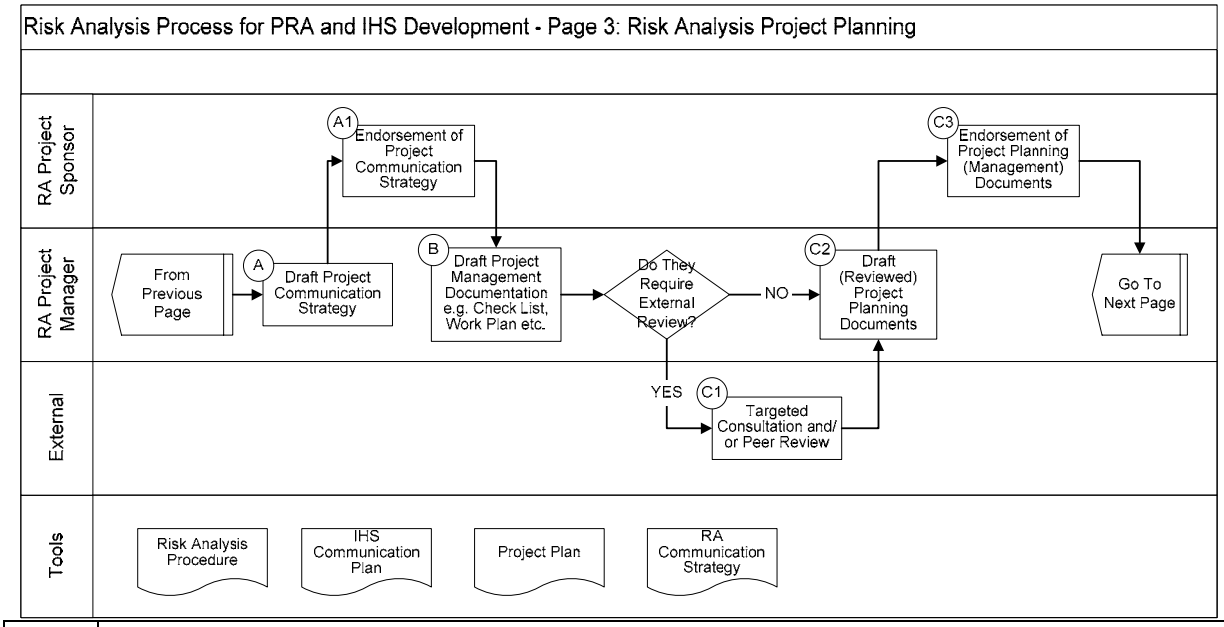
A decision box where a decision will lead to two or more pathways.



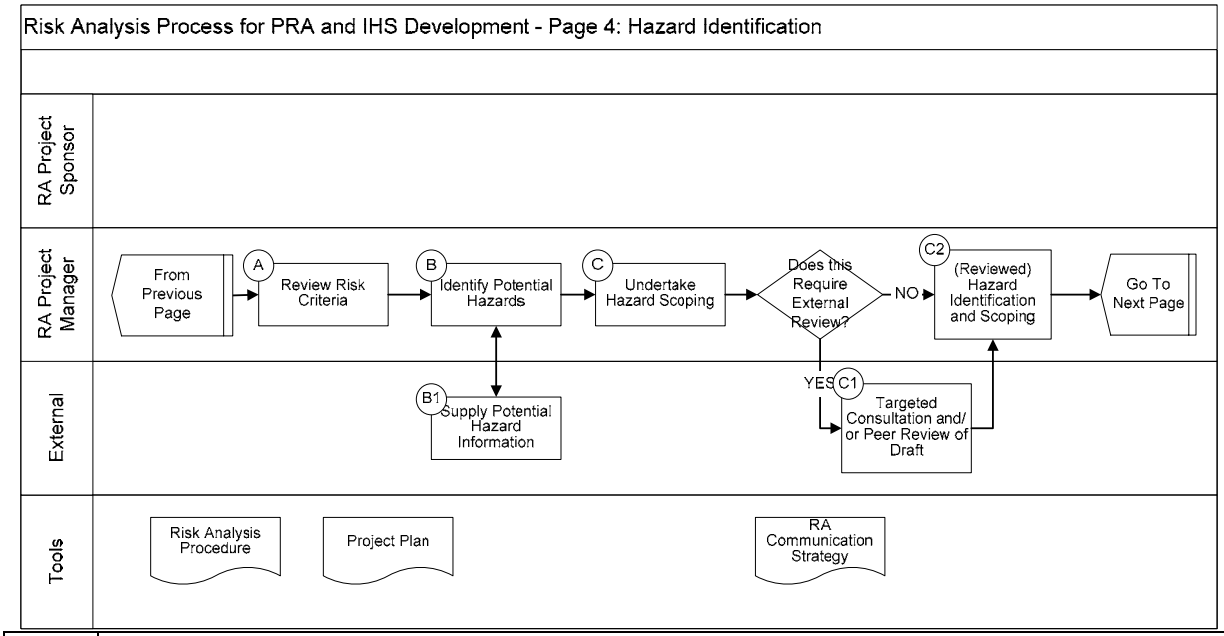
Step	Action (see Chapters 2 and 3)
A1	This step is for projects that come to the risk analysis group through less regular channels e.g. from EMT, Policy etc. 1) The proposed Project Manager or Sponsor applies the IRMF criteria to suggested projects. 2) Record recommendations providing sufficient information to allow the RA managers to compare priorities to those of other projects. • IRMF Criteria • IRMF Recommendation Template
A2	Documented as part of import health standard processes.
B	1) Managers within the Risk Analysis Group meet to review and discuss the priority recommendations for risk analysis projects 2) If required, request RA, IHS, or S&IR groups provide further explanation of priority recommendations 3) Endorse or modify and endorse priority recommendations for RA work programme 4) Record process and endorsements • Risk Analysis Procedures (Chapter 2)
C	Managers with the Risk Analysis Group schedule and assign resource to develop project work plan (e.g. assign project leader)
D	The assigned Project Manager establishes and documents, in consultation for instance with IHS and/or Post-clearance, the risk analysis project context and scope. • Risk Analysis Procedures (Section 3.4 (part))
E	Risk Analysis Group Managers develop or modify the risk analysis group work plan. • Risk Analysis Group Business Procedures



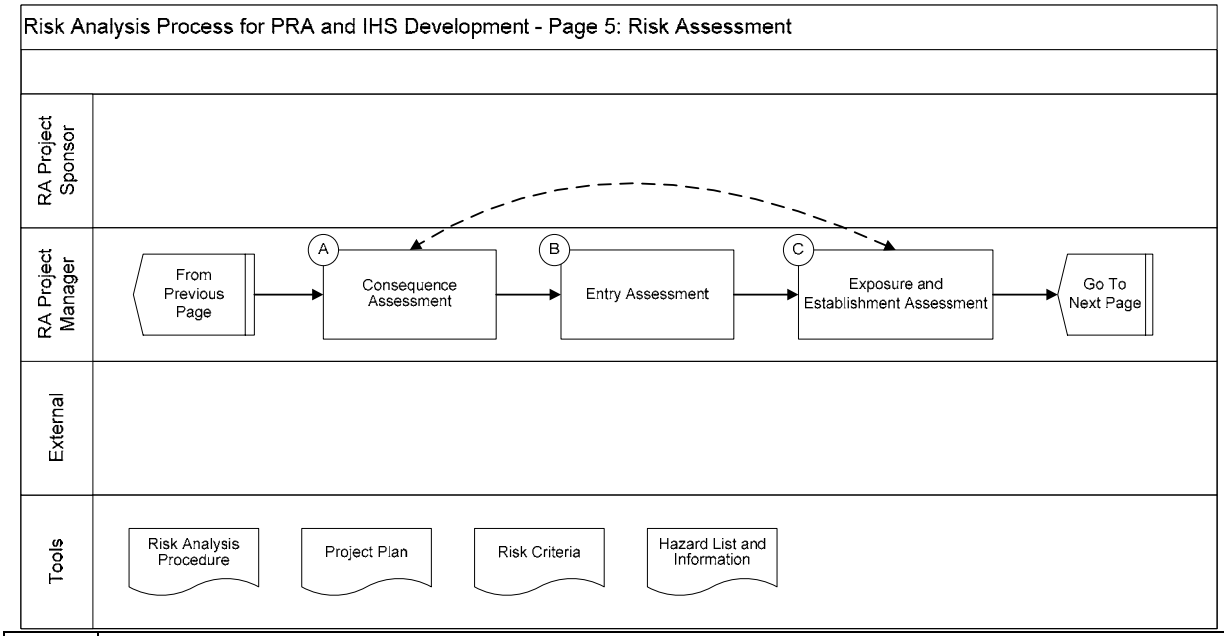
Step	Action (see Chapter 3 – Sections 3.1 to 3.5)
A	1) The Project Manager drafts the project plan. 2) Record draft project plan. • Risk Analysis Procedures (Section 3.4) • IHS or Post-clearance project development plans (if applicable) • Risk Analysis Group work plan
A1	Project Sponsor endorses project plan (with modifications as required)
A2	The Project Manager finalises the project plan
B	The Project Manager establishes the Project Team: 1) Invites project team members to participate in Project Team (provides project plan) 2) Arranges first Project Team meeting and then agrees necessary Project Team meetings for the project. • Risk Analysis Procedures • Risk Analysis Project Plan



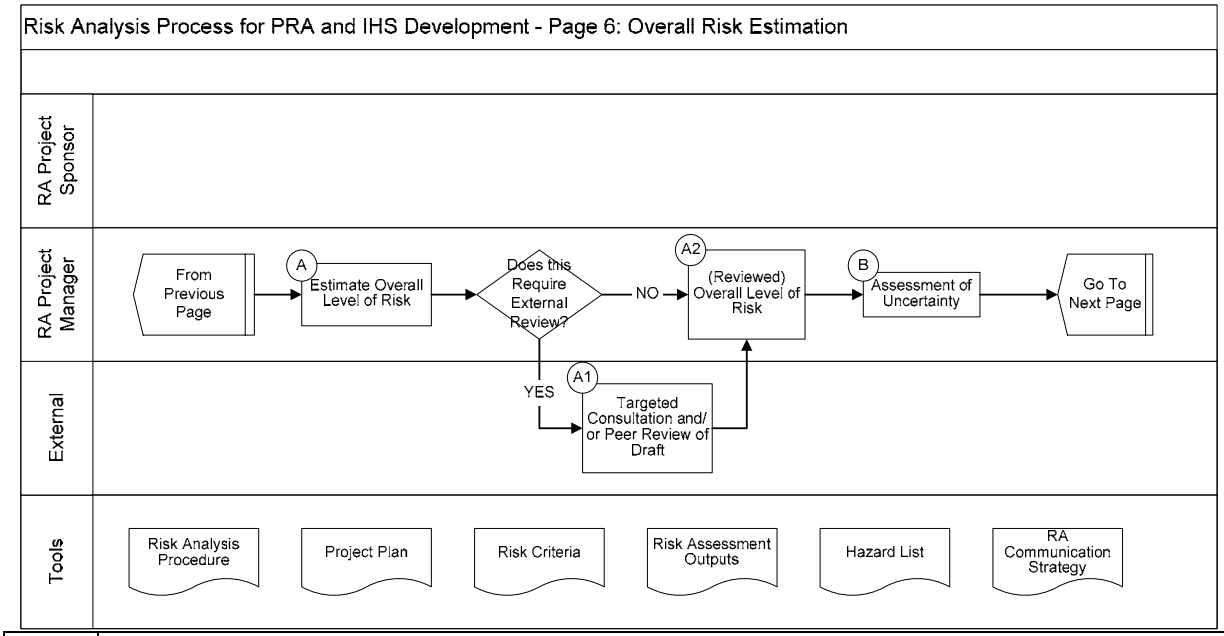
Step	Action (see Sections 3.4 to 3.5)
A	The Project Manager ensures the project risk communication strategy is documented. • Risk Analysis Procedures (Section 3.3) • Project Plan • IHS or Post-clearance project communication strategies (if applicable)
A1	The Project Sponsor endorses the project risk communication strategy (with modifications as required).
B	The Project Manager ensures the required project management documentation are completed. These include a work plan and check list, and may also include a project risk register. • Risk Analysis Procedures • Project Plan
C1	The Project Manager ensures targeted consultations and/or peer reviews on the project documents are undertaken as per the communication plan. • Project Communication Strategy
C2	The Project Manager ensures the project documents are reviewed in light of consultation and/or peer review submissions (as appropriate)
C3	The Project Sponsor endorses the project management documents (with modifications as required).



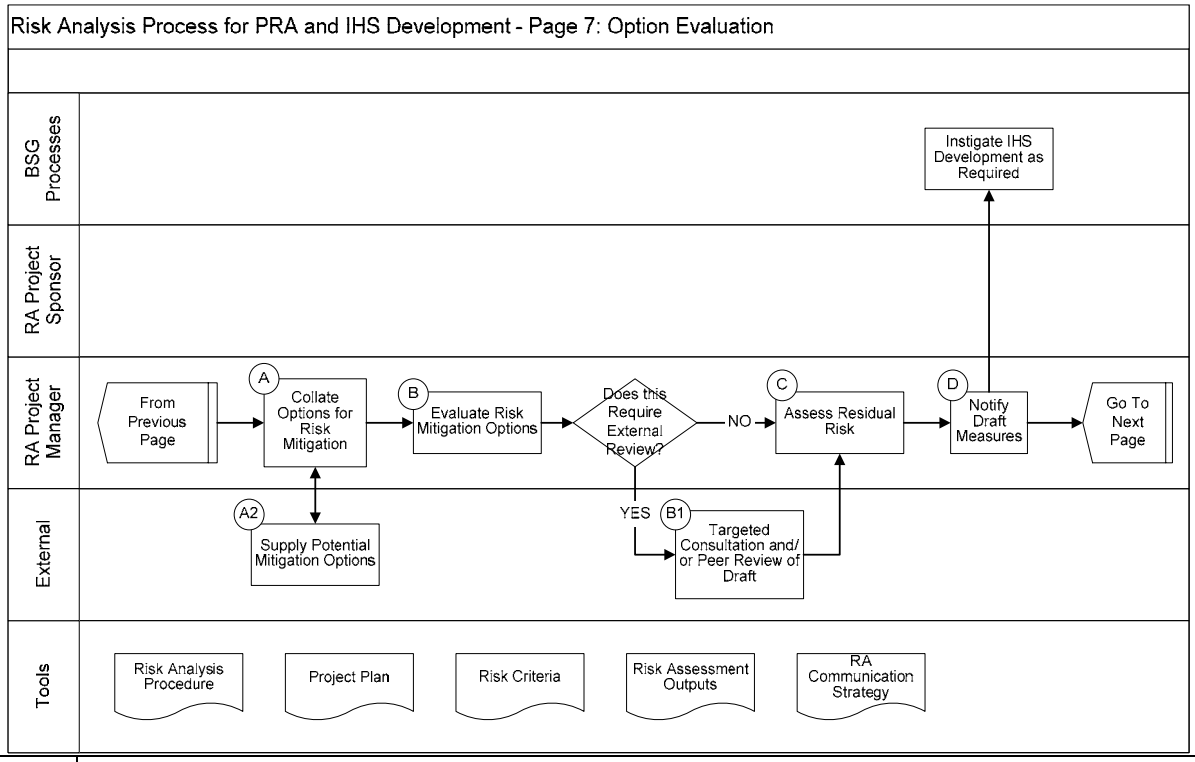
Step	Action (see Sections 3.5.3, and 4.1 to 4.3)
A	The Project Manager ensures the risk criteria are reviewed in the context of the project scope. • Risk Analysis Procedures (Section 3.4) • Project Plan
B	The Project Manager ensures hazard identification is undertaken in compliance with these procedures and within the scope of the project. • Risk Analysis Procedures (Sections 4.1 and 4.2) • Project Plan • Risk Criteria
B1	The Project Manager ensures hazard information is sort from stakeholders/industry experts as required. • Project Communication Strategy
C	The Project Manager ensures hazard scoping is completed in compliance with these procedures and within the scope of the project. • Risk Analysis Procedures (Section 4.2) • Project Plan • Risk Criteria
C1	If required, the Project Manager ensures targeted consultation and/or peer review of the hazard identification/hazard scoping documents is completed. • Project Communication Strategy
C2	The Project Manager ensures the hazard identification and scoping documentation is reviewed in light of submissions received during consultation and/or peer reviewer.



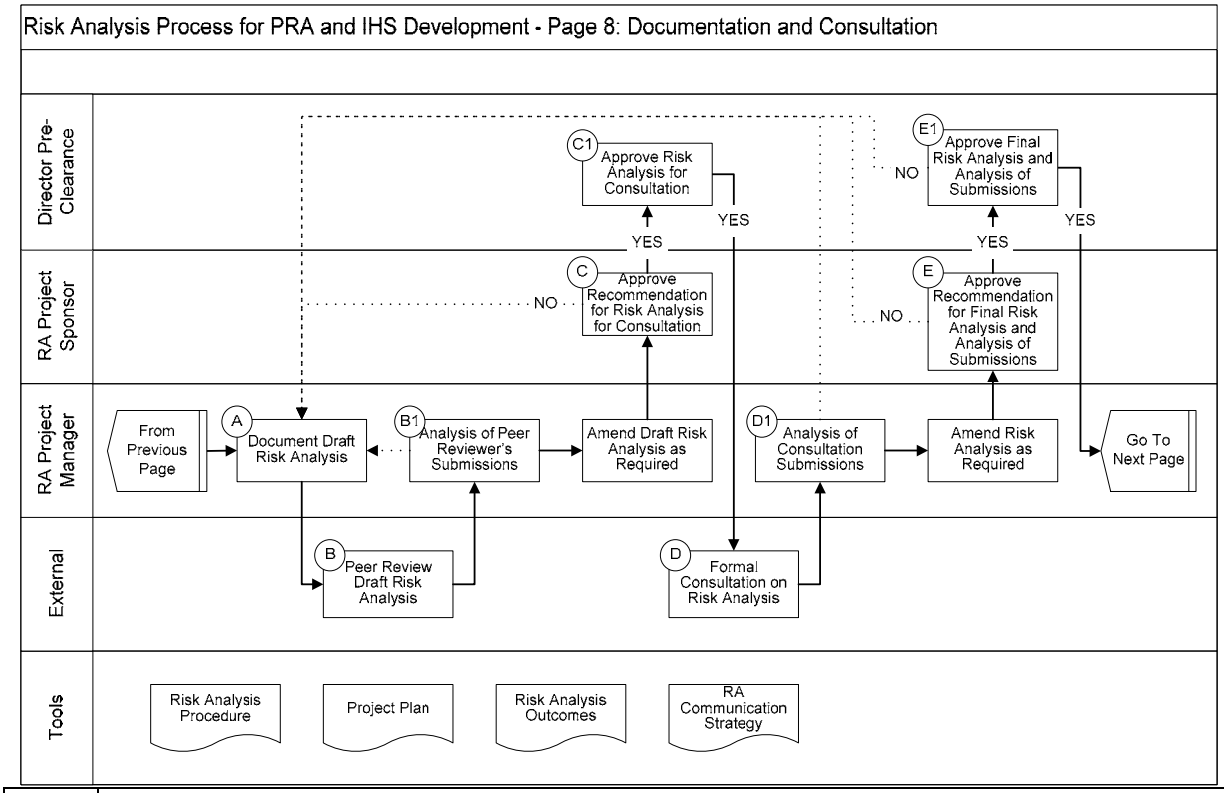
Step	Action (see Section 4.4)
A	The Project Manager ensures a consequence assessment is completed in compliance with these procedures and within the scope of the project. • Risk Analysis Procedures • Project Plan • Risk Criteria
B	The Project Manager ensures an entry assessment is completed in compliance with these procedures and within the scope of the project. • Risk Analysis Procedures • Project Plan • Risk Criteria
C	The Project Manager ensures an exposure and establishment assessment is completed in compliance with these procedures and within the scope of the project. • Risk Analysis Procedures • Project Plan • Risk Criteria
Note: Step A may follow step C in some cases.	



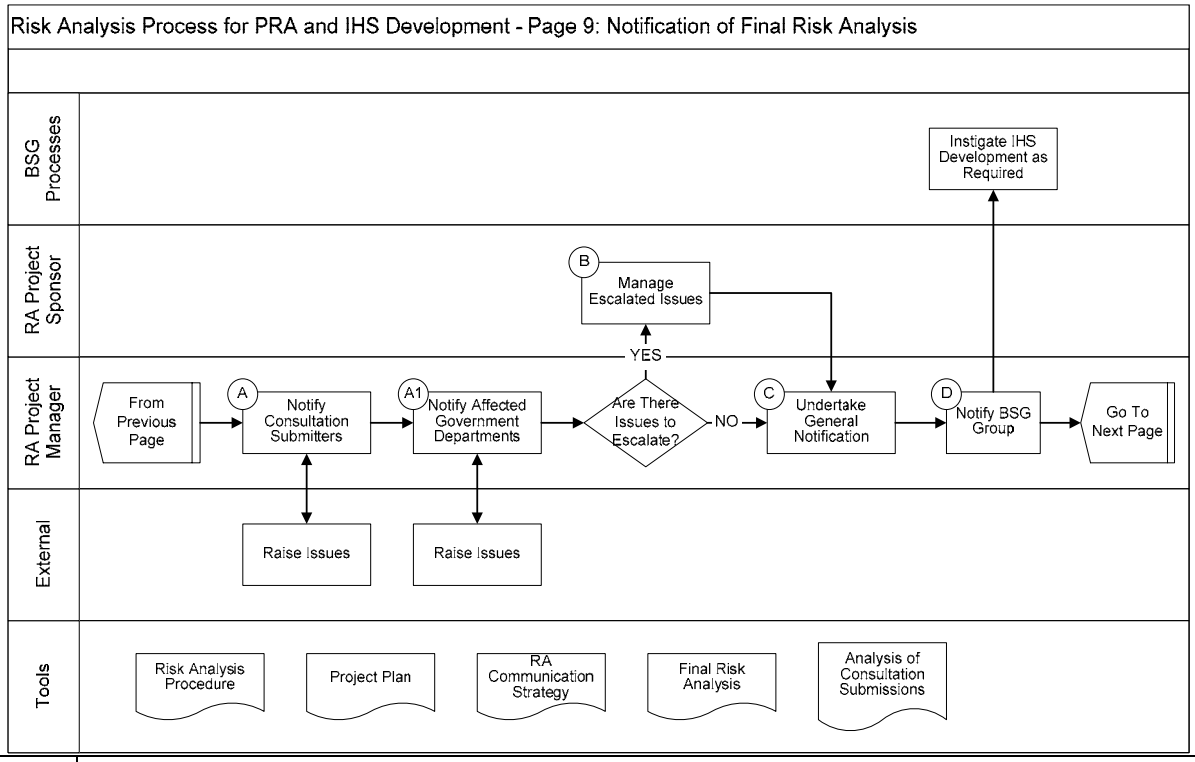
Step	Action (see Section 4.4)
A	The Project Manager ensures the level overall level of risk is estimated in compliance with these procedures and within the scope of the project. • Risk Analysis Procedures • Project Plan • Risk Criteria
A1	If required, the Project Manager ensures targeted consultation and/or peer review of the documented estimation of overall risk is completed. • Project Communication Strategy
A2	The Project Manager ensures a review the estimation of overall risk is completed in light of any submissions received during consultation and/or peer reviewer.
B	The Project Manager ensures an assessment of uncertainty underlying assumptions and risk estimates is completed in compliance with these procedures and within the scope of the project. The Project Manager ensures that the results of this assessment are passed on to the science strategy team as appropriate. • Risk Analysis Procedures • Project Plan



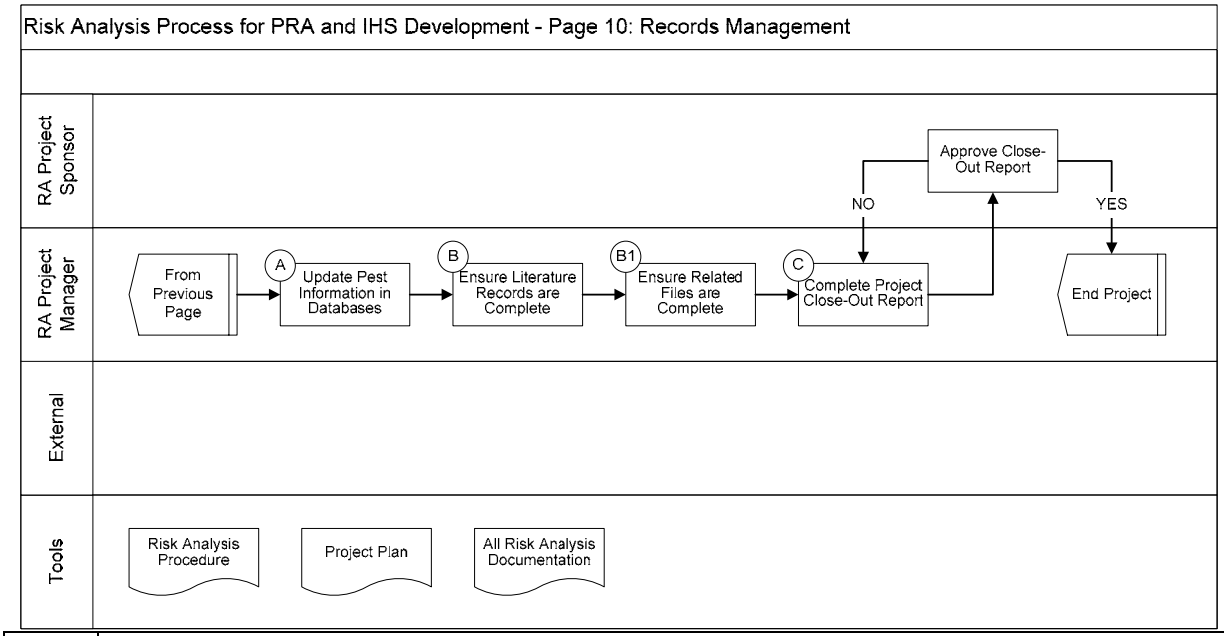
Step	Action (see Sections 4.5 and 4.6)
A	The Project Manager ensures options for risk mitigation are collated in compliance with these procedures and within the scope of the project. • Risk Analysis Procedures • Project Plan
A1	The Project Manager ensures information on potential mitigation options is sort from the Biosecurity Standards Group as required. For many of the risk analyses undertaken to support the development of an import health or operational standard it is expected that a representative from the Biosecurity Standards Group will be on the project team. In those instances this can be used as the point at which the import health or operation standard development and risk analysis processes begin to be co-ordinated. • Project Communication Strategy
A2	The Project Manager ensures information is sort on potential mitigation options from stakeholders/industry experts as required. • Project Communication Strategy
B	The Project Manager ensures an evaluation of risk mitigation options is completed in light of any submissions received during consultation and/or peer reviewer. • Risk Analysis Procedures • Project Plan • Risk Criteria
B1	If required, the Project Manager ensures targeted consultation and/or peer review of the documented evaluation of risk mitigation options is undertaken. The Project Manager ensures a review of the evaluation of risk mitigation options is undertaken in light of any submissions received during the consultation and/or peer reviewer. • Project Communication Strategy
C	The Project Manager ensures levels of residual risk are assessed in compliance with these procedures and within the scope of the project. • Risk Analysis Procedures • Project Plan • Risk Criteria



Step	Action (see Sections 3.3, 3.4 and Chapter 5)
A	The Project Manager ensures the draft risk analysis is documented in compliance with these procedures and within the scope of the project. • Risk Analysis Procedures • Project Plan
B	The Project Manager ensures an expert peer review of the draft risk analysis is completed in compliance with these procedures and within the scope of the project. • Risk Analysis Procedures • Project Communication Strategy
B1	The Project Manager ensures a review of the draft risk analysis is completed in light of reviewers' submissions, and a risk analysis for consultation is produced for approval. • Risk Analysis Procedures
C	The Project Sponsor approves for recommendation the risk analysis for consultation or returns the document to the Project Manager for further development.
C1	The Director Pre-Clearance (or designate) approves the risk analysis for consultation or returns the document to the Project Sponsor for further development.
D	The Project Manager ensures a stakeholder consultation of the risk analysis is undertaken in compliance with these procedures and within the scope of the project. The Project Manager ensures a review of the risk analysis is completed in light of any submissions received during the stakeholder consultation. • Project Communication Strategy
D1	The Project Manager ensures a review of the risk analysis is completed in light of any submissions received during the stakeholder consultation. The Project Manager ensures a review of submissions document is completed. • Risk Analysis Procedures
E	The Project Sponsor approves for recommendation the analysis of submissions and the final risk analysis.
E1	The Director Pre-Clearance (or designate) approves for notification the analysis of submissions and the final risk analysis.



Step	Action (see Section 3.4 and Chapter 5)
A	The Project Manager ensures those who made submissions during consultation of the risk analysis are notified of the outcome of the consultation and provided with a copy of the review of submissions document. • Risk Analysis Procedures • Project Plan • Project Communication Strategy
A1	The Project Manager ensures other government departments are notified of the finalised risk analysis and are provided with a copy of the review of submissions document. • Risk Analysis Procedures • Project Plan • Project Communication Strategy
B	The Project Sponsor manages any issues escalated by the Project Manager during the consultation or notification process. • Risk Analysis Procedures
C	The Project Manager ensures a general notification is completed through the MAF web site and, if required, the SPS notification service. • Risk Analysis Procedures • Project Plan • Project Communication Strategy
D	The Project Manager ensures other MAF groups are notified of the outcomes of the risk analysis project as it relates to their area of accountability. • Risk Analysis Procedures • Project Plan • Project Communication Strategy



Step	Action (see Section 3.7 and Chapter 5)
A	The Project Manager ensures the appropriate organism information is updated in the relevant organism databases. • Risk Analysis Procedures
B	The Project Manager ensures that the literature records associated with the risk analysis are complete. • Risk Analysis Procedures
B1	The Project Manager ensures that the files associated with the risk analysis are complete. • Risk Analysis Procedures
C	The Project Manager ensures that the close-out report is completed and submits it to the Project Sponsor for approval. • Risk Analysis Procedures