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This report compares the import risk analysis systems deployed by Australia, Canada, New Zealand and the United States. It identifies the strengths and weaknesses of the different approaches, assesses their performance against international standards, and evaluates their implementation in a number of case studies. The report concludes with recommendations for desirable technical attributes of import risk analysis systems.		
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ACERA Project 0709

Comparing Biosecurity Risk Assessment Systems

Final Report

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Disclaimer

1. Introduction

Risk can be defined as the product of the likelihood of an event occurring within some timeframe and the consequences should that event occur. This report reviews the frameworks used by Australia, the USA, Canada and New Zealand to assess the biosecurity risks associated with the importation or proposed importation of animals, plants or their derivatives, including methods for assessing risk, evaluating risk management options and communicating risk. In this report, the term **pest and disease** includes any species, strain or biotype of plant, animal or pathogenic agent that causes infection or may injure plants (including plant products) or animals. In this context, biosecurity is the protection of the economy, the natural and social environment and human health from the negative impacts associated with entry, establishment or spread of exotic pests (including weeds) and diseases.

The World Trade Organization (WTO) is responsible for establishing rules of trade between nations. The WTO Agreement on the Application of Sanitary and Phytosanitary Measures makes provisions for the protection of human, animal and plant health within a trade framework. The World Organization for Animal Health (OIE) and the International Plant Protection Convention (IPPC) are recognized by the SPS Agreement as the international standard setting bodies. Specifically, Annex A of the SPS Agreement states

"International standards, guidelines and recommendations

(a) for food safety, the standards, guidelines and recommendations established by the Codex Alimentarius Commission relating to food additives, veterinary drug and pesticide residues, contaminants, methods of analysis and sampling, and codes and guidelines of hygienic practice;

(b) for animal health and zoonoses, the standards, guidelines and recommendations developed under the auspices of the International Office of Epizootics;

(c) for plant health, the international standards, guidelines and recommendations developed under the auspices of the Secretariat of the International Plant Protection Convention in cooperation with regional organizations operating within the framework of the International Plant Protection Convention; …"

The OIE defines **risk analysis** as '*hazard identification, risk assessment, risk management and risk communication*'. Similarly, the IPPC defines **pest risk analysis** as '*evaluating biological or other scientific and economic evidence to determine whether a pest should be regulated and the strength of any phytosanitary measures to be taken against it*'. The OIE defines **risk assessment** as '*the evaluation of the likelihood and the biological and economic consequences of entry, establishment and spread of a hazard within the territory of an importing country*'. Similarly, the IPPC defines **pest risk assessment** as '*the evaluation of the probability of the introduction and spread of a pest and the magnitude of the associated potential economic consequences*'.

One or more (pest) risk assessments may be necessary to evaluate the risk associated with a specific pathway or commodity. The term import risk analysis (IRA) has been used internationally by Australia and several other countries for such analyses. This is analogous to risk analysis (as defined above) which itself includes one or more risk assessments. An IRA may also include an administrative framework for policy

development and delivery. The term **risk analysis/ses** will be used in this report with this meaning. Other terms will only be used when citing text verbatim.

Risk analyses are important instruments for preventing plant and animal pest and disease incursions. In general, developed economies including the USA, New Zealand, Canada, Australia and the European Union have taken the lead in developing methods for risk analysis. Although these methods have evolved from different foundations and within different settings they share many similarities. Some information on different approaches to risk analysis was compiled by Nairn et al. (1996). There are a few commentaries on appropriate levels of protection (e.g. Bigsby 2001) and one brief comparison of risk analyses performed by Canada, Chile, the EU, Ghana and New Zealand (IPPC 2005). However, to date there has been no comprehensive international comparison, and no assessment of how the systems deal with uncertainty.

The project's original objectives were to:

1. Evaluate the information needed to provide a comprehensive qualitative and subsequent quantitative review of the methods used internationally in biosecurity risk analyses;
2. Gather examples of biosecurity risk analyses from Australia, Canada, New Zealand, Japan, USA, UK, Chile and Thailand;
3. Investigate and develop standardised measures of effectiveness for these analyses systems, including quantitative biosecurity risk analyses;
4. Evaluate and compare qualitatively how different countries perform biosecurity risk analyses; and
5. Evaluate how different countries deal with uncertainty in their biosecurity risk analyses.

The project objectives were revised, and the focus limited to Australia, the USA, Canada and New Zealand, once it became apparent that it was not possible to obtain analyses from Japan, Chile or Thailand. No standard exists with which to measure the efficacy of biosecurity risk analyses and the relative rarity of quantitative analyses made a quantitative comparison impossible. Objective 3, the development of measures of effectiveness, was omitted when it was established that sufficient data were not made available by any jurisdiction to validate performance empirically.

This report presents a comparative analysis of IRA approaches, focusing on objectives 4 and 5 above. It includes an examination of initiation, hazard identification/pest categorization, likelihood assessment, consequence assessment and uncertainty analysis. The review also assesses compliance with relevant international standards, expression of appropriate level of protection (ALOP), communication with stakeholders and review and appeal mechanisms.

Risk analyses must comply with the provisions of the SPS Agreement (WTO 1995) and be consistent with the OIE or IPPC guidelines. The report provides an outline of the international context for IRAs, and then examines the details of IRA systems used in each of the four countries, before providing a comparative assessment based on key provisions from the SPS Agreement and these guidelines, and identifying features of an ideal system. Thus, the revised objectives were:

1. To review the biosecurity frameworks used by Australia, Canada, New Zealand and the USA;
2. To evaluate the application of these frameworks by examining representative plant and animal IRAs;
3. To assess compliance of the IRAs with the SPS Agreement;

4. To compare the similarities, differences, strengths and weaknesses of the alternative approaches; and
5. To outline the features of an ideal IRA framework.

1.1 International trade policy and law[1]

Governments have made substantial efforts to minimise animal and plant health risks associated with global trade since the formation of the OIE[2] in 1924 and the IPPC in 1951 (FAO 1999; see DPIW 2009 for a more complete outline). The OIE aims to improve coordination of animal health issues at a global level, and human health to the extent that it is directly affected by agents of animal diseases. It comprises more than 170 member countries and territories and is recognised by the SPS agreement and as a reference organisation by the World Trade Organisation (WTO). It promotes the harmonisation of trade by publishing animal health Codes and maintaining lists of the most significant pest organisms, the spread of which can be trade-related. The relevant international standards for animal health and zoonoses are the *Terrestrial Animal Health Code (OIE 2001)* and *Aquatic Animal Health Code* (OIE 2008).

The IPPC is an international treaty for plant health that is charged by its governing body, the Commission on Phytosanitary Measures (CPM), to set International Standards for Phytosanitary Measures (ISPMs) and facilitate information exchange. The ISPMs provide guidance to countries on the application of measures to protect their plant resources from pests and diseases that can be moved in the course of trade. ISPM No. 2 (Guidelines for pest risk analysis, IPPC 2007), ISPM No. 11 (Pest risk analysis for quarantine pests, including analysis of environmental risk and living modified organisms; IPPC 2006) and ISPM No. 21 (Pest risk analysis for regulated non-quarantine pests; IPPC 2004) describe the main elements of the biosecurity risk analysis process.

The SPS Agreement (WTO 1995) specifies that SPS measures cannot be used to restrict competition or trade unnecessarily. Specifically, Article 2 stipulates that *"Members shall ensure that any sanitary or phytosanitary measure is applied only to the extent necessary to protect human, animal or plant life or health, is based on scientific principles and is not maintained without sufficient scientific evidence…"*

The IPPC also specifies an approach to setting measures based on risk assessments that can be characterised in three steps:

- identify the pests or diseases of concern
- evaluate their likelihood of entry, establishment and spread, and the associated potential economic consequences, and
- re-evaluate the likelihoods and consequences against potential SPS measures (IPPC 2006, 2009). (The process of risk analysis, incorporating further elements including risk mitigation, is not covered in the SPS Agreement).

WTO case law affirms that the SPS Agreement covers environmental risks such as threats to biodiversity and risks whose effects may be protracted or delayed (Gruszczynski 2008, in DPIW 2009). *ISPM No. 5 Glossary of Phytosanitary Terms*

1 Much of the background for this section of the report is drawn from DPIW (Tasmanian Department of Primary Industries and Water, 2009, C. Hanson, pers. comm.)

2 Now known as the World Organisation for Animal Health (OIE) (http://www.oie.int/eng/OIE/en_about.htm?e1d1)

(IPPC 2009) notes that potential economic importance includes environmental and social impacts. *ISPM No. 11* (IPPC 2006) includes species that cause indirect harm through competition, or by injuring beneficial organisms such as pollinators, seed dispersers, detritus feeders and root symbionts. The IPPC is also considering how best to take into account risks posed by plant pests that may further endanger native plant species, affect keystone plant species, change plant biological diversity in ways that destabilise ecosystems and the impacts on biodiversity of control and eradication programs (IPPC 2006).

The SPS Agreement (WTO 1995) lays out the principles for the application of SPS measures, providing a basis on which to assess alternative approaches to risk analysis Objective 1 of the project, above). These principles include consistency, harmonization, equivalence, transparency, risk assessment methods, and recognition of regional conditions. These principles are outlined in detail and form the foundation for the comparative method applied below.

1.2 Method

Australia, Canada, New Zealand and the USA are members of the WTO and must comply with the SPS Agreement which states '*This Agreement applies to all sanitary and phytosanitary measures which may, directly or indirectly, affect international trade...*' (Article 1, SPS Agreement, WTO 1995). Members performing biosecurity risk analyses must comply with the provisions of the SPS Agreement and be consistent with the OIE or IPPC guidelines.

The SPS Agreement lays out the principles for the application of SPS measures. In addition to the SPS Agreement, the International Sanitary and Phytosanitary Measures ISPMs 2, 5 and 11 (IPPC 2006, 2007, 2009) and OIE code for terrestrial animal health (OIE 2001) identify important principles. Principles for IRAs were evaluated in a summary of each country's risk analysis framework in the first part of this report, and in a comparative evaluation of the frameworks in the second part, under the following headings:

1. Does the framework for risk analyses comply with the SPS Agreement and is it consistent with the OIE or IPPC guidelines, including the following principles?
    a. Harmonisation / Appropriate Level of Protection / Consistency and non-discrimination / Equivalence and Regional Conditions
    b. Transparency
2. Are the risk analyses consistent with risk analysis theory, considering the following issues?
    a. Use of scientific evidence / treatment of uncertainty / consistency with scientific theory
3. Are risk analyses consistent with the country's own guidelines (i.e. is what is said to occur actually what occurs)?

Only official documents published by each country's designated international biosecurity agency were considered. The steps to complete these reviews were to:

- collate national guidelines for biosecurity risk analyses and recent examples of these analyses from Australia, Canada, New Zealand, and the USA;
- summarise and evaluate the important elements of each countries biosecurity risk analyses methods;
- compare each countries biosecurity risk analyses methods to international standards;

- compare the methods used for biosecurity risk analyses between countries;
- evaluate how different risk analysis approaches deal with uncertainty; and,
- provide a critical appraisal of the strengths and weaknesses of these approaches.

The aim was to review representative, recent plant and animal biosecurity risk analyses from each country. However, insufficient analyses were available. The national guidelines expressed current intended practices. Table 1.1 summarises the materials used in this review.

Table 1.1. Biosecurity risk analyses and other national documents considered

Country	Biosecurity risk analyses	National guidelines	Official Organisation	National legislation
Australia	Capsicum from Korea (Biosecurity Australia, 2008a)	IRA Handbook 2007 (updated 2009)	Biosecurity Australia	Quarantine Proclamations *Quarantine Regulations 2000 (Commonwealth of Australia, 2008b)* *Quarantine Act 1908* (Commonwealth of Australia, 2008a)
Australia	Mangoes from India (Biosecurity Australia, 2008b)			
Australia	Unshu Mandarin from Japan (Biosecurity Australia, 2008c)			
Australia	Chicken meat (Biosecurity Australia 2008d)			
Australia	Pig meat (Biosecurity Australia 2004)			
Australia	Ornamental finfish (AQIS 1999)			
Canada	Wooly Cupgrass (CFIA 2002)	Plant health risk assessment template (CFIA 2007a)	Canadian Food Inspection Agency	*Plant Protection Act, 1990* c.22.
Canada	European Stone Fruit Yellows Phytoplasms (CFIA 2004)			
Canada	Paterson's curse (CFIA 2007b)			
Canada	Swede Midge in canola (CFIA 2008a)			
Canada	No animal IRAs obtained	Animal Health and Production Risk Analysis Framework (CFIA 2000)		

NZ	Fresh Citrus Fruit from Samoa (Biosecurity New Zealand 2008a)	Risk Analysis Procedures (Biosecurity New Zealand 2006a)	Ministry of Agriculture and Forestry, Biosecurity New Zealand	*Biosecurity Act 1993* *Agricultural Compounds and Veterinary Medicines Act 1997*
NZ	Litchi from Australia Biosecurity New Zealand, 2008b)			
NZ	Litchi from Taiwan (Biosecurity New Zealand 2007)			
NZ	Fresh Water Prawns (Biosecurity New Zealand 2006b and 2006c)			
NZ	Honey Bee (MAF 2003)			
NZ	Avian Paramyxovirus (MAF 2001)			
USA	Longan from Taiwan (USDA 2008)	Guidelines for Pathway-Initiated Pest Risk Assessments, Version 5.02 (USDA 2000).	United States Department of Agriculture-Animal and Plant Health Inspection Service (USDA-APHIS)	*Plant Protection Act, June 2002*.
USA	Citrus Fruit from Chile (USDA 2007a)			
USA	Mangoes from India (USDA 2006)			
USA	Importation of Exotic Newcastle Disease (END) virus from Denmark (USDA 2005b)	Importation of Animals and Animal Products (USDA 1997) Foreign Animal Disease Status Evaluations, Regionalization, Risk Analysis, and Rulemaking (USDA 2004)		Importation of animals and animal products. Federal Register 56000-56026.
USA	Importation of whole cuts of boneless beef from Japan (USDA 2005c)			
USA	Evaluation of the FMD from Argentina (USDA 2005a)			

Some of the risk analyses reviewed here were quantitative, while others were semi-quantitative or qualitative (*sensu* ISO 31000). A qualitative risk analysis is a 'reasoned and logical discussion of the relevant commodity factors and epidemiology of

the hazard where the likelihood of entry and exposure and the magnitude of consequences are expressed using non-numerical terms …' (Biosecurity New Zealand 2006a). A probabilistic approach was employed in some examples, and semi-quantitative methods were deployed in some jurisdictions. These details are explored in this report.

A qualitative approach was taken to the comparative analysis because most biosecurity risk analyses are qualitative or semi-quantitative. Indeed, this is one of the most apparent features of these analyses globally. This does not imply that quantitative analyses would have been preferable. Rather, it constrained the set of possible evaluations.

2. Australia's Risk Analysis System

In Australia, the Department of Agriculture, Fisheries and Forestry (DAFF) is responsible for biosecurity, including setting standards and regulations for protecting plant and animal health. Australia's national guidelines are described in the *Import Risk Analysis Handbook* (Biosecurity Australia 2009), which covers both animal and plant import risk assessments. The Handbook describes the administrative framework for IRAs; the elements include;

- announcement of IRAs,
- issues-paper preparation,
- consultation on issues papers,
- managing import proposals,
- steps in the import risk analysis,
    - criteria for an IRA,
    - discussion of Standard and Extended IRAs,
    - regulated steps,
    - expected time frames for completion,
    - rules under which an IRA can be terminated,
    - the processes for engaging stakeholders (including processes for confidential submissions and public files),
- details on draft reports, peer reviews and the final report, and
- determinations by the Director and steps that follow the IRA process.

A draft IRA report is required to include;

- confirmation of the pests and diseases being assessed,
- description of the major pathways by which Biosecurity Australia considers these could enter, establish or spread in Australia,
- for each pest and disease on identified pathways, determination of the likelihood of its entry, establishment or spread, and the harm (consequences) that could result,
- specification of whether the resulting risks exceed Australia's ALOP,
- in cases where the risks exceed Australia's ALOP, potential risk management measures and assessments of whether application of the measures could reduce the risks to achieve Australia's ALOP; and,
- a preliminary view of the preferred options for risk management.

The Beale Report (Beale et al. 2008) reviewed Australia's biosecurity systems and recommended more risk-based approaches across the biosecurity continuum. It noted that Australia has not published detailed guidelines for pest risk analysis. Instead, the details of the method and assumptions employed in risk assessments are described in the individual IRAs.

We include assessments of three Australia plant and three animal IRAs, including capsicum from Korea, mangoes from India, mandarins from Japan, live ornamental fish, chicken and pig meat (AQIS 1999, Biosecurity Australia 2004, 2008a, 2008b, 2008c, 2008d). Two of the animal IRAs (Biosecurity Australia 2004, 2008d) were global in that the risks associated with the importation of chicken and pig meat from any exporting country were considered.

Australian IRAs consist of three stages termed, Initiation/Scoping, Risk Assessment, and Risk Management (Table 2.1; animal and plant IRAs use slightly different terminology). These stages are not defined in the Australian Import Risk

Analysis Handbook (Biosecurity Australia 2009) but they appear in the individual IRAs. Australian analyses use terms that are consistent with the ISPM standards and relevant OIE documents. Glossaries in some of the IRAs define a number of these terms and refer consistently to international definitions.

Table 2.1. Steps in the Australian, IPPC and OIE frameworks

Australian plant biosecurity framework	IPPC Framework	Australian animal biosecurity framework	OIE Framework
1. Initiation	***Stage 1: Initiation***	***Scoping the risk analysis***	***Scoping the risk analysis***
Identification of new pathway or change in pest status …	*1.1 PRA Initiated by a pathway or change in status*		
	1.2 Identification of PR area		
	1.3 Compilation of background information		
	1.4 Conclusion of initiation	***1. Hazard Identification***	***1. Hazard Identification***
2. Pest Risk Assessment	***Stage 2: Pest risk assessment***	*1.1 Formation of hazard list*	*1.1 Formation of hazard list*
2.1 Hazard identification / pest categorization	*2.1 Pest categorization*	*1.2 Categorization of hazard*	*1.2 Categorization of hazard*
		2. Risk assessment	***2. Risk assessment***
2.2 Probability of entry *2.3 Probability of establishment* *2.4 Probability of spread*	*2.2 Assessment of the probability of introduction and spread*	*2.1 Release assessment* *2.2 Exposure assessment* *2.3 Establishment and Spread*	*2.1 Release assessment* *2.2 Exposure assessment*
2.5 Assessment of consequences	*2.3 Assessment of potential economic consequences*	*2.3Consequence assessment*	*2.3Consequence assessment*
2.6 Unrestricted risk estimation	*2.4 Degree of uncertainty* *2.5 Conclusion of the pest risk assessment stage*	*2.4 Unrestricted risk estimation*	*2.4 Risk estimation*
3. Risk management	***Stage 3: Pest risk management***	***3. Risk management measures***	***3. Risk management***
	3.1 Level of risk *3.2Technical information required* *3.3 Acceptability of risk*		*3.1 Risk evaluation*

	3.4 Identification and selection of appropriate risk management options *3.5 Phytosanitary certificates and other compliance measures*	*3.1 Restricted risk evaluation*	*3.2 Option evaluation*
	3.6 Conclusion of pest risk management		*3.3 Implementation*
	3.7 Monitoring and review of phytosanitary measures		*3.4 Monitoring and review*
4. Review and publication	***4. Documentation of Pest Risk Analysis***	***4. Reporting***	***4. Risk communication***

2.1 Initiation / Scoping

The Australian *Quarantine Act 1908* prohibits imports of agricultural commodities unless they are specifically permitted. An IRA often is initiated when a submission is received for access to the Australian market for a commodity. A PRA or IRA is triggered "where there is no quarantine policy or a significant change in existing quarantine policy" (Biosecurity Australia 2009). A new pathway is an application to import a new commodity and pest/disease combination for which no relevant biosecurity measure exists, or to import a commodity from a new source area.

According to the Australian IRA guidelines (Biosecurity Australia 2009), Biosecurity Australia's Chief Executive determines if an import risk analysis will be conducted. An IRA will be undertaken when relevant risk management measures have not been established or relevant risk management measures for a similar commodity and pest/disease combination exist, but the likelihood and/or consequences of entry, establishment or spread of pests or diseases could differ significantly from those previously assessed.

The animal and plant IRAs reviewed here commence with a description of existing commercial practices in the exporting country, assumed for the purposes of estimating 'unrestricted risk' (the risk associated with the import of the commodity without any sanitary or phytosanitary measures applied). Considerations include seasonality, growing areas, pest and disease management, cultural practices, cultivation, stock management practices, harvesting, processing systems, packing procedures, transport conditions, inspection protocols and export quarantine systems.

2.2 Risk Assessment

2.2.1 Hazard identification / pest categorization

Hazard identification is a systematic appraisal of what can go wrong, a categorisation that discriminates hazards that are worth analysing in more depth from those that are not. The OIE calls the process '*hazard identification'*. The analogous IPPC term is '*pest categorisation'*. For both plant and animal biosecurity, it is identifying which pests and diseases may be of quarantine concern to Australia. For instance, OIE (Chapter 2.1,

Article 2.1.1) states that hazard identification involves '*identifying the pathogenic agents which could potentially produce adverse consequences associated with the importation of a commodity*'. Hazard identification usually begins with a list of many organisms and ends with a shorter list of potential pests and/or diseases, the risks of which are subsequently analysed in greater detail.

The lists of potential pests and diseases are derived from published and grey literature, national and international databases, source country advice and expert judgement. For example, the animal IRAs document OIE-listed disease agents and 'other disease agents' and evaluate their potential hazard status (e.g., Biosecurity Australia 2008d). Factors that contribute to categorization include taxonomy, presence of the organism in Australia or the PRA area, regulation status, association with the commodity, climatic suitability, barriers to life cycle, dispersal mechanisms, and potential to cause harm (e.g., Biosecurity Australia 2008c, d). The assessments provide brief reasoning for the pests not to be considered further (e.g. the climate is unsuitable, the host is unavailable). This raises the prospect that such assessments may change in the future, but there are provisions for IRAs to be repeated periodically (at 5-year intervals, if trade persists, or sooner if other conditions change). Each pest or disease identified as being of potential quarantine concern is treated in more detail.

2.2.2 Probability of entry

The probability of entry is the probability that a quarantine pest or disease will enter Australia in a viable state as a result of trade in a commodity (*introduction*), be distributed in a viable state in the PRA area and be transferred to a suitable host (*distribution*; Biosecurity Australia 2008c). International animal guidelines use the term 'release' to describe '*the biological pathway(s) necessary for an importation activity to 'release' (that is, introduce) pathogenic agents into a particular environment*' (OIE Chapter 2.2, Article 2.1.1).

Biosecurity Australia normally considers the likelihood of entry based on the estimated volume of one year's trade (e.g., Biosecurity Australia 2008a-d). The implications of this assumption are examined below.

Probability of entry is based on scenarios (pathways) depicting steps in the sourcing of the commodity for export, its processing, transport and storage, its utilisation in Australia and the generation and disposal of waste (e.g., Biosecurity Australia 2008a-d). The ability of a pest or disease to survive is considered at each of these stages. The probability estimates are based on existing commercial production, packaging and shipping practices of the exporting country.

In the reports examined here, Biosecurity Australia separates the probability of entry into the probability of importation and the probability of distribution through, for example, processing, consumption or disposal. Factors considered in the probability of importation include distribution and incidence of the pest in the source area, association with the commodity, the import season, volume and frequency of movement of the commodity along each pathway, pest management, cultural and commercial procedures and speed of transport and conditions of storage. Factors considered in the probability of distribution include commercial procedures during distribution, dispersal mechanisms and vectors of the pest or disease, distribution of the commodity, its waste and its hosts.

Analysts make a subjective estimate of the probability of introduction and distribution based on text describing these factors (see Table 2.2). The probability of distribution is, implicitly, a conditional probability, assuming introduction has occurred.

It estimates the probability of at least one 'event', where an event is the entry and establishment of at least one propagule, and its subsequent spread throughout its potential range. The Australian protocols assess the likelihood of entry, based on the volume of trade expected in a year. The issue of volume is treated in detail in Section 6.7.

2.2.3 Probability of establishment

In plant guidelines, establishment is defined as the '*perpetuation for the foreseeable future, of a pest within an area after entry*' (IPPC 2007). In most of the Australian IRAs evaluated here (except the quantitative analyses; e.g. Biosecurity Australia 2004), analysts made subjective estimates of the probability of establishment based on biological information (life cycle, host range, epidemiology, survival, etc.) from the areas where the pest currently occurs, compared to the situation in the PRA area. Analysts considered the availability of suitable hosts, alternative hosts and vectors, suitability of the environment, reproductive strategy and potential for adaptation, the minimum population needed for establishment, cultural practices and existing control measures. As for the probability of entry, analysts make a subjective estimate of the conditional probability of establishment of at least one pest (Table 2.2) based on text describing these factors.

2.2.4 Probability of spread / exposure assessment

For animals, exposure assessment describes '*the biological pathway(s) necessary for exposure of animals and humans in the importing country to the hazards (in this case the pathogenic agents) released from a given risk source*' (OIE Chapter 2.2, Article 2.1.1). For plants, spread is '*the expansion of the geographical distribution of a pest within an area*' (IPPC 2007). The probability of spread depends on the factors relevant to the movement of the pest pathogen or disease, after establishment on a host, to other susceptible hosts of the same or different species in other areas. As for the probability of establishment, biological information from areas where the pest currently occurs was presented and compared to the situation in the PRA area.

In most of the IRAs, analysts made subjective estimates of the conditional probability of spread (Table 2.2), supported by a consideration of the published or unpublished evidence. Factors considered included suitability of the environment, presence of natural barriers, potential for movement, intended use of the commodity, and potential vectors and natural enemies.

2.2.5 Qualitative likelihoods

In its recent, qualitative PRAs (e.g., Biosecurity Australia 2008a-d), Biosecurity Australia uses the term 'likelihood' for estimates of probability of entry, establishment and spread. Qualitative likelihoods are assigned to each step. Six descriptors are used ranging from high to negligible (Table 2.2). The 'indicative probability ranges' illustrate the boundaries of the descriptors. The descriptive definitions and the associated ranges are intended to '*provide guidance to the risk analyst and promote consistency between different risk analyses*' and should '*not used beyond this purpose in qualitative PRAs*' (Biosecurity Australia 2008c).

In the plant applications (Biosecurity Australia 2008a, 2008b, 2008c), estimates are provided for each of four steps in the pathway, namely, importation, distribution, establishment and spread. One of the terms in Table 2.2 is estimated for each step.

Table 2.2. Nomenclature for qualitative likelihoods.

Likelihood	Descriptive definition	Indicative probability (P) range
High	The event would be very likely to occur	$0.7 < P \leq 1$
Moderate	The event would occur with an even probability	$0.3 < P \leq 0.7$
Low	The event would be unlikely to occur	$0.05 < P \leq 0.3$
Very low	The event would be very unlikely to occur	$0.001 < P \leq 0.05$
Extremely low	The event would be extremely unlikely to occur	$0.000001 < P \leq 0.001$
Negligible	The event would almost certainly not occur	$0 \leq P \leq 0.000001$

Analysts reaching conclusions about likelihoods substantiate their judgements with relevant information and reference their sources. Where data were available, they are provided to support the judgements. This information makes the risk assessment more transparent and open to review, especially as to whether all available data were used and interpreted appropriately. For example, the likelihood that European flower thrips (*Franklinella intonsa*) will arrive in Australia with fresh capsicum from Korea was estimated to be 'high' because of the insect's cold tolerance, small size, long lifespan and its association with fresh capsicum in Korea (Biosecurity Australia 2008a). These likelihood estimates are subject to differences of opinion, but the IRAs do not include dissenting views.

The likelihood of entry, establishment and spread is determined by combining the likelihood that the pest will be imported into the PRA area with the likelihood that the pest will establish and spread within the PRA area, using a matrix of rules (Table 2.3).

Table 2.3. Matrix of rules for combining qualitative likelihoods.

	High	**Moderate**	**Low**	**Very low**	**Extremely low**	**Negligible**
High	High	Moderate	Low	Very low	Extremely low	Negligible
Moderate		Low	Low	Very low	Extremely low	Negligible
Low			Very low	Very low	Extremely low	Negligible
Very low				Extremely low	Extremely low	Negligible
Extremely low					Negligible	Negligible
Negligible						Negligible

In applications, the rules summarized in Table 2.3 are applied sequentially to each of the four steps in the invasion process for which likelihood was estimated. For example, the likelihoods of entry, establishment and spread of *F. intonsa* were moderate, high and high respectively, which combine using Table 2.3 to give an overall likelihood of 'moderate'. The rules are designed to be roughly consistent with the rules of probability for conditional, independent events. Implicitly, the probabilities are multiplied. Thus, the combination of two 'low' values results in 'very low'.

2.2.7 Semi-quantitative likelihoods

The two generic (imports from all countries) animal IRAs reviewed here (Biosecurity Australia 2004, 2008d) used 'semi-quantitative' likelihood models, incorporating a mixture of probabilistic and qualitative (expert judgement) analysis. The analyses were based on explicit import and exposure pathways, represented as scenario trees that incorporated the main exposure pathways for the commodities. The models included the probability that the disease is present in the source population, the probability the disease will be detected, given that the commodity is infected (the true positive prediction rate for the test), the probability of cross-contamination, and the probability that the disease agent will remain viable after exposure to the environment before consumption. Quantitative data and other scientific evidence were used to estimate probabilities and other quantities such as counts and volumes.

Where data were insufficient to derive probability distributions, uniform and triangular distributions were used to represent expert judgements of likelihood. The limits of the uniform distribution in each case were taken from Table 2.2, representing the interval in which the experts' best estimate lay (although the PERT distribution was used in the risk assessment for pig meat (Biosecurity Australia 2004). Results were interpreted based on the median of the output distribution, again using the intervals in Table 2.2 to translate values into language-based equivalents (e.g., Biosecurity Australia 2008d).

The generic animal IRAs (Biosecurity Australia, 2004, 2008d) emphasised that 'team members' used their expert judgement to assess predictions of the probabilities of entry, establishment and spread, and to evaluate inconsistencies between the outputs and expectations. Analysts provided explanations for inconsistencies. The conclusions represented the 'opinions' of the IRA team, 'after consideration of the output of the quantitative model and any other relevant material' (Biosecurity Australia 2008d).

2.2.7 Assessment of consequences

The IRAs reviewed here assess the likely consequences if pests or diseases were to enter, establish and spread in Australia. The assessments consider direct and indirect pest effects and their economic and environmental consequences. Direct pest effects include consequences for plant or animal life or health, and 'other' environmental aspects. Indirect effects include the consequences of eradication and control measures, effects on domestic and international trade and the environment. These criteria are consistent with international specifications (Article 5.3 of the SPS Agreement, WTO 1995, ISPM 5 and ISPM 11). For each of these criteria, consequences are estimated (see below) over four geographic levels, defined as:

- *Local:* an aggregate of households or enterprises (a rural community, a town or a local government area).
- *District:* a geographically or geopolitically associated collection of aggregates (generally a recognised section of a state or territory, such as 'Far North Queensland').
- *Regional:* a geographically or geopolitically associated collection of districts in a geographic area (generally a state or territory, although there may be exceptions with larger states such as Western Australia).
- *National:* Australia wide (Australian mainland states and territories and Tasmania).

For each criterion, the magnitude of the potential consequence at each of these levels is described using four categories, defined as:

- *Indiscernible:* Pest impact unlikely to be noticeable.
- *Minor significance:* Expected to lead to a minor increase in mortality/morbidity of hosts or a minor decrease in production but not expected to threaten the economic viability of production. Expected to decrease the value of non-commercial criteria but not threaten the criterion's intrinsic value. Effects would generally be reversible.
- *Significant:* Expected to threaten the economic viability of production through a moderate increase in mortality/morbidity of hosts, or a moderate decrease in production. Expected to significantly diminish or threaten the intrinsic value of non-commercial criteria. Effects may not be reversible.
- *Major significance:* Expected to threaten the economic viability through a large increase in mortality/morbidity of hosts, or a large decrease in production. Expected to severely or irreversibly damage the intrinsic 'value' of non-commercial criteria.

Values are translated into a qualitative impact score (A–G) using Table 2.4.

The semi-quantitative animal IRAs reviewed here (Biosecurity Australia 2008c,d) assessed consequences by means of a small number of 'outbreak scenarios'. They ranged from 'disease agent does not establish', to 'disease agent establishes in the directly exposed population, spreads, including to other exposure groups, and becomes endemic in Australia'. Likelihoods and impacts were assessed separately for each scenario. The analysts evaluated direct and indirect impacts on trade, the environment, and society, essentially the same protocol as that applied in the qualitative plant IRAs. In qualitative plant IRA, consequence estimation starts with the premise that EES has occurred to its full extent (i.e. its maximum potential) in susceptible areas.

Table 2.4. Decision rules for determining consequences impact scores

		Geographic scale			
		Local	**District**	**Region**	**Nation**
Magnitude	**Indiscernible**	A	A	A	A
	Minor significance	B	C	D	E
	Significant	C	D	E	F
	Major significance	D	E	F	G

The applications (Biosecurity Australia 2004, 2008a-d) provide a table that summarises the significance of the threat posed by the hazard under consideration, the spatial scale (the geographic level) at which the consequence is expected to be felt, and the rationale for the judgement. Thus, the consequences of *F. intonsa* for plant life were 'significant at the district level' (impact score D) because of the potential to harm a wide range of crop and ornamental species. Consequences of *F. intonsa* for other aspects of the environment were of 'minor significance at the local level' (impact score B) because thrips may compete for resources with native species (Biosecurity Australia 2008a).

The overall consequence for each pest is achieved by combining the qualitative impact scores (A–G) for each direct and indirect consequence using a series of decision rules (Table 2.5). These rules are mutually exclusive, and are assessed in numerical order until one applies. In the example here, the overall rating of consequences of *F. intonsa* was 'low'.

Beale et al. (2008, p. 108-109) were '*perplexed*' by the lack of use of formal economic analysis to quantify consequences of pest and disease incursions. They pointed to the use of such economic analysis in Australia to determine whether or not to attempt eradication (e.g., Bhati et al. 1996) and to choose between management options where an incursion has occurred (e.g., Abdalla et al. 2005). They acknowledged the need to deal explicitly with non-market values and economic values integrated into multi-attribute analysis. They advised that estimates of consequences should take into account adjustment options available to producers in the event that they are affected by a pest or disease incursion, and that a focus on gross rather than net consequences creates an inbuilt bias to overestimate pest or disease consequences. They recommended consideration of absolute net value of production at risk for consequence assessment. They also noted that Biosecurity Australia and the Eminent Scientists Group do not possess significant skills in economic analysis.

Table 2.5. Decision rules for determining overall consequence rating

	The impact scores for consequences of direct and indirect criteria	Overall consequence rating
1	Any criterion has an impact of 'G'; or more than one criterion has an impact of 'F'; or a single criterion has an impact of 'F' and each remaining criterion an 'E'.	Extreme
2	A single criterion has an impact of 'F'; or all criteria have an impact of 'E'.	High
3	One or more criteria have an impact of 'E'; or all criteria have an impact of 'D'.	Moderate
4	One or more criteria have an impact of 'D'; or all criteria have an impact of 'C'.	Low
5	One or more criteria have an impact of 'C'; or all criteria have an impact of 'B'.	Very Low
6	One or more but not all criteria have an impact of 'B', and all remaining criteria have an impact of 'A'.	Negligible

2.2.8 Estimation of the unrestricted risk

Once the above assessments are completed, the unrestricted risk is determined for each pest or groups of pests through the risk estimation matrix (Table 2.6), which combines the estimates of the probability of entry, establishment and spread with the overall consequence rating. Therefore, risk is the product of likelihood and consequence. The matrix uses six categories of likelihood and six categories of consequence magnitude to produce six categories (ranks) of risk from 'negligible' to 'extreme'.

This process was followed in each of the applications reviewed here. In the example of *F. intonsa*, the combination of a moderate probability of entry, establishment and spread with a low consequence resulted in an estimate of unrestricted risk of 'low', which did not satisfy Australia's ALOP, resulting in the specification of risk management measures (Biosecurity Australia 2008a). However, if the risk was estimated as very low or lower Australia's ALOP would be satisfied, the proposed importation could be

recommended to proceed, without any risk mitigation warranted or indeed permissible under the international SPS framework.

Table 2.6. Risk estimation matrix.

Likelihood of pest entry, establishment and spread	Negligible	Very low	Low	Moderate	High	Extreme
High	Negligible risk	**Very low risk**	Low risk	Moderate risk	High risk	Extreme risk
Moderate	Negligible risk	**Very low risk**	Low risk	Moderate risk	High risk	Extreme risk
Low	Negligible risk	Negligible risk	**Very low risk**	Low risk	Moderate risk	High risk
Very low	Negligible risk	Negligible risk	Negligible risk	**Very low risk**	Low risk	Moderate risk
Extremely low	Negligible risk	Negligible risk	Negligible risk	Negligible risk	**Very low risk**	Low risk
Negligible	Negligible risk	Negligible risk	Negligible risk	Negligible risk	Negligible risk	**Very low risk**

Consequences of pest entry, establishment and spread

2.3 Risk Management

This stage includes the evaluation of risk management options for any hazard that is considered to be unacceptable. Thus, it involves identifying and implementing sanitary and phytosanitary measures to reduce risks to an acceptable level, while ensuring that any negative effects on trade are minimized. In doing so, the Australian system makes reference to ISPM 11 (FAO 2004) for guidance on appropriate risk management options. Examples of measures include inspection, testing for disease freedom, reduction of infestation of the crop or herd, eradication or prohibition (if no satisfactory measures can be found). A range of measures were outlined and deployed in the reports reviewed here.

2.4 Australia's Appropriate Level of Protection

Australian current interpretation of ALOP was developed between relevant Australian Federal, State and Territory Ministers after an Australian Senate committee inquiry into the importation of Canadian salmon[3], in which Canada won its WTO appeal against the Australian Government's Import Risk Analysis[4].

Australia expresses its ALOP in qualitative terms. Australia's ALOP is currently expressed as providing '*a high level of sanitary and phytosanitary protection aimed at reducing risk to a very low level, but not to zero'* (Biosecurity Australia 2009). The band of cells in Table 2.6 marked 'very low risk' represents Australia's ALOP. Measures are

3 Senate Rural and Regional Affairs and Transport Committee, An Appropriate Level of Protection? The Importation of Salmon Products. [online] www.aph.gov.au/SEnate/committee/rrat_ctte/completed_inquiries/1999-02/salmon_final/report/contents.htm

4 WTO Dispute Settlement DS18[online]: www.wto.org/english/tratop_e/dispu_e/cases_e/ds18_e.htm

required on one side (low) and measures are not required on the other (very low risk). This position recognises the impracticality of achieving zero risk in the face of natural non-regulated pathways, international trade and travel, and reflects community expectations about the importance of protecting Australia's environment, economy and people from new pests and diseases (Biosecurity Australia 2009; Beale et al. 2008). If an analysis is undertaken which indicates the estimated risk posed by a pest or disease is at or below 'very low' in the matrix (Table 2.6), that risk is deemed acceptable without the need for Australia to impose SPS measures. If the estimated risk falls above 'very low' on the matrix, mitigating actions may be undertaken to reduce risk to 'very low'.

The risk matrix provides an assessment of overall risk relative to Australia's ALOP, but a time frame was not considered explicitly in the IRAs reviewed here. Thus, the step between assessing a probability for a pest as 'very low', or 'moderate' was translated into an overall risk rating in the matrix, implying the matrix is scaled to adjust evaluations based on a single year of trade into a judgement of probabilities over longer, but unspecified, timeframes. The basis for this scaling was not apparent in the reports evaluated here, or the IRA Handbook. This is important in the context of IRAs because the likelihood of entry, establishment and spread increases for volumes of trade expected over periods longer than a year. The change in likelihood also depends on whether incursion events are clustered in space or time, for example, as a result of cultural or production practices in Australia or the source areas.

2.5 Reviews, Appeals, Timing and Communication

Biosecurity Australia provides copies of guidelines and risk assessments, deals with notifications, allows time for other members to make comments in writing, and discusses these comments upon request. It takes stakeholder comments and the results of discussion into account.

Once an IRA has been completed, Biosecurity Australia publishes and releases the document for stakeholder consultation. The period of stakeholder consultation is usually 60 days from the date of publication of the risk analysis. Biosecurity Australia maintains a database of registered stakeholders who may indicate areas of interest and the way they prefer to receive information. Responses to technical issues and methods are published in the final IRA Reports (e.g., Biosecurity Australia 2008d). Usually, all communications from stakeholders are published (on www.biosecurityaustralia.gov.au). Stakeholders can submit requests and comments to Biosecurity Australia using this web link. Biosecurity Australia maintains formal and informal links with stakeholders and information from them affects the development of IRAs. For instance, Biosecurity Australia (2008d) noted that comments from stakeholders and discussion in IRA team meetings led to several alterations to the original hazard list for pig meat (Biosecurity Australia 2008d).

Expanded IRA reports are reviewed by DAFF staff and by a group of independent experts constituting the Eminent Scientists Group (ESG), who provide oversight of certain aspects of IRA processes. Before 2007, the Eminent Scientists Groups' role was limited to examining final drafts of IRAs to ensure Biosecurity Australia had properly taken account of all technical issues in submissions received. This role was expanded to include consideration of whether the conclusions of Import Risk Analysis reports were scientifically reasonable, based on the evidence presented. To this end, the Group is able to co-opt additional expertise. Thus, the Eminent Scientists provide scientific review but do not provide an appeal mechanism (Beale et al. 2008). An appeal may be made once a provisional IRA has been published, but the appeal may only address process and not the

final decision. A 'provisional' final IRA may be reviewed by an IRA Appeal Panel administered by the Department, a non-judicial review independent of Biosecurity Australia.

Biosecurity Australia (2009) indicates that the time frame for conducting a 'Standard' IRA is 24 months and an 'Expanded' IRA is 30 months (Biosecurity Australia 2009, AGD 2008). However, the period only begins when the IRA has commenced, and there may be a lag between an initial import request and the IRA commencement. Within the prescribed period, the deadline for an IRA may be extended to acquire additional 'essential' information, research or advice, or if a *'significant national or international quarantine circumstance*' arises that limits Australia's ability to complete the IRA in the specified time (Biosecurity Australia 2009). If the Chief Executive of Biosecurity Australia extends the deadline ('stops the clock'), Biosecurity Australia issues a notice to this effect on its website. The notice states the reason and when the IRA will restart.

Stakeholders have 30 days from the publication of the provisional final import risk analysis report to lodge an appeal. Appeals must outline a claim that there was a significant deviation from the regulated IRA process that adversely affected the interests of a stakeholder. The appeal process does not consider matters relating to the scientific merits of the IRA or the merits of the recommendations made or the conclusions reached by Biosecurity Australia or the Eminent Scientists Group.

Biosecurity Australia has the right to terminate an IRA. For example, an IRA may not be required if investigations indicate that the risk is not different to an existing approved importation, and existing policy can be extended to cover the new application, or a proposer notifies that they no longer wish to proceed with an import proposal (AGD 2008). Information on Biosecurity Australia's work program and on the status of IRAs is available on Biosecurity Australia's website[5].

With regard to the specifications in Annex 7 and Annex B of the SPS Agreement, the Australian protocols 1) publish regulations, 2) maintain an enquiry point, 3) engage stakeholder communications, 4) release reports on the world wide web, and 5) specify the time periods of the risk assessment for regulated IRAs.

2.6 Uncertainty

In this report, natural variation (termed 'variability') is naturally occurring, irreducible variation in the environment. This uncertainty is separate from lack of knowledge about a system (termed 'incertitude'). Unlike variability, it can be reduced by collecting additional data (Burgman 2005). The qualitative risk assessments reviewed here do not deal explicitly with uncertainty (either variability or incertitude).

The probabilistic analyses (Biosecurity Australia 2004, 2008d) are unique among all the reports reviewed here in attempting to accommodate uncertainty in the likelihood estimates assigned to individual steps in pathways. Uncertainty was incorporated into the probability distributions described in Section 2.2.7. For example, Biosecurity Australia (2008d, p. 79) noted that '*Estimates of the sufficient quantity of contaminated chicken meat required to initiate infection were based on the best available scientific data. However, there were instances where this value was either unknown or contentious. In these situations, estimates were derived by comparing existing information with that obtained for similar pathogenic agents. As was the case for all variables in this analysis,*

5 www.biosecurityaustralia.gov.au

uncertainty in this quantity was represented in the limits of each probability distribution.' This is dome to some extent in qualitative IRAs when arguments are developed and supported by data.

Biosecurity Australia (2008d) noted that any incertitude and natural variation in individual estimates may be 'incorporated'. This comment appears in reference to quantitative steps in the analysis, considered important because quantitative assessments may otherwise appear to convey a degree of 'precision' that is not present in either the underlying science, or in the model parameter being estimated. We discuss options for dealing with different kinds of uncertainty in Section 6 below.

In several instances in the probabilistic analyses (Biosecurity Australia 2004, 2008d), the parameter values were based solely on expert opinion. The reliability of these expert opinions was not justified. Even though this is applicable to the qualitative assessments as well, this was one of the most highly criticised aspects of these IRAs (Biosecurity Australia 2008d). While Monte Carlo simulations addressed some elements of uncertainty, uncertainty arising from lack of knowledge was not discriminated from natural variation in the analyses.

The reports provided estimates of risk associated with each pest before risk management and mitigation measures. Then, 'least trade restrictive' interventions were considered and the risks associated with each pathway were re-evaluated (Biosecurity Australia 2004, 2008d). In general, the re-evaluations were qualitative or based mainly on expert judgement. This platform for assessing the interventions relies on an assessment of the step-by-step effect they have on the overall risk.

2.7 Discussion

The Australian IRA Handbook (Biosecurity Australia 2009) documents administrative procedures, enhancing transparency. However, it does not provide information on how to conduct an IRA nor recommend the terminology to be used by the risk assessors. It does not provide guidelines for dealing with uncertainty in the risk assessment or overall risk management. It does not provide examples illustrating the style of recording and reporting the information on pests and risk analysis. Thus, the IRA Handbook provides a general administrative framework, as is its purpose. It avoids technical method detail, which is developed, to varying extents, in individual IRAs.

Within IRAs, the transparency of the technical method of the risk assessments is enhanced by the use of a probability scale, the rules for combining probabilities, and the risk matrix. These rules ensure that the combinations of qualitative intervals are roughly consistent with the rules of probability, although they deviate from these rules in ways that may be important in some circumstances. This issue has been explored in detail in other ACERA reports (see ACERA Project 0901).

As noted above (Section 2.4), the risk matrix identifies an ALOP. The period of trade for which the risk is acceptable is unspecified. However, implicitly, it is longer than a year, even though likelihoods are evaluated for the volume of trade expected in a year. Thus, the risk matrix is scaled to account for periods of trade longer than a year. Unfortunately, it is not clear in the Handbook or the individual IRAs how this scaling is achieved. An explanation of how longer time horizons were considered in the scaling of the risk matrix would make the system more transparent.

The three plant IRA considered here (Mangoes, Mandarins, Capsicum) did not consider uncertainty explicitly. Many of the likelihood estimates for importation, distribution, establishment and spread are inherently uncertain, because the physical and

biological environments are uncertain, or because critical knowledge is missing, or both. If analysts use 'conservative' judgements under uncertainty, these conservatisms will compound through the analysis, generating an answer that is conservative, and for which the degree of conservatism is unknown and idiosyncratic. Answers will depend to some extent on the contexts, motivations, personal experiences and psychology of the individual assessors (Burgman 2005).

To improve the treatment of uncertainty, qualitative methods should deal with uncertainty explicitly. Appropriate technical tools include fuzzy arithmetic and related methods (Burgman 2005). However, a practical and straightforward solution may be to ensure analysts use best estimates rather than conservative or risk averse judgements, to have several analysts provide independent interval assessments for qualitative likelihoods, provide a range of verbal descriptors whenever judgements overlap boundaries, and present results as a range of possible likelihoods, together with 'best estimates'. This would defer the interpretation of uncertainty to the step in which risk is evaluated using the risk matrix.

The IRAs for chicken and pig meat sampled variation in exposure pathways from statistical distributions linked to the table of probability intervals. While these analyses are more transparent than their qualitative alternatives, they do not clearly discriminate between incertitude and variability. The increased transparency does not make the semi-quantitative methodology more credible to stakeholders. In fact, it allows for increased criticism of method details. The potential for detailed inspection and comment is not possible to the same extent for qualitative methods, but does not imply that these approaches are more accurate or reliable, as a result. Any moves towards a more quantitative framework need to anticipate the costs of greater transparency, and whether it will result in substantially different outcomes.

As noted above, limited use has been made of economic or environmental analysis in the evaluation of economic, social and environmental costs resulting from pest or disease spread, despite the availability of potentially useful methods. Uncertainty in the consequence estimates are not addressed in any of the IRAs. The details of the strengths and weaknesses of the Australia IRA methodology are explored more fully below, in the comparative evaluation of the systems employed internationally.

The Australian IRA Handbook (Biosecurity Australia 2009) indicates that measures should be least trade restrictive. Evaluation of the trade restrictions resulting from alternative measures could be the subject of detailed analysis. However, the evaluations are usually subjective and qualitative. Opportunities for extending consequence assessments to deal with the implications trade restriction are explored in the overall discussion in Section 6 below.

Beale *et al.* (2008) stated that there is no coherent understanding among domestic governments or the community, about Australia's ALOP or how it is applied to import regulation. However, Beale *et al*. (2008) also concluded no other country appears to have devised a formulation of ALOP that renders its meaning any clearer. We discuss the interpretation of ALOP employed by Australia and the other countries in Section 6.1. The attributes of each system are listed and compared with respect to the SPS criteria in Tables 6.1 to 6.4.

3. New Zealand's Risk Analysis System

In New Zealand, the Ministry of Agriculture and Forestry (MAF) sets standards and regulations to protect plant and animal health. New Zealand describes its national guidelines for conducting plant and animal health risk assessments in *Risk Analysis Procedures* (Biosecurity New Zealand 2006a). The legislation is in the *Biosecurity Act* (1993) and the *Agricultural Compounds and Veterinary Medicines Act* (1997).

New Zealand has combined the OIE and IPPC standards to develop its national guidelines for risk analysis. Biosecurity New Zealand (2006a) provides information on the announcement of IRAs, initiating processes, communication strategies, editorial guidelines and terminology, engaging stakeholders (including processes for confidential submissions and public files), revising draft reports, peer review and final reports.

The detail in Biosecurity New Zealand (2006a) is repeated in a condensed form in the introductions of the plant IRAs for Citrus fruit from Samoa, Litchi from Taiwan and Litchi from Australia, reviewed here (Biosecurity New Zealand 2007, 2008a, 2008b; see Table 1.1). This review also includes the Ministry of Agriculture and Fisheries (MAF's, 2003) IRA for honey bee genetic material, where the primary hazard was the introduction of genes for varroa tolerance, and IRAs for live prawns (Biosecurity New Zealand 2006b) and avian paramyxovirus (MAF 2001). All relevant information for New Zealand is available publicly at www.biosecurity.govt.nz.

Biosecurity New Zealand (2006a) points out that the Biosecurity Act (1993) does not provide a framework for undertaking risk assessments. Instead, when developing import requirements for risk goods, the Chief Technical Officer must have regard to New Zealand's international obligations, particularly those under the OIE and the IPPC. Biosecurity New Zealand (2006a) identifies key principles that 'define the nature and performance of the risk analysis programme delivered by Biosecurity New Zealand'; they are that the system should be effective, efficient, transparent, consistent, comprehensive, precautionary, science-based and compliant.

The system has four main parts (release, exposure, consequence assessment, and risk management) that conform in structure to the OIE and IPPC frameworks (Table 3.1). New Zealand uses the terminology defined in the ISPM guidelines for risk assessments. Biosecurity New Zealand (2006a) does not provide details on how to undertake an IRA, but makes recommendations on the structure of an analysis and some of the tools that may be deployed (such as scenario tress; see Section 3.2.2 below).

Table 3.1. Steps in the Biosecurity New Zealand, OIE and IPPC frameworks. The Table refers to PRAs, but applies to PRAs and IRAs.

Biosecurity New Zealand Plant IRA Framework	IPPC Framework	Biosecurity New Zealand Animal IRA Framework	OIE Framework
1. Managing a risk analysis	***1. Stage 1: Initiation***	***1. Initiation***	***Scoping the risk analysis***
1.1 Initiation and prioritising	*1.1 PRA Initiated by a pathway (may include review of a policy)*	Commodity definition	
1.2 Project management (scoping, planning,	*1.2 Identification of PRA area*		

communication strategy)			
2. Hazard Identification		***1. Hazard Identification***	***1. Hazard Identification***
2.1 Formation of a hazard list		*1.1 Organisms of potential concern*	*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 categorisation	*1.2 Categorisation of hazard; organisms requiring further consideration*	*1.2 Categorisation of hazard*
3. Risk assessment		***2. 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*	*2.1 Release assessment* *2.2 Exposure assessment*
3.3 Consequence assessment	*2.3 Assessment of potential economic consequences*	*2.3Consequence assessment*	*2.3Consequence assessment*
3.5 Risk estimation	*2.4 Degree of uncertainty* *2.5 Conclusion of the pest risk assessment*	*2.4 Risk estimation*	*2.4 Risk estimation*
3.6 Assessment of uncertainty			
4. Risk management options	***3. Stage 3: Pest risk management***	***3. 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*	*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*	*3.2 Option evaluation*
4.3 Estimating residual risk	*3.6 Conclusion of pest risk management*	*3.3 Implementation; recommended measures*	*3.3 Implementation*
4.4 Monitoring and review	*3.7 Monitoring and review of phytosanitary measures*	*3.4 Monitoring and review*	*3.4 Monitoring and review*
5. Risk communication and documentation	***4. Documentation of Pest Risk Analysis***		***4. Risk communication***

3.1 Initiation

Risk assessments are initiated by an internal 'request' to import a commodity and requests may come from Senior Managers (through strategic projects) or Group Managers (Border Standards, Surveillance and Response, Pest Management). Resource and time limitations, and technical detail, practicality, benefit-cost, strategic importance and public acceptability determine priorities for risk assessments.

Once a decision is made to undertake a pest or import risk assessment, the scope of the risk analysis is determined by taxonomy of the pest or disease, characteristics of the commodity, production and processing methods, surveillance and monitoring systems, intended distribution and use, and the volume of trade.

The third step in initiation is to plan the risk analysis project. The fourth and final step is to develop a communication strategy. In applications, these first four steps are considered to be the 'establishment' phase, part of internal project management. The details are not provided in the IRA.

3.2 Pest Risk Assessment

In the risk assessment step, according to Biosecurity New Zealand (2006a), the risk analyst evaluates subjectively the likelihood and environmental, economic, and human health consequences of the entry, exposure and establishment of a potential hazard within New Zealand. The analyst estimates the likelihoods of entry, exposure and establishment, and the severity of consequences. Likelihood and consequence are then combined in the 'risk estimation' step. This structure accords closely with OIE and IPPC recommendations (Table 3.1).

3.2.1 Hazard identification

Once the project is established, Biosecurity New Zealand (2006a) guidelines recommend that analysts identify all hazards associated with a commodity or pathway, where a hazard is any organism or disease that has the potential to produce adverse consequences. Each organism or disease is dealt with separately. The list may be generated by scientific and literature searches, overseas and New Zealand experience, national and international databases, targeted surveys or requests for information from other countries.

The next stage in hazard identification is equivalent to the procedures specified under pest and hazard categorisation by the OIE and IPPC. In evaluating whether a pest risk assessment is necessary, Biosecurity New Zealand (2006a) considers whether the organism is associated with the commodity or conveyance, whether more virulent strains are known to exist in other countries, or the organism or disease is absent from New Zealand, or is present but is geographically restricted or controlled. These protocols reflect IPPC and OIE recommendations. The IRAs provide appendices that indicate which organisms were not considered to quarantine risks because;

- the organism has no recorded association with the commodity,
- the organism is already present in New Zealand,
- the organism is not under official control,
- there is no evidence that the arrival (and subsequent establishment) of the organism in New Zealand would lead to any significant increase in the existing exposure, or
- the organism would not introduce new pathogens/diseases/strains into New Zealand.

3.2.2 Entry assessment

The aim of this step is to assess the likelihood of movement of a potential hazard from its area of origin into a risk analysis area via the imported pathway. The risk analyst describes biological mechanisms and then estimates the likelihood of a commodity or pathway being infected, infested or contaminated when imported into New Zealand.

Biosecurity New Zealand (2006a) recommends scenario trees be used to show the pathways for the introduction of the organism or disease, showing the systems logic that leads to establishment and spread. For organism-based assessments that include a number of different pathways, a scenario tree may be needed for each pathway.

Analysts are asked to consider biology (susceptibility of a commodity to infection or contamination, means of transmission, virulence, reproductive strategy, demographics, and routes of infection), country of origin (incidence and prevalence, disease management systems, seasonality, hazard-free areas), and the commodity/pathway (ease of contamination, volume and frequency of trade, vulnerability of the life-stages to transport or storage). The risk analysis may be finalised at this point if the likelihood of the potential hazard being able to enter into New Zealand is negligible.

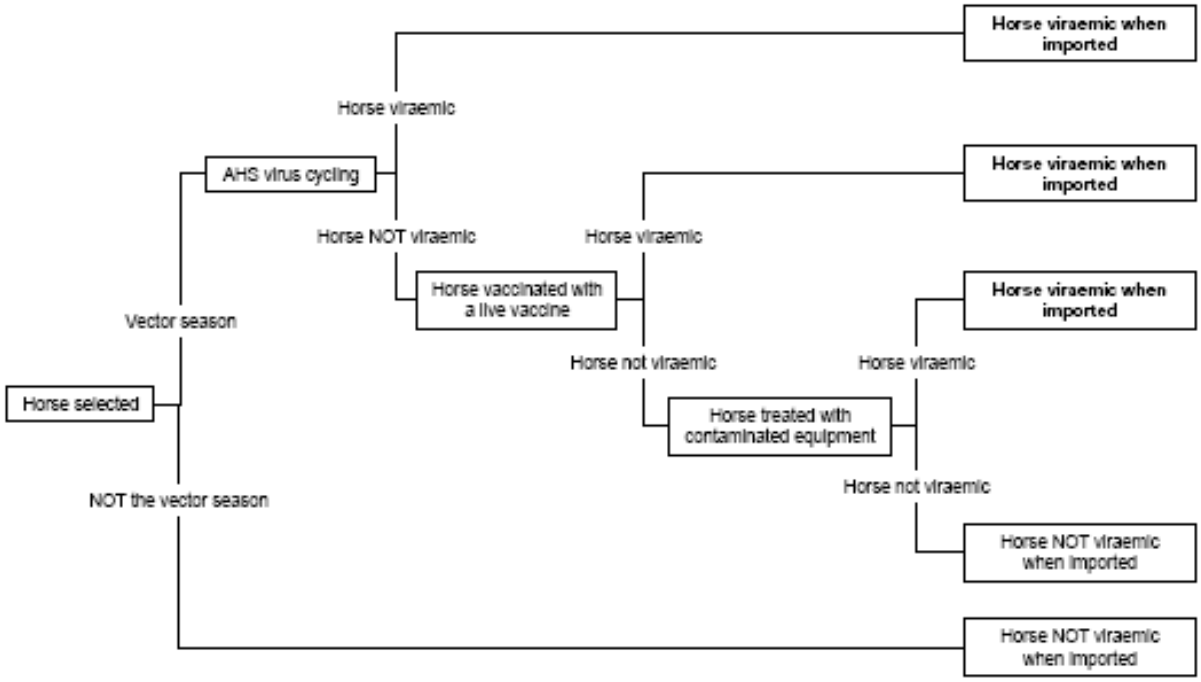

Figure 3.1. A scenario tree for an entry assessment outlining the biological pathways for an imported horse to be infected with African horse sickness virus (from Biosecurity New Zealand 2006a).

In the applications reviewed here (MAF 2001, 2003, Biosecurity New Zealand 2006, 2007, 2008a, 2008b), scenario trees were not employed. Pathway diagrams showing the steps in exposure pathways were used in several cases. These diagrams clarified the trade process but they did not contribute directly to the assessment of likelihoods or consequences in the risk assessments.

The Entry Assessment sections in all the applications concluded with a summary and judgement about the likelihood of entry. For example, when assessing the likelihood

of entry of fruit flies with Australian litchis (Biosecurity New Zealand 2008b), the IRA concluded '*The likelihood of entry of B. tyroni into New Zealand is low, given its occasional association with litchi fruit…*' (p. 44).

3.2.3 Exposure and Establishment Assessment

The Biosecurity New Zealand (2006a) guidelines suggest that the objectives of this stage of the risk assessment are to describe the biological mechanisms necessary for the potential hazard to become established, to describe the mechanisms for exposure of the environment and to estimate the likelihood of establishment and/or exposure.

As for entry, Biosecurity New Zealand (2006a) recommends the construction of scenario trees outlining the biological pathways necessary for the exposure and establishment of the organism or disease. The guidelines indicate that case histories concerning comparable hazards may be considered and expert judgement may be required to assess the likelihood. Analysts are asked to consider biological and area factors (transmission, route of infection, minimum population needed for establishment, potential hosts, environmental characteristics, potential competitors or predators) and commodity factors (uses, quantity and distribution of commodity and waste, likelihood of repeated introductions). The guidelines suggest that the scenario tree and information on related factors may be used to reach a conclusion on the likelihood of establishment of each potential hazard, group of hazards or pathway.

As for entry assessments, scenario trees were not employed in applications, but tree diagrams were used to represent exposure pathways associated with the commodities. Exposure and establishment assessments also commenced with a written description of relevant biological, area and commodity factors.

It is not clear if or how volumes of trade are considered when computing the risks. This topic is treated in more detail in Section 6.7. The Exposure and Establishment Assessment section concludes with a subjective judgement about the likelihood of exposure and establishment. The likelihoods for fruit flies associated with Australian litchis (Biosecurity New Zealand 2008b) were '*The likelihood of exposure for all three Bactrocera species is high, establishment for B. tryoni is high…*" (p. 45).

3.2.4 Consequence assessment

Biosecurity New Zealand (2006a) defines the New Zealand environment to include ecosystems and their constituent parts, people and their communities, all natural and physical resources, amenity values and aesthetic, cultural, economic, and social conditions. Direct consequences include production, environment and human health. Indirect consequences may be economic (control, eradication, surveillance, tourism, market share) or environmental (amenity, other species, ecological communities, ecosystem processes, structures, society and culture). The protocol suggests impacts should be integrated 'over space and time'.

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 (Biosecurity New Zealand 2006a). Biosecurity New Zealand (2006a) states that it is necessary to examine impact factors in greater detail when the level of unwanted consequences is in question, or when the level is needed to evaluate the strength of measures used for risk management or in assessing the cost-benefit of exclusion or control. Consequence assessment then involves identifying the likely spread

within the risk analysis area and the potential biological, environmental, economic and human health consequences, and estimating the likelihood of these consequences.

Biosecurity New Zealand (2006a) recommends that analytical techniques be used in consultation with experts in economics to complete detailed analysis of the potential economic effects. For non-commercial and environmental consequences, they suggest the use of qualitative information about the consequences, and that analyses document areas and degrees of uncertainty in the assessment, and indicate where expert judgement has been used. As in the Australian examples, none of the IRAs reviewed here used explicit economic tools, or clearly identified the economic measure used in making assessments.

In the applications reviewed here, economic and environmental impact were assessed separately, but an overall judgement of the severity of consequences was provided at the conclusion of the sections on consequence assessment, subsuming both economic and environmental impacts. It was not clear what the proportional contributions of potential consequences to the overall assessment were. For example, the assessment of fruit flies associated with Australian litchis (Biosecurity New Zealand 2008b) scoped impacts on commercial species, trade disruption, damage to native species and ornamental plants, but concluded simply that '*The consequences of establishment of B. tyroni, jarvisi and neohumeralis are likely to be moderate to very high and therefore non-negligible.'* (p. 46).

Even though the risk analysis procedures of New Zealand emphasise the consideration of time and place factors for consequence assessment, the summaries suggest that the consequences were evaluated over unlimited time frames. The use of open-ended time frames for the evaluation of consequences encapsulates the time lag involved in their establishment and the uncertain dynamics that occur when new organisms disperse in novel environments.

3.2.5 Risk estimation

According to Biosecurity Australia (2006a), 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. An evaluation of the likelihood of each of these factors must be undertaken.

Within the Biosecurity New Zealand (2006a) risk assessment framework, 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. 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

In the applications reviewed here, Risk Estimation involves the qualitative combination of the assessments of the likelihoods of entry, exposure and establishment, with the consequences of establishment. For example, in the assessment of fruit flies associated with Australian litchis, Biosecurity New Zealand (2008b) noted '*The likelihood of B. tyroni … entering the country is high,… exposure and establishment are high. The consequences of establishment are highest for B. tyroni…As a result the risk estimate for B. tyroni is non-negligible … therefore risk management measures can be justified*.' (p. 46). These statements involve the implicit convolution of likelihood assessments associated with each of the three steps in the invasion process, and their combination with the evaluation of consequences. The adjectives described in Table 3.2 are applied to both likelihoods and consequences.

Applications imply a logical structure behind the interpretation of risk descriptors. Consider the following list of judgements made in IRAs (Biosecurity New Zealand 2008a, 2008b). Table 3.3 reflects the decisions documented in the applications reviewed here. These decisions imply a structure that may be captured in a two dimensional table (Table 3.4).

Table 3.3. Examples of decisions taken in applications of New Zealand IRAs.

Species	Entry	Exposure	Establishment	Consequence	Risk
A.lutescens	Very low	Very low	Very low	Moderate[6]	Non-negligible
I.seychellarium	Moderate	-	Negligible	-	Negligible
B.hawaiiensis	Low	Low	Very low	Low	Non-negligible
M.citricola	Low	Very low	Low	Very low	Non-negligible
M.citrii	High	Negligible	-	-	Negligible
M.citrii	High	Negligible	-	-	Negligible
RLOs	Likely	Low	-	Negligible	Negligible
A.cantonensis	Low	Very low	-	Moderate	Non-negligible

Neither the applications reviewed here nor Biosecurity New Zealand (2006a) indicate how the likelihood terms should be combined. The 'rules' in Table 3.4 are implied by the decisions on pests and diseases described in the import risk assessments.

In animal risk assessments, MAF (2003) and Biosecurity New Zealand (2006b) use essentially the same logic, classifying steps in the risk pathway (release, exposure, consequence) as either negligible (sometimes described with words such as 'moderate' or 'high') or non-negligible. If any of the likelihoods or the consequence were considered to be negligible, then the risk evaluation concluded the overall risk was negligible. Otherwise, risks were considered to be non-negligible. IPPC (2005) noted that New Zealand's protocol is 'risk averse' because steps that are '*low likelihood'* combine to make a '*non-negligible risk*'.

6 The term moderate is not defined in Biosecurity New Zealand (2006a)

Table 3.4. Combination of likelihood of entry, exposure and establishment with consequences implied by assessments in Biosecurity New Zealand applications. The shaded areas represent New Zealand's ALOP because pests associated with these risk ratings require no specific phytosanitary measures.

Likelihood of Entry/Exposure/ Establishment					
High/v. High	Negligible	Non-negligible	Non-negligible	Non-negligible	Non-negligible
Medium	Negligible	Non-negligible	Non-negligible	Non-negligible	Non-negligible
Low	Negligible	Non-negligible	Non-negligible	Non-negligible	Non-negligible
Very low	Negligible	Non-negligible	Non-negligible	Non-negligible	Non-negligible
Negligible	Negligible	Negligible	Negligible	Negligible	Negligible
Consequence	**Negligible**	**Very Low**	**Low**	**Medium**	**High/v. High**

3.3 Pest Risk Management

Biosecurity New Zealand (2006a) considers risk management to be the process of deciding which biosecurity measures will effectively mitigate the risks posed by the hazard(s) associated with the commodity under consideration. If the risk estimate is non-negligible, measures can be justified. The process has three steps; identifying options, re-evaluating the likelihood of the entry, exposure, establishment or spread of the hazard under each option, and lastly, selecting the least trade-restrictive option that reduces the risk to an acceptable level. Biosecurity New Zealand (2006a) defines residual risk as the risk remaining after measures have been implemented. They point out that the residual risk, while being 'acceptable', may still result in what could be interpreted as failures.

Biosecurity New Zealand (2006a) recommends measures be audited to ensure that they achieve the results intended, for example through inspections and random checks. The residual risk information is used to develop a monitoring protocol.

In the applications reviewed here, the risk management sections outline various interventions and treatments to mitigate the hazards. These are then listed in 'order of stringency'. Finally, the section concludes with an evaluation of uncertainty, which evaluates the reliability of the measures in dealing with the hazards. The uncertainty assessments concentrate on highlighting gaps in knowledge, and identifying measures that will be robust to these gaps.

3.4 New Zealand's Appropriate Level of Protection

In cases where 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. This implies the risk is 'acceptable', meeting New Zealand's ALOP. Biosecurity New Zealand (2006a) commented that a level of risk of 'non-negligible' may be considered acceptable and 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. There were no examples of these outcomes in the applications reviewed here. The application of this provision would need to be very carefully reasoned, or it may appear that it provide scope for unjustifiable measures or unreasonable trade restrictions, contravening the SPS Agreement.

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. Hazards are deemed *high consequence* hazards if the hazard is likely to cause an unwanted impact to people, the New Zealand environment, 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.

3.5 Reviews, Appeals, Timing and Communication

General information is provided on the web regarding import permits, fees for conducting risk analyses, reports on risk analyses, appeals mechanisms, duration of consultations and stakeholder comments and reports (e.g., www.biosecurity.govt.nz/enter/animals). MAF provides copies of regulations and IRA reports, provides opportunity for comments in writing, replies to comments, and takes comments and discussion into account in revisions.

Biosecurity New Zealand (2006a) suggests that analyses must be well documented and supported with references to the scientific literature and other sources of information, including expert opinion. They must provide reasoned and logical discussions that support the conclusions and recommendations. There must be comprehensive documentation of all data, information, assumptions, methods, results, and uncertainties.

Biosecurity New Zealand (2006a) stipulates that each analysis must be submitted to a peer review process involving recognised and relevant experts from New Zealand or overseas, '*to ensure the analysis is based on the most up to date and credible information available*'. Initially, the analysis may be reviewed by appropriate staff within government departments with applicable biosecurity responsibilities. Following internal review, external reviewers may 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. Targeted peer review (internal and/or external) may be helpful when the potential mitigation measures are likely to be contentious and/or costly, or when there is a high level of uncertainty.

Biosecurity New Zealand (2006a) notes that the objective of 'consultation' is to check that the risk assessment process is transparent and rigorous and that the list of hazards or pathways requiring risk mitigation measures is justifiable. Biosecurity New Zealand (2006a) recommends that stakeholder communications should be undertaken throughout the life of the risk analysis project in the manner described in the communication strategy developed at the beginning of the project. This is consistent with best practice in risk management, as reflected in the Australia/New Zealand standard for

risk management AS/NZS 43607. Unfortunately, as noted above, this communication strategy is not documented in the relevant IRA.

Each risk analysis is documented, to facilitate the understanding of a risk analysis, to ensure that the reasons for the conclusions reached and recommendations made are clear, and to allow for review when additional information becomes available. Completed risk analyses are released for a public comment period of 60 days. Biosecurity New Zealand publishes reviews of submissions of IRAs (e.g. Biosecurity New Zealand 2006c). The reviews consider issues raised in the submissions and specify re-analysis and additional measures, where necessary.

Once an import risk analysis has been completed, Biosecurity New Zealand publishes and releases the documents for stakeholder consultations. The period of stakeholder consultation is 6 weeks from the date of publication of the risk analysis. All communications from stakeholders is available and is published on www.biosecurity.govt.nz. Stakeholders submit their communications to Biosecurity New Zealand through the website. The names and affiliations of reviewers are documented in the IRAs. There is no specification on the time limits for conducting an IRA. The animal IRAs reviewed here did not specifically address risk communication.

3.6 Uncertainty

Biosecurity New Zealand (2006a) recognises that there may be good information about some steps in a chain, and very poor or no information about other steps and suggests that '*the impact of these uncertainties on the overall estimate of risk needs to be carefully considered*', and that when there there is significant uncertainty, '*a precautionary approach to managing risk may be adopted*', meaning that assessments should protect the New Zealand environment. The documents do not indicate how precautionary decisions should be made or combined. When this approach is invoked, it should be segregated from the likelihood estimates, and embedded transparently in the comparison of the risk with thresholds for ALOP.

This does not over-ride the requirement that the measures to manage risks must take into account available scientific information. Measures should be reviewed as soon as additional information becomes available and be consistent with other measures where equivalent uncertainties exist. The rationale for selecting measures must be made apparent.

The reports reviewed here mention uncertainties. For example in the import risk analysis of Litchi from Australia in section 6.7.10 (p. 80) '*Some uncertainty exists around the likelihood of a pathogen being vectored by N.vinitor*' (Biosecurity New Zealand, 2008). Single judgements about risk levels associated with each pest are provided. There is no way of knowing how reliable each of these judgements is considered to be by the experts who made them. Similarly the judgements of consequences are not accompanied by measures of reliability. The handbook suggests the analyst must ensure that the options they consider in devising the acceptable limit do not result in unjustified trade restriction, and must strive to reduce negative trade effects. However, there is no way of knowing how conservative the decisions are.

Biosecurity New Zealand (2006a) notes that biological pathways considered in the entry and exposure assessments must be 'ascertainable'. In some cases, '*a pathway may*

7 http://www.riskmanagement.com.au/

be hypothetical rather than ascertainable. It is not appropriate to consider such pathways in a risk assessment'. It is not clear what the word 'ascertainable' means in this context. The issue does not arise in the applications reviewed here, so there are no concrete examples of this constraint.

In the plant IRAs reviewed here, uncertainty is treated explicitly in sections that describe the unknown and poorly known aspects of biology, taxonomy, distribution and behaviour, the characteristics of the exposure pathways and the efficacy of various steps in the application of treatments.

Whenever severe uncertainties arise, the analyses specify how assumptions were made. For example, where indigenous species are potential hosts, the reports extrapolate from the host's range overseas at the genus or family level. In some cases, the efficacy of risk management measures is extrapolated for similar species. For example, 'There is very little information available on *B. kirki*. The biology is assumed to be similar to that of *B. xanthodes* and *B. cucurbitae*' (Biosecurity New Zealand 2008a, p. 46).

Of the three animal IRA examples considered, only in the honey bee IRA is there an explicit (qualitative) description on uncertainties. MAF (2003) noted that for many honey bee pathogens, and in particular for honey bee viruses, there is generally limited available scientific information. However, bee viruses are considered to be very vulnerable outside the host, and the risk analysis assumes that viruses present at the time of collection will be quickly inactivated. However, elsewhere when such uncertainty is encountered, 'a precautionary approach is adopted'. It is not clear how this description reflects the actions of the analysts, to what extent individual analysts applied subjective precaution, and how sensitively the outcomes depend on these (unspecified) levels of uncertainty.

The reports evaluated here did not attempt sensitivity analysis to explore the implications of assumption about things such as the efficacy of inspection systems, treatments or pest prevalence. However, they discussed uncertainties around the efficacy of inspection protocols, in-field treatments and risk management measures.

3.7 Discussion

The New Zealand risk assessment procedures (Biosecurity New Zealand, 2006a) provide a consistent reporting format, enhancing transparency, peer review and communication with stakeholders. Terms other than those in the ISPM 5 guidelines are clearly defined. New Zealand provides a rationale for sanitary and phytosanitary measures in its IRA reports, has a contact point for enquiries, and provides systematic procedures for notification and publication of sanitary and phytosanitary measures. In addition New Zealand has clearly written, well organised materials, provided to stakeholders in a timely fashion.

It is unclear that the logic in Tables 3.3 and 3.4 could be made consistent with a formal interpretation of a probability scale and the rules for combining independent probabilities. Furthermore, as noted in the description of the Australian procedures, if an analyst includes 'conservative' estimates in qualitative risk estimates, then outputs will be susceptible to individual idiosyncracies and the degree of conservatism will be uncontrolled. Attitudes to uncertainty should be considered when the level of risk is compared with an ALOP.

NZ uses the term 'Acceptable Risk', equivalent to ALOP. In the procedures, there is no precise rule that defines acceptable risk. Instead, guidelines are recommended for consideration when selecting options that will reduce the risk to an acceptable (in the NZ

case, ‘negligible’) level. Specific criteria for each import commodity are not listed in the examples considered in this study. Transparency could be improved if IRAs presented the combination of criteria assessed for each import. The NZ scheme lacks some transparency by not providing rules or guidance on how to combine the components of likelihood of introduction, and the likelihood of introduction with consequences.

It is unclear how uncertainties are addressed and how decisions are made in cases of insufficient information. Even though the guidelines indicate that some negligible risks may be managed and some non-negligible risk may be acceptable, in the examples reviewed here risk management measures were not recommended for those pests whose risk estimate was described as negligible. In practice, the New Zealand ALOP/acceptable risk limit appears to be ‘negligible’. This approach seems risk averse because a set of steps that are ‘very low’ typically will still be classified as non-negligible.

4. USA's Risk Analysis System

The United States Department of Agriculture, Animal and Plant Health Inspection Service (USDA-APHIS) is responsible for setting standards to protect plant and animal health. Unlike Australia and New Zealand, the United States has separate guidelines for conducting plant and animal health risk assessments. The USDA system for plant IRAs is summarised in detail by USDA (2000). Procedures were created to serve the requirements of the *Plant Protection Act* (June 2002) and the standards developed by the North American Plant Protection Organization (NAPPO). The system for animals is outlined in detail in USDA (1997, 2004). Relevant information for the United States is available publicly at the websites http://www.aphis.usda.gov/ and www.regulations.gov. Federal Registers are developed for each pest.

The approaches note the stages of pest risk analysis outlined by IPPC (2007; Table 4.1). The prescriptions for both animal and plant risk assessments note that assessments may be quantitative or qualitative. USDA (2000) outlines the process for qualitative risk assessments and all of the examples considered here were largely semi-quantitative; the details are described in the following sections. The three animal IRA examples are importation of exotic Newcastle disease from Denmark, BSE in beef from Japan and FMD from Argentina (USDA 2005 a, b, c). The plant IRAs are for longan from Taiwan, mangoes from India and citrus from Chile (USDA 2006, 2007, 2008).

Table 4.1. Steps in the USDA, OIE and IPPC frameworks

USDA Plant IRA Framework	IPPC Framework	USDA Animal IRA Framework	OIE Framework
Step 1. Initiation	***Stage 1: Initiation***	***Scoping the risk analysis***	***Scoping the risk analysis***
Document the initiating event(s) for the PRA	*1.1 PRA Initiated by a pathway (may include review of a policy)*		
	1.2 Identification of PRA area		
Step 2. Assess weediness		***1. Hazard Identification*** [8]	***1. Hazard Identification***
			1.1 Formation of hazard list
Step 3. Information; previous risk assessments, status of imports, pest interception data	*1.3 Information*		
	1.4Conclusion of initiation		
	Stage 2: Pest risk assessment		
Step 4. Pest	*2.1 Pest categorisation*		*1.2 Categorisation of*

8 The applications reviewed here were for single diseases and regions.

categorisation *4a. Identify pests associated with the commodity of quarantine significance* *4b. Identify pests likely to follow the pathway*			*hazard*
		2. Risk assessment	***2. Risk assessment***
Step 6. Likelihood of introduction via the pathway	*2.2 Assessment of the probability of introduction and spread*	*2.1 Release assessment* *2.2 Exposure assessment*	*2.1 Release assessment* *2.2 Exposure assessment*
Step 5. Consequences	*2.3 Assessment of potential economic consequences*	*2.3Consequence assessment*	*2.3Consequence assessment*
Step 7. Risk Potential	*2.4 Degree of uncertainty* *2.5 Conclusion of the pest risk assessment stage*	*2.4 Risk estimation*	*2.4 Risk estimation*
	Stage 3: Pest risk management	***3. Risk management***	***3. Risk management***
	3.1 Level of risk *3.2Technical information required* *3.3 Acceptability of risk*		*3.1 Risk evaluation*
	3.4 Identification and selection of appropriate risk management options *3.5 Phytosanitary certificates and other compliance measures*		*3.2 Option evaluation*
	3.6 Conclusion of pest risk management		*3.3 Implementation*
	3.7 Monitoring and review of phytosanitary measures		*3.4 Monitoring and review*
	4. Documentation of Pest Risk Analysis		***4. Risk communication***

The steps outlined for the OIE and the IPPC are commensurate with those identified for the USA, except that the US procedures do not deal explicitly with Risk Management or Risk Communication. Although USDA (1997, 2000, 2004) focuses on risk assessment (IPPC Stages 1 and 2), it admits that risk management (IPPC Stage 3) stages are interrelated, so that '*the risk assessor may occasionally make brief comments regarding risk management options associated with the requested commodity importations*' (USDA 2000, p. 2).

4.1 Initiation and Hazard Identification

Protocols for animal risk assessment (USDA 1997, 2004) focus on disease risk assessment associated with trade in animals or animal products from specified regions. Analysts assess disease status within regions by considering the organization and infrastructure of veterinary services, disease surveillance, diagnostic capabilities, animal and disease demographics and emergency response capacity in the exporting region. Animal disease risks are assessed as belonging to one of five risk categories ranging from 'negligible' to 'high'. The assessments reviewed here focused on a single disease, so hazard identification was not an issue.

Pest risk analysis may be initiated by discovery of a pest in a new area, or the interception of a pest at a port (termed 'pest initiated') or when international trade is proposed for a new commodity (termed 'pathway initiated'), more or less consistent with other countries, and with OIC and IPPC guidelines. The USDA (2000) protocol provides guidance for 'pathway initiated' pest risk assessments. A 'pest initiated' risk assessment may be initiated if the commodity itself poses a threat. This is determined if the species is not widely prevalent in the US and is listed on national or international weed lists (Step 2), or scientific literature or previous risk assessments indicate weediness (Step 3).

The next stage in the plant IRA protocol (USDA 2000) is to create a list of potential pest species associated with the commodity (Step 4). The USDA makes explicit use of pest interception data to create this list. For example, in the assessment of mangoes from India, USDA (2006) noted over two thousand arthropod interceptions on mango were made at US ports of entry since 1985 including 627 records of *Sternochetus mangiferae* (Fabricius) (Curculionidae) and 269 records of *Sternochetus* sp. The report noted that most potential pests were intercepted rarely (less than 10 times, including *Sternochetus frigidus*) and that there were few fungal interceptions, probably because 'noticeable disorders of mango may not be easily attributable to a single cause at ports of entry' (USDA 2006, p. 7). Similarly, the IRA for citrus from Chile (USDA 2007) lists interception records (year of interception, type of transport, type of cargo) for all species of quarantine concern.

The USDA's definition of quarantine pests is consistent with the IPPC, namely, they are pests of potential economic importance to the area and not yet present there, or present but not widely distributed and being officially controlled. All of the listed organisms are potential quarantine pests. The USDA (2000) protocol specifies that it must be reasonable to assume these quarantine pests will be present in the exporting country, be associated with the commodity at the time of harvest and remain with the commodity in viable form during harvesting, packing and shipping procedures. Applications include discussion of pests that were not further analysed because they are unlikely to follow the pathway.

4.2 Pest Risk Assessment

Following OIE guidelines, animal IRAs consist of release, exposure and consequence assessments, and risk estimation (USDA 2004). In the release assessment, the US considers veterinary services, disease status for the country, and disease surveillance. It also takes note of the country's mitigation measures and these are reported in the evaluations. While the methods qualify as semi-quantitative (ISO 31000), the conclusions are assessed subjectively.

The plant IRA system has seven steps that conform in structure to the IPPC framework (Table 4.1). Notably, the US plant risk analysis publications (USDA 2000, 2006) do not deal with risk management or communication issues. These are dealt with in separate Risk Management Documents (e.g., USDA 2008). While most analyses are semi-quantitative, USDA (2007) used Probit-9 to evaluate standards for the application of measures.

4.2.1 Spread and Consequence Assessment

Unlike the systems in Australia and New Zealand, the US system commences with consequence assessment. Step 5 in the plant IRA protocol (USDA 2000) is labeled 'Assess Consequences'. It results in a score termed a Cumulative Risk Rating that is considered to be an indicator of the potential of the pest to establish, spread, and cause economic and environmental impacts. This stage is also labeled 'Risk Assessment' in some IRAs (e.g., USDA 2007). Background information includes regulation decision history (approval / disapproval) for the relevant country and commodity.

In the animal IRAs (USDA 2005 a, b, c), consequences were assessed separately for animal health, public health, environmental and economic values. Control and eradications costs were considered under economic consequences. The assessments were conducted subjectively, using published studies to support judgements.

In the plant IRAs, consequence assessment was based on a subjective judgement of five 'Risk Elements', each assigned a score of between 1 and 3. They include;

1. suitable hosts and climates exist in the US,
2. host range (1 for monospecific pests, 3 for pests of multiple families),
3. dispersal (spread) potential (including reproductive potential and movement capabilities),
4. economic impact (damage to host crops, commodity value or loss of markets), and
5. environmental impact (including ecological disruption, effects on threatened species or habitat, or the indirect impacts of control actions).

If no suitable hosts or climates exist in the US, then the PRA ceases. Otherwise, the scores for each risk element are added and compared with a Cumulative Risk Rating scale;

- Low: 5 - 8 points
- Medium: 9 - 12 points
- High: 13 - 15 points

For example, *Sternochetus frigidus* (F.) and *Sternochetus mangiferae* (F.) were scored as Low because they may spread to two Plant Hardiness Zones (2), they are species specific (1), they have strong dispersal potential (3), they may affect export opportunities (1) and mangoes are not threatened (1), making a total score of 8. Adding terms that represent probabilities can lead to perverse outcomes that are inconsistent with the rules for combining the likelihoods of independent events. For example, the likelihood of a joint event may be dominated by one very low probability element, making the overall likelihood very low (at most), a result that would be masked when scores are added. Adding scores implies that the elements are substitutable. These issues are discussed in greater detail below.

4.2.2 Probability of entry and establishment

In the animal IRA exposure assessments, all possible pathways were listed and the risks were assessed qualitatively. An overall judgement from the pathways was presented, in

which historical and epidemiological data were considered subjectively. For example, when considering the disease-free status of Denmark for exotic Newcastle disease, USDA (2005) noted the disease had been effectively controlled and eradicated in domestic flocks, there had been an 'extensive' surveillance program, there had been no outbreak since 2002, Denmark had improved its record-keeping and had implemented a mandatory vaccination program. There were '*no additional risk factors*' that would justify maintaining the disease status for Denmark. The qualitative judgements are combined subjectively into an overall estimate of risk. For example, 'the risk of introducing END into the United States with the resumption of trade in poultry … from Denmark is low. Although consequences of an END outbreak are potentially substantial, the likelihood of an outbreak occurring from exposure of the domestic poultry population to poultry products imported from Denmark is low (USDA 2005, p. 5).' The applications reviewed here did not attempt to quantify any of the criteria (including the surveillance program) and did not use standardised language to communicate assessments of likelihood.

The USDA (2000) plant IRA guidelines use the term 'Pest Opportunity (Survival and Access to Suitable Habitat and Hosts)'for the probability of entry and establishment. To make their assessment, analysts consider six elements, again using a 3-point scoring system for each element;

1. The quantity of the commodity imported annually (from < 10 to > 100 containers per year)
2. Survival of post-harvest treatment (manipulation, handling or specific phytosanitary treatment)
3. Survival during shipment
4. Non-detection at the port of entry (assuming standard inspection protocols for like commodities)
5. Movement to a climatically suitable area
6. Contact with suitable host(s)

In estimating elements 5 and 6, the analyst considers dispersal mechanisms, intended destinations for the imported commodity, proximity of entry, transit and destination points to suitable hosts, time of year, Intended use of the commodity, and by-products and waste, consistent with ISPM 11 (IPPC 2006). These factors contribute to an estimate of risk in the absence of additional 'measures' that might be applied to reduce risk to an acceptable level.

Elements 2 to 6 in the above list are estimated as independent probabilities, and the time frame is annual. The guidelines stipulate '*The events … should be considered as a series of independent events that must all take place before a pest outbreak can occur, i.e., the estimates for one element should not affect estimates for other elements*' (USDA 2000, p. 10). They are then assigned point scores according to the following thresholds;

Table 4.2 Likelihood definitions employed by the USDA

Category	Probability interval	Score
Low	< 0.01	1
Medium	0.01 – 0.1	2
High	> 0.1	3

The scores are then added to produce a 'Cumulative Risk Rating for the Likelihood of Introduction' that is compared to the scale,

- Low: 6 - 9 points
- Medium: 10 - 14 points
- High: 15 - 18 points

For example, *Sternochetus frigidus* (F.), *Sternochetus mangiferae* (F.) were scored because the quantity of containers is medium (2), are highly likely to survive post-harvest treatment (3), are highly likely to survive shipment (3), can only be detected by destructive sampling (3), a re likely to be shipped to susceptible areas (2) but are unlikely to contact host material because of limited host range (1). The sum of these elements is 14 (a Medium Cumulative Risk Rating). As noted above, adding scores that represent independent probabilities may generate perverse outcomes.

4.2.3 Risk estimation

The USDA (2000) arrives at a summary interpretation of entry, establishment, spread and consequence assessment by summing the two Cumulative Risk Rating scores. This generates a score termed the Pest Risk Potential, defined by the following scale;

- Low: 11 - 18 points
- Medium: 19 - 26 points
- High: 27 - 33 points

Thus, the Pest Risk Potential for *Sternochetus frigidus* (F.) and *Sternochetus mangiferae* (F.) is 14 + 8 = 22 (Medium), indicating that risk mitigation measures 'may' be necessary. It is not stipulated under what conditions risk measures would or would not be necessary, making their specification entirely subjective.

4.3 Pest Risk Management

Identification and selection of appropriate sanitary and phytosanitary measures to mitigate risk is undertaken as part of the risk management phase and is not discussed by USDA (1997, 2000, 2004). APHIS risk management programs depend on characteristics of the risks posed by specific pests. Pest risk mitigation measures are not discussed in specific applications of the methods (e.g., USDA 2006), but are included in separate Risk Management Documents (e.g., USDA 2008). These documents list the species identified in the pest risk assessment stages as having high or medium unmitigated risk potential. Phytosanitary measures are listed (including heat and cold treatments, sampling, inspection, types of shipments, packaging and distribution specifications) and their efficacy for each potential pest is discussed. In other IRAs (e.g. USDA 2007) risk management measures are outlined in a separate section in the IRA.

4.4 The US's Appropriate Level of Protection

The US has no clear definition of 'acceptable' risk, nor does it provide guidelines or criteria that an analyst must consider when estimating the unrestricted risk. Even though the North American Plant Protection Organisation (NAPPO) guidelines provide example options to be considered when defining the acceptable risk, it is not clearly stated whether USDA uses these guidelines. However, in the decisions in the examples reviewed here (mangos, citrus, *Dimocarpus* and three animal diseases), pests and regions scored as 'Low' typically do not require specific mitigation measures. This implies that the appropriate level of protection for the US is characterized as 'low'. Pests scored medium or high may require specific phytosanitary measures.

4.5 Reviews, Appeals, Timing and Communication

Documents (risk assessment and notifications, communications with stakeholders) are available on the web, although not on a single, readily accessible website as in Australia and New Zealand. Thus, the US guidelines and Federal Register together comply with the SPS Agreement with respect to the availability of materials. USDA provides copies of regulations and IRA reports. It elicits comments from stakeholders, and considers these comments when revising draft document.

The USDA publishes a 'proposed rule', a document in the *Federal Register* describing regulations, or changes to regulations, that the Agency is considering, inviting public comment for a specified period of time. Once an IRA (risk assessment and risk management) has been completed, the USDA publishes and releases the documents for stakeholder consultations. Stakeholders submit their communications to USDA through the website. The period of stakeholder consultation is 60 days from the date of publication of the risk analysis. There are no guidelines for consultation and the terms and the scope of consultations are not explicitly limited. For example, a notice to import mangoes from India was published in 2006 and comments concerning the proposal were solicited for 60 days. All communications from stakeholders are published on www.regulations.gov. General information common to all PRAs is also listed on the website, including initiation, scope, time limits for a PRA, and the appeals process.

A 'final rule' is a document published in the *Federal Register* implementing a proposed rule, with or without changes. The document includes discussion of comments made on the proposed rule and any changes to the proposed rule, and discussion of why suggested actions were or were not adopted (e.g., US Federal Register 2007). For example, as a condition of entry, mangoes must undergo irradiation treatment and be accompanied by a phytosanitary certificate providing specific information regarding the treatment and inspection of mangoes and the orchards in which they were grown (US Federal Register 2007).

There is no specific timeline for completion of an animal or plant IRA. The US does not distinguish between a short IRA and an extended IRA. It specifies that the process of IRA can take several years depending on the complexity of the problem and also the data provided by the stakeholder. The time for conducting a PRA is usually 18 months, some take 2 to 3 years, a few take much longer.

The IRA reports are reviewed both by internal members of USDA-APHIS and a small group of experts from other organisations who provide an independent oversight. The names and affiliations of the reviewers are documented at the end of conclusions of the risk assessment.

4.6 Uncertainty

The US plant IRA guidelines (USDA 2000) and the individual applications reviewed here do not mention uncertainty. None of the plant or animal examples considered here considered uncertainty explicitly. In contrast, the Agricultural Quarantine Inspection Monitoring Handbook (USDA 2007b) provides extensive advice on estimating and interpreting uncertain information. However, there is no guidance in the IRAs on how this should be managed in the analyses. This is a striking omission in risk analysis documents, and is in sharp contrast to the analyses documented in other jurisdictions.

4.7 Discussion

In animal IRAs, risk management is pest specific and risk dependent. Where risk management measures were applied, an entry to the Federal Register was developed. This complies with the OIE and IPPC and the SPS Agreement. Rating scales and other terminology are defined in the guidelines (USDA 1997, 2000, 2004). US pest risk assessments are in compliance with the ISPM guidelines in that additional terms not in ISPM No 5 are defined clearly in the guidelines and in the Federal Register.

Animal PRAs employ subjective methods for assessing likelihood and consequence and estimating risk. Plant IRAs use a cumulative point scoring system that provides some transparency, but the structure may provide counterintuitive, perverse or inconsistent assessments, even with good data and without subjective biases. Consequence estimation is enhanced in the plant IRAs by classifying indirect and direct economic effects and providing examples under the three categories. However, as in the Australian and New Zealand case studies, there was no apparent application of explicit economic analysis, no discussion of the measure employed to assess economic cost, and no explanation of how different kinds of values were reconciled.

US use the term ‘acceptable risk’ rather than ‘appropriate level of protection’. The guidelines for plants and animals do not provide a clear rule to define acceptable risk or the criteria to be considered. However, in general, risk mitigation measures are not required in situations where the risk is considered to be ‘low’ (p 11, USDA 2000).

In one PRA reviews here reference was made to ‘Probit 9’(USDA, 2007), suggesting that different types of analysis are used depending on context and the availability of data. The treatment of uncertainty is explored in detail in section 6 below.

5. Canada's Risk Analysis System

The Canadian Food Inspection Agency (CFIA) is responsible for Canada's animal and plant biosecurity. Canada has separate national guidelines for plant and animal import risk assessments. Plant health risk assessment are described in the risk assessment template (CFIA, 2007a), implementing the provisions of the *Plant Protection Act* (1990 C.22). Guidelines for animal IRAs appear in CFIA (2000).

The Canadian system outlined in CFIA (2000, 2007) comprises stages explicitly related to the OIE and IPPC frameworks (Table 5.1). All relevant information regarding country legislation and import regulations are available on http://www.inspection.gc.ca/english/corpaffr/recarapp/recaltoce.shtml.

However, information relating to applications of import risk analysis and examples of the latest IRAs are not publicly available, but on request to the Plant and Animal Health Division. Three examples considered here (Table 1.1) each comprised two documents relating to pest risk assessment and risk management.

Table 5.1. Steps in the Canadian biosecurity, OIE and IPPC frameworks

Canadian Plant IRA Framework	**IPPC Framework**	**Canadian Animal IRA Framework**	**OIE Framework**
Stage 1. Initiation	***Stage 1: Initiation***	***Stage 1. Initiation***	***Scoping the risk analysis***
1.1 Preliminary risk profile Delineation of PRA area	*1.1 PRA Initiated by a pathway (may include review of a policy)*		
Previous PRAs, current status	*1.2 Identification of PRA area*		
Weediness of commodity			
	1.3 Information		
	1.4Conclusion of initiation	**Stage 2. Hazard Identification**	***1. Hazard Identification***
Stage 2. Identify potential quarantine pests	***Stage 2: Pest risk assessment***		*1.1 Formation of hazard list*
	2.1 Pest categorisation		*1.2 Categorisation of hazard*
Stage 3. Pest risk assessments		***Stage 3. Risk assessment***	***2. Risk assessment***
3.1 Hazard identification 3.2 Geographical and regulatory status			
3.3 Likelihood of introduction	*2.2 Assessment of the probability of introduction and spread*	3.1 Release assessment 3.2 Exposure assessment	*2.1 Release assessment* *2.2 Exposure assessment*
3.4 Economic importance Establishment Natural Spread Economic Impact	*2.3 Assessment of potential economic consequences* *2.4 Degree of uncertainty*	*3.3 Consequence assessment* *3.4 Risk estimation*	*2.3Consequence assessment* *2.4 Risk estimation*

Environment Impact	*2.5 Conclusion of the pest risk assessment stage*		
		Stage 4. Peer Review	
	Stage 3: Pest risk management	***Stage 5. Risk Management***	***3. Risk management***
	3.1 Level of risk *3.2Technical information required* *3.3 Acceptability of risk*	5.1 Risk evaluation	*3.1 Risk evaluation*
	3.4 Identification and selection of appropriate risk management options *3.5 Phytosanitary certificates and other compliance measures*	5.2. Option evaluation	*3.2 Option evaluation*
	3.6 Conclusion of pest risk management	5.3. *Implementation*	*3.3 Implementation*
	3.7 Monitoring and review of phytosanitary measures	*5.4. Monitoring and review*	*3.4 Monitoring and review*
	4. Documentation of Pest Risk Analysis	***6. Risk Communication***	***4. Risk communication***

The steps outlined for Canada are commensurate with those identified for the OIE and the IPPC, except that the Canadian Guidelines for plant IRAs, like the US guidelines, do not make reference to Risk Management or Risk Communication.

The plant pest risk assessments reviewed here follow closely the structure of the template. From the examples and the template, Canada uses the terminology defined in ISPM guidelines, including likelihood of introduction, economic impact, establishment potential, spread potential and environmental impact (CFIA 2007a). There are no separate definitions provided for these terms in the template or the reports. Terms are consistent in all the three applications (CFIA 2002, 2007b, 2008a).

5.1 Initiation

Initiation of plant and animal IRAs follows a request to import a commodity. Plant IRA initiation involves outlining the reason for the request, delimiting the PRA area, the 'values' potentially at risk from the commodity, and conducting an assessment of the weediness of the commodity (CFIA 2007). Analysts review previous PRAs from Canada or other countries where they are relevant, other sources of information including pest fact sheets and alerts.

For animal IRAs, a risk assessment is required for any importation of a new species, a new product or a commodity from a new country. For the case in which a new species, genus, product or country is considered to present the same risk as that for which a risk assessment has been completed, only an addendum to the original risk assessment may be required. Initiation documentation outlines history, background and rationale for the request, description of the commodity, the volume, quantity and frequency of trade, and the associated time frames (CFIA 2000).

5.1.1 Identification of potential pests

Once a commodity based risk assessment is initiated, analysts create tables listing the pests that have been reported in, on, or associated with the commodity from the country in question. Those that are presently regulated or that have been identified as potential quarantine pests are noted. Potential plant pests are organisms that (in accordance with IPPC 2004) are not present in a PRA area, or are present but limited, have important potential economic impacts and may be associated with the commodity under the conditions specified (CFIA 2007).

5.2 Pest Risk Assessment

5.2.1 Hazard identification

According to the Canadian animal IRA guidelines (CFIA 2000), hazard identification is a categorisation step in which potentially hazardous biological agents are identified that may be introduced with a commodity or activity. Hazard identification establishes the taxonomic status of the pest species, and its geographical and regulatory status. This includes evaluation of whether the species is a quarantine pest according to IPPC criteria listed above and whether there are any existing regulations for the pest in the PRA area.

5.2.2 Likelihood of introduction / Release assessment

In animal IRAs (CFIA 2000), 'release assessment' consists of describing and quantifying the potential of a source (the importation activity or pathway) to introduce biological agents into the environment. The release assessment describes the types, amounts, timing, and probabilities of the release of biological agents, and how these attributes might change as a result of various actions, events or measures. Analysts consider a range of factors including prevalence, veterinary services, ease of contamination, diagnostic testing, inspections, temperature and duration of storage during transport. Inputs that 'may be required' include incidence, prevalence, veterinary services in the exporting country, the contamination process, processing, treatments, storage and transit conditions.

This stage of the assessment is very similar for plants and animals. Plant PRAs evaluate introduction potential by examining factors that affect the likelihood of entry of a pest into the PRA area. The rating does not take into account the effect of future regulations designed to mitigate the risk of the pathway. Thus, initial assessments are equivalent to 'unrestricted' risk assessments in other jurisdictions (Australia and New Zealand). Estimates of the likelihood of introduction consider prevalence in area of origin, pathways, survival in transit, probability of surviving existing phytosanitary procedures, ease of detection, frequency of trade, seasonal issues, and the use and disposal of the commodity. Analysts consider these factors and then decide one of four ratings:

1. Negligible, scoring 0
2. Low, scoring 1
3. Medium, scoring 2
4. High, scoring 3

These labels and scores reflect subjective judgements for a range of situations for which the conditions are described qualitatively. For example, a rating of 'negligible' includes situations where the likelihood of introduction is 'extremely low' given the distribution of the pest at source, management practices, commodity volume, low

probabilities of pest survival in transit and contact with susceptible hosts in the PRA area, or unsuitable climate. A rating of 'high' applies where introduction is very likely or certain given the combination of factors necessary for introduction. These scores contribute to a sum (see 5.2.7 below).

5.2.3 Consequences: likelihood of establishment

The use of the term 'consequence' associated with likelihood of establishment (and spread; see below) in the Canadian system contrasts with the definition of consequence in the other protocols described above, where it is used to describe the social, environmental and economic impacts of pest or disease spread. In the protocols for Canadian animal IRAs (CFIA 2000), exposure assessment consists of describing the relevant conditions and characteristics of animal and human exposures to risk agents produced or released by a given risk source. Exposure assessments typically consider the intensity, timing, frequency, and duration of exposure, routes of exposure (e.g., ingestion, inhalation, or insect bite), and the number, species and characteristics of populations that might be exposed. Thus, it encompasses both likelihood of establishment and likelihood of spread outlined in plant IRAs. Inputs to exposure assessment include evaluation of potential vectors, exposure pathways, modes of transmission, host distributions, cultural practices and environmental characteristics of the PRA.

In Canadian plant IRAs (CFIA 2007), the analyst considers factors that affect the likelihood of establishment of a pest into the PRA area, including distribution and abundance of potential hosts in PRA area, climatic suitability, potential for adaptation of the pest, and cultural practices and control measures. As above, analysts then decide one of four ratings,

1. Negligible, scoring 0
2. Low, scoring 1
3. Medium, scoring 2
4. High, scoring 3

This rating reflects the potential host ranges of a pest introduced into new areas. A rating of 'negligible' means the pest has 'no potential to survive and become established' in the PRA area because, for example, winter temperatures throughout the PRA are too low for the pest to survive. A rating of 'high' implies the pest has the potential to survive and become established throughout most or all of the range of host(s) in the PRA area.

The Canadian protocols recommend that analysts assume introduced pests will behave as they do in their native area if host plants are present in PRA area and the climate is similar to its area of origin. Establishment potential is rated from 'negligible' to 'wide', after considering the number of hosts, their geographic range and pattern of distribution, and attributes of the abiotic environment (precipitation, temperature, soil type). CFIA (2007) suggests analysis may include geographic information systems (GIS) and spatial modeling tools to model and map potential pest distributions in the PRA area.

5.2.4 Consequences: probability of spread

According to CFIA (2000, 2007), probability of spread reflects the propensity of the pest or disease to disperse by natural means (via wind, water, soil, seed and pollen, and insect, fungal or nematode vectors) throughout the PRA area. Regulatory control may not be feasible depending on the pest's current distribution and mode of dispersal. Analysts consider suitability of natural and managed environments for natural dispersal and potential natural vectors and then decide one of four ratings, as for likelihood (above). A

rating of 'negligible' means that the pest has 'no potential for natural spread' in the PRA area. A rating of 'high' implies the pest has potential for rapid natural spread to all production areas of the PRA area.

5.2.5 Economic consequences

The animal IRA guidelines (CFIA 2000) define consequence assessment as describing the relationship between specified exposures to a risk agent and the economic consequences of those exposures. Consequence assessments typically include a specification of the impact on health in the animal and human populations sustained under given exposure scenarios. In other words, the consequence assessment is the process of developing a description of the relationship between the specified exposures to a risk agent and the health and other consequences to animals and humans exposed. Consequences may include animal and production losses, trade embargoes, monitoring, control and eradication costs, treatment costs and human health effects.

The Canadian plant IRA guidelines (CFIA 2007) specify that analysts consider the direct effects the pests may have on the specific crop concerned, either during production or in storage. Factors include production costs, yield, quality, marketability, and variability of impact among cultivars or varieties. Hosts considered include cultivated and forest species, but only those that are managed. In this step of the Canadian system, impacts on "wild" hosts that have no economic value to domestic agriculture or forestry are excluded from consideration.

Indirect impacts the pest might have on potential trade, such as export significance are not the focus of this assessment. This issue is dealt with as a trade component of risk management. Thus, the Canadian protocols (CFIA 2007) suggest that when a pest or disease has the potential to affect international or domestic trade, this fact should be noted but should not contribute to the score. Analysts consider type(s), amount and frequency of damage, yield losses and reduced marketability, effect on existing production practices and the cost of control measures and then decide one of the four ratings; negligible, low, medium and high, scored as described above.

A rating of negligible means there is no impact on yield, host longevity, production costs or storage, with no treatment necessary and no economic losses. In the applications reviewed here, a rating of 'high' means the pest has a severe impact on the standing crop with significant yield loss, host mortality and / or losses in storage. Assessments are provided together with a summary of the reasoning that leads to the assessment. For example, Patterson's Curse (*Echium plantagineum*) is rated as 'high' because it has caused major economic impacts in other countries where introduced and may lead to pasture degradation, livestock and crop yield losses, hay and seed contamination, and increased costs of control (CFIA 2007b).

5.2.6 Environmental consequences

Non-human and non-production environmental impacts are not mentioned explicitly in the Canadian animal IRA guidelines (CFIA 2000). The plant IRA protocol (CFIA 2007) considers potential impacts on non-agricultural host(s) and natural ecosystems. This may include subjective consideration of direct biotic effects on endangered or threatened natural species (e.g., feeding) and reduction of biodiversity. Examples of abiotic impacts considered include ecosystem destabilisation, environmental degradation, fire hazard, erosion, and impact on recreation and aesthetic values. It may also be appropriate to consider potential negative impacts of risk management options (e.g., pesticides) as

indirect environmental impacts. Analysts consider these factors and decide one of the four ratings.

The guidelines note that a rating of 'negligible' means there is no potential to degrade the environment or otherwise alter ecosystems by affecting species composition or reducing longevity or competitiveness of wild hosts. A rating of 'high' means there is potential to cause major damage to the environment with significant losses to plant ecosystems and subsequent physical environmental degradation. As for economic consequences, the reasoning behind assessments is provided. For example, the potential environmental consequences of Patterson's Curse are also 'high' because of its potential negative impacts on human and animal health due to the plant's toxic alkaloids and the potential consequences of herbicide resistance. In addition, it may have the potential to affect ecosystem processes (erosion processes, fertility) and community composition (CFIA 2007b).

5.2.7 Risk Rating

The Canadian animal IRA guidelines (CFIA 2000) define risk estimation as the integration of results from release, exposure and consequence assessment to produce measures of health and environmental risks. These measures typically include estimated numbers of people experiencing health impacts, measures of the nature and magnitude of adverse consequences to the natural environment, and probability distributions, confidence intervals, and other means for expressing the uncertainties in these estimates. Thus risk estimation takes into account the whole of the risk pathway from hazard to unwanted outcome.

The plant IRAs (CFIA 2007) add the individual ratings given for the four 'consequence' factors (i.e., establishment potential, natural spread, economic and environmental impacts) to produce a cumulative score. The overall consequence score is rated as

1. negligible (0-2),
2. low (3-6),
3. medium (7-10) or
4. high (11-12).

For example, in the assessment of Woolly Cupgrass (CFIA 2008b) cumulative scores were assigned as follows (Table 5.2):

Table 5.2. Cumulative risk scores for Woolly Cupgrass (CFIA 2002). 'Consequence' scores in other systems would be limited to economic and environmental impact.

Cumulative Scores for Consequences of Introduction	Assigned Rating	Numerical Score
Establishment potential	High	3
Natural spread potential	Medium	2
Economic impact	Medium	2
Environmental impact	Low	1
Total Score	**Medium**	**8**

The Canadian plant guidelines provide a Table as a 'guide' for combining likelihood of introduction with the cumulative score for consequence (Table 5.3). This table combines the likelihood of entry (essentially, a probability) with the sum of the scores from Table 5.2 (a mixture of summed probabilities and consequence scores). The implicit time scale is annual; for example, CFIA (2007) states that when assessing entry and establishment, analysts should evaluate if the pest has potential for natural spread locally in the PRA area within a year.

Like the systems described for Australia, New Zealand and the USA, the majority of analyses are subjective. Like the systems in New Zealand and the USA, it sums probability values. The implications of this approach are discussed in detail in section 6. Implicitly, IRAs consider the volume of trade expected in a year, although this is not made explicit in the applications or the guidelines.

Table 5.3 Guide to the combination of likelihood of entry with consequences (the summation of scores for likelihood of entry, establishment, spread, and economic and environmental consequences). The shaded areas represent Canada's ALOP because pests associated with these risk ratings may require no specific phytosanitary measures. The usage of these terms is not consistent with their use in systems elsewhere.

Likelihood of Entry				
High	Negligible	Low	Medium	High
Medium	Negligible	Low	Medium	Medium
Low	Negligible	Low	Low	Low
Negligible	Negligible	Negligible	Negligible	Negligible
Consequence	*Negligible*	*Low*	*Medium*	*High*

5.3 Canada's Appropriate Level of Protection

The Canadian animal IRA guidelines (CFIA 2000) define risk evaluation as the process of interpreting risks, including determining levels of risk acceptable to individuals, groups or society as a whole (Covello and Merkhofer 1993), and safety as the degree to which risks are judged acceptable; a subjective decision. In the plant IRAs reviewed here, the judgements are incorporated in the assessment endpoints where 'negligible' means no specific phytosanitary measures are necessary. The borderline category is 'low', where no specific phytosanitary measures 'may' be necessary, and where production practices, inspection, packaging, end-use, season and so on. Mitigation measures are expected to provide 'sufficient phytosanitary security'. Thus, Canada's ALOP essentially equates to risks assessed as 'negligible' (Table 5.3).

5.4 Reviews, Appeals, Timing and Communication

Important general information common to all PRAs is listed on the website, including initiation, time limits, scope and the appeals process (www.inspection.gc.ca/english/reg/rege.shtml). As noted above, IRAs are not available.

For animal IRAs, a request form indicates the need for a risk assessment. This is completed by a relevant officer and forwarded to the Animal, Plant and Food Risk Analysis Network (APFRAN). APFRAN is responsible for identifying the hazards

associated with the import and conducting animal risk assessment for each hazard. The importer may be contacted for further description of and information on the commodity to complete the request. The completed and approved request is forwarded to APFRAN. APFRAN informs the Officer within 3 working days of the anticipated delivery date for the risk assessment.

New pest risk assessments may be triggered by the need for a response strategy to a newly identified pest or the need for a scientific analysis when an importer proposes a new type of import. The Canadian protocols (CFIA 2007) note that the import protocol for a commodity that has never been imported should receive industry consultation. If there are further questions and concerns, APFRAN and/or the Centers of Expertise may be contacted to mitigate these concerns. The consultative process may be curtailed due to 'trade-related time constraints', although it is not entirely clear what this implies.

The Auditor General of Canada (AGC 2008) found that, as of 31 March 2008, there was a backlog of 42 requests for full pest risk assessments and 4 requests for updates—some dating back to as early as 1999. They also found that over the past two years, the completion rate has been about 63 percent.

All IRA reports are reviewed by members of CFIA and USDA-APHIS. Once an import risk analysis (risk assessment and risk management) has been completed, Canada publishes the documents for stakeholder consultations. For Plant IRA's the period of stakeholder consultation is not found in the risk management documents or the guidelines. All communications from stakeholders is available in the form of the risk management documents (CFIA, 2009) and can be obtained on request from CFIA.

Risk management documents outline stakeholder communications. For example, CFIA (2009) notes that 'Stakeholders' comments received back following the circulation of the CFIA's Swede midge risk management document (RMD-08-03) in November 2008, were mostly in favor of the CFIA's proposal to deregulate the insect in Canada. Further discussions with the concerned stakeholders were held in February 2009 to address concerns that were raised by these stakeholders'.

5.5 Uncertainty

The Canadian guidelines request that analysts discuss ratings and note 'uncertainty and gaps'. The plant IRA guidelines (CFIA 2007) note that reports should include a summary of the sources and magnitude of uncertainty 'as this information could be useful in determining research needs.'

At the end of each section there is a description of the overall rating and any uncertainties. For example in the Woolly Cupgrass example (CFIA, 2002), the analysts note 'There is some uncertainty on present evidence as to 1) the pathway responsible for the introduction of woolly cupgrass into south western Quebec and the most likely pathways for future movement across the Canada-U.S. border, 2) the means of natural dispersal employed by woolly cupgrass, including vectors used and distances covered…..'. The other two reports acknowledge uncertainty in a similar fashion.

Information from the risk assessments and the deliberations on uncertainty are used in risk management and decision making, although it is not clear exactly how this information contributes to decisions. In the examples considered here (CFIA, 2008b, 2009), the risk management documents provide a summary of the pest risk assessment and include information on pest risk management options, consultation and communication plans.

5.6 Discussion

The descriptions of the rating scales, and the terminology defined in the guidelines (CFIA, 2007a) provide a systematic procedure for conducting and communicating risk assessments. Where risk management measures were applied, the commodity-specific risk management practices are published as risk management documents (CFIA, 2008b, 2009).

The overall process of conducting an IRA by CFIA is transparent but does not fall within the guidelines of the SPS Agreement. In particular, the probability of introduction in ISPM 11 (IPPC 2006) includes the probability of entry, establishment and spread, whereas in the Canadian system, the term applies only to entry. The potential to establish and spread are considered to be part of the consequences of introduction (CFIA, 2007a). While the reasons behind the assessments for each step in the Canadian system are outlined extensively. The implications of this approach are discussed in more detail in Section 6 below.

Canada does not use the terms ‘acceptable risk’ and ‘appropriate level of protection’. However risk mitigations measures are not specified in situations where the risk is considered to be ‘low’ or ‘negligible’ (CFIA, 2007a). This suggests that the appropriate level of protection for Canada is ‘negligible-low’. The three examples reviewed here described uncertainty qualitatively.

6. Discussion of risk analysis systems of four countries

The descriptions above summarise the most important features of the four systems. This section compares and contrasts the features of these systems. The ultimate aim is to identify the most important features of a technically ideal system that may provide a framework for further developing international standards and harmonization of risk analysis methods. Tables 6.1 – 6.4 summarise the similarities and differences between the systems under four headings; compliance of national guidelines with international standards, transparency, risk analysis methodology, and compliance of applications with local specifications.

Table 6.1. Compliance with the SPS Agreement and consistency with OIE/IPPC guidelines.

Harmonisation / Appropriate Level of Protection / Consistency and non-discrimination / Equivalence and Regional Conditions	
Harmonisation: The SPS Agreement promotes the use of common sanitary and phytosanitary measures. It states (SPS Agreement Article 3) "*To harmonize sanitary and phytosanitary measures on as wide a basis as possible, Members shall base their sanitary or phytosanitary measures on international standards, guidelines or recommendations, where they exist,…*" and "*Members may introduce or maintain sanitary or phytosanitary measures which result in a higher level of sanitary or phytosanitary protection than would be achieved by measures based on the relevant international standards, guidelines or recommendations, if there is a scientific justification*". *ALOP*: Article 5 allows each Member to determine an '*the measure to be applied for achieving the appropriate level of sanitary or phytosanitary protection from such risk'*, the level of protection deemed appropriate by the WTO Member to protect human, animal or plant life or health within its territory (ALOP). A range of national interest values and considerations – social, economic, environmental – have been applied in setting ALOP. *Consistency*: Article 5 also advocates that ALOP must be applied consistently across different situations and take into account the objective of minimising negative trade effects, stating "*each Member shall avoid arbitrary or unjustifiable distinctions in the levels it considers to be appropriate in different situations, if such distinctions result in discrimination or a disguised restriction on international trade."* *Equivalence:* Article 4 requires that SPS measures of an exporting country shall be accepted "*if the exporting Member objectively demonstrates to the importing Member that its measures achieve the importing Member's appropriate level of sanitary or phytosanitary protection…"*, acknowledging implicitly that protection may be achieved by alternative means. When economically and technically feasible alternatives for meeting ALOP are available, the least trade restrictive option must be chosen. Article 6 recognises that specified areas (e.g., a country or part of a country) may form a region in terms of pest and disease presence or absence, specifically "*Members shall, in particular, recognize the concepts of pest — or disease-free areas and areas of low pest or disease prevalence. Determination of such areas shall be based on factors such as geography, ecosystems, epidemiological surveillance, and the effectiveness of sanitary or phytosanitary controls.*"	
Country	**Evaluation**
Australia	• Terms and measures in IRAs are consistent with OIE and IPPC guidelines. Hazard identification / pest categorization is comprehensive – all potential pests and diseases are listed and the reasons for further assessment, where necessary, are indicated. • ALOP is identified as being 'very low' but not zero. • Australia permits the exporting country to propose alternative measure, provided they offer

	equivalent efficacy, supported by data. • Apart from differences between the animal and plant IRAs, and evidence of an evolution in the risk assessment methodology, the protocols were applied consistently in the IRAs examined. Risk management recommendations are based on qualitative expert descriptions of the efficacy of the recommended measures and potential alternatives. • The IRAs accept areas of disease and pest freedom and low prevalence.
Canada	• The guidelines and plant pest risk assessments use stages reflecting the OIE and IPPC frameworks. The PRAs reviewed here follow closely the structure recommended by the IPPC and the terminology defined in ISPM guidelines, including likelihood of introduction, economic impact, establishment potential, spread potential and environmental impact. The term 'consequence' is associated with likelihood of establishment and spread, in contrast with its use in other jurisdictions to describe the social, environmental and economic impacts of pest or disease spread. • ALOP is not stated explicitly, but can be inferred from guidelines and appendices that indicate that generally, risk mitigation may be necessary if overall risks are more than negligible. • Guidelines recommend identifying least trade-restrictive risk management options.
New Zealand	• Hazard identification and categorization, entry, establishment and exposure procedures reflect IPPC and OIE recommendations. The IRAs provide appendices that indicate which organisms were not considered to be quarantine risks, and why. • ALOP is not stated explicitly, but can be inferred from decisions taken in IRAs to be 'negligible'. • The protocols were applied consistently in the cases examined here. • The IRAs accept areas of disease and pest freedom and low prevalence.
USA	• The steps outlined in US Guidelines and applied in the IRAs are consistent with the OIE and the IPPC guidelines, except that the US IRAs do not deal explicitly with Risk Management or Risk Communication. The USDA focuses on risk assessment, but admits that risk management stages are interrelated, and that risk assessors may occasionally make brief comments about risk management options. Appendices list all species considered, indicating whether they 'follow' the pathway under consideration. The appendices note that some pests do not fit the IPPC definition of a quarantine pest, but are included because they are USDA actionable pests. The term 'actionable pest' is not defined in the documents reviewed here. • The US has no clear definition of ALOP, nor does it provide guidelines or criteria that an analyst must consider when estimating unrestricted risk. However, in the decisions that appear in the examples reviewed here, pests and regions scored as 'Low' typically do not require specific mitigation measures. • The protocols were applied consistently in the cases examined here. • The IRAs accept areas of disease and pest freedom and low prevalence.

Table 6. 2. Transparency

Transparency
Both the OIE and IPPC state transparency (including documentation, communication and notification) is a core principle in biosecurity risk analyses. The IPPC prescribes '*Contracting parties shall, on request, make available to any contracting party the rationale for phytosanitary requirements, restrictions and prohibitions.'* (Article VII.2c). ISPM No. 11 interprets this to mean *'...that countries should, on request, make available the rationale for phytosanitary requirements. The whole process from initiation to pest risk management should be sufficiently documented so that when a review or a dispute arises, the sources of information and rationale used in reaching the management decision can be clearly demonstrated.*' The OIE terrestrial code states '*transparency is essential in order to ensure fairness and rationality, consistency in decision making and ease of understanding by all the interested parties*' (Article 1.3.2.3.), and defines transparency as '*the comprehensive documentation of all data, information, assumptions, methods, results, discussion and conclusions used in the risk analysis. Conclusions should be supported by an objective and logical discussion and the document should be fully referenced.*

The SPS Agreement states '*Each Member shall ensure that one enquiry point exists which is responsible for the provision of answers to all reasonable questions from interested Members as well as for the provision of relevant documents regarding: ...(c) risk assessment procedures, factors taken into consideration, as well as the determination of the appropriate level of sanitary or phytosanitary protection.*' (Annex B.3c).

The SPS Agreement states '*Whenever an international standard, guideline or recommendation does not exist or the content of a proposed sanitary or phytosanitary regulation is not substantially the same as the content of an international standard, guideline or recommendation, and if the regulation may have a significant effect on trade of other Members, Members shall: ... (d) without discrimination, allow reasonable time for other Members to make comments in writing, discuss these comments upon request, and take the comments and the results of the discussions into account.*' (Annex B.5d).

Country	Evaluation
Australia	• Administrative procedures are described in the IRA handbook and technical details are provided in the individual IRAs. The guidelines and web material provide timelines and opportunities for written comments and discussion. • Draft and final IRAs are posted on the web outlining ALOP and rationales for sanitary requirements. Sources of data are referenced in individual IRAs, apart from occasional oversights. Most assumptions are documented. • There is a single point of contact, DAFF, which provides copies of guidelines and risk assessments, deals with notifications, allows time for other members to make comments in writing, and discusses these comments upon request. • Stakeholder comments are incorporated in revised IRAs. • IRAs are reviewed by external scientists and by stakeholders who provide comments on draft IRAs. Stakeholder comments are published. • Responses to Stakeholder comments are evaluated by an independent scientific committee.
Canada	• Guidelines for plant and animal IRAs appear in the web. Guidelines include initiation, time limits, scope and the appeals process. • Information relating to applications of import risk analysis and recent IRAs are not publicly available. In theory, but not in practice, they are available on request. Three plant pest risk analysis examples were available. We could not obtain animal IRAs. • There is a single point of contact; the CFIA Plant and Animal Health Division. • Some IRAs are published for stakeholder consultations. • IRAs are reviewed by scientists in CFIA and USDA-APHIS. • Communications from stakeholders are recorded in risk management documents and may (in theory) be obtained on request from CFIA.
New Zealand	• National guidelines for plant and animal health risk assessments are published on the web. The detailed procedures are repeated in a condensed form in the IRA introductions. • Final IRAs are published on the web. • There is a single point of contact, Biosecurty New Zealand, which provides information on the announcement of an IRA, initiating processes, communication strategy, editorial guidelines, engaging stakeholders, revising draft reports, peer review and final reports. • Stakeholder communications are undertaken throughout the life of the project but the communication strategy is not documented in the relevant IRA. • All IRAs are peer reviewed by experts from New Zealand or overseas. Critical external reviews may be commissioned by the Project Manager. The names and affiliations of reviewers are documented in the IRAs. • Stakeholder communications are published on the web.
USA	• Guidelines, risk assessments and notifications, and communications with stakeholders are available on the web, although not on a single, readily accessible website. Thus, the US guidelines and Federal Register together comply with the SPS Agreement with respect to the availability of materials. General information common to all PRAs is also listed on the web, including initiation, scope, time limits for a PRA, and the appeals process. • The single point of contact, the USDA, provides copies of regulations, deals with notifications, provides copies of the IRA reports, allows time for members to make comments in writing, and discusses the comments upon request. • Once an IRA has been completed, the USDA publishes and releases the documents for stakeholder consultations. Stakeholders submit their communications to USDA through the website. The period of stakeholder consultation is 60 days from the date of publication of the risk analysis. There are no guidelines for consultation and the terms and the scope of consultations are not explicitly limited.

	• All communications from stakeholders are published on the web. • The IRA reports are reviewed both by internal members of USDA-APHIS and a small group of experts from other organisations who provide an independent oversight. The names and affiliations of the reviewers are documented.

Table 6.3. Risk analysis methods.

Scientific evidence / uncertainty / consistency with scientific theory
Article 3.2 of the SPS Agreement states "*Sanitary or phytosanitary measures which conform to international standards, guidelines or recommendations shall be deemed to be necessary to protect human, animal or plant life or health, and presumed to be consistent with the relevant provisions of this Agreement and of GATT 1994."* Article 5 of the SPS Agreement states '*Members shall ensure that their sanitary or phytosanitary measures are based on an assessment, as appropriate to the circumstances, of the risks to human, animal or plant life or health, taking into account risk assessment techniques developed by the relevant international organizations*.' The OIE prescribes that '*risk assessment should be based on the best available information that is in accord with current scientific thinking*' and should be '*supported with references to the scientific literature and other sources, including expert opinion*.' The IPPC does not state this explicitly but ISPMs 11 and 21 make it clear that scientific and economic information and assessments are integral to risk analysis. The OIE defines **risk assessment** as '*the evaluation of the likelihood and the biological and economic consequences of entry, establishment and spread of a hazard within the territory of an importing country*'. Similarly, the IPPC defines **pest risk assessment** as '*the evaluation of the probability of the introduction and spread of a pest and the magnitude of the associated potential economic consequences.*' Article 5 requires that SPS measures to maintain ALOP are based on risk assessment. Technical guidance developed by the IPPC or OIE (e.g., IPPC 2009) must be considered but Members may undertake their own form of risk assessment. In devising SPS measures, "*In assessing the risk …, Members shall take into account as relevant economic factors: 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 in the territory of the importing Member; and the relative cost-effectiveness of alternative approaches to limiting risks."* Members may "*provisionally adopt sanitary or phytosanitary measures on the basis of available pertinent information"* (Article 5.7, WTO 1995). However, the country must establish that the import poses pest or disease risk above the risk target (i.e., ALOP), and that "*such measures are not more trade-restrictive than required to achieve their appropriate level of sanitary or phytosanitary protection, taking into account technical and economic feasibility"* (Article 5.6). Pest and disease risk assessments are consistent with international guidelines when they have clear definitions of likelihood of introduction (including entry, establishment and spread), magnitude of impact, and uncertainty. The magnitude of impacts must clearly separate economic, environmental and social impacts (or their equivalents). Assessments must treat direct and indirect effects and estimate 'unrestricted' risk.

Country	**Evaluation**
Australia	• Probabilities of introduction, distribution, establishment and spread are estimated qualitatively using words linked to probability intervals. The nature of the estimates (conditional and marginal probabilities of 'at least one' event) is implicit, rather than explicit. • The rules for combining the probabilities are roughly consistent with the rules of probability for conditional, independent events, but they deviate from formal probability calculations in

	some ways (see ACERA Report 0901). • Consequences consider six criteria that are not linked to specified intervals or scales, making them difficult to apply consistently. The system combines extent and severity of impact in a sensible way, but the measure of severity is simply the maximum of any of the six criteria, which may lead to underestimation of some consequences, when a pest or disease has important impacts over a number of criteria. • The consequence assessments lack formal economic, social or environmental analysis. • Consequence assessment does not include time discounting and may underestimate consequences associated with entry and/or establishment. • It's not clear how probabilities assessed for a volume of trade expected in a year are scaled to account for longer periods. • Qualitative IRAs do not deal explicitly with uncertainty, assuming that natural variation and lack of knowledge are contained within the subjective intervals. There is no way of knowing how reliable each judgement is considered to be by the experts who made them.
Canada	• Scores reflect subjective judgements of the probabilities of entry, establishment and spread, and the severity of consequences. Ratings consider subjectively the distribution of the pest at source, management practices, commodity volume, low probabilities of pest survival in transit and contact with susceptible hosts in the PRA area, or unsuitable climate. • Consequence estimates consider production costs, yield, quality, marketability, and variability of impact among cultivars or varieties. It is unclear whether animal and plant IRAs consider impacts on non-market values, the environment or social amenity. • There are no explicit social, economic or ecological analyses in the PRAs reviewed here. • The point scoring system sums values representing probabilities, which is likely to produce counterintuitive and incorrect combinations of probabilities. • The Canadian plant PRAs confound probability and consequence scales, implying that elements of consequence can substitute for elements of the likelihood of establishment and spread. This system will produce outcomes that are at odds with formal logic, intuition and common sense. • Analysts are advised to 'consider' uncertainty and gaps, but there is no explicit treatment of uncertainty. There is no way of knowing how reliable each judgement is considered to be by the experts who made them. • The consequence assessments lack formal economic, social or environmental analysis. • Consequence assessment does not include time discounting and may underestimate consequences associated with entry and/or establishment. • It's not clear how probabilities assessed for a volume of trade expected in a year are scaled to account for longer periods. • Qualitative IRAs do not deal explicitly with uncertainty, assuming that natural variation and lack of knowledge are contained within the subjective intervals. There is no way of knowing how reliable each judgement is considered to be by the experts who made them.
New Zealand	• Guide-words describe levels of probability but are not linked to a probability scale or intervals. • Exposure and establishment assessment concludes with a subjective judgement of likelihood. Neither the applications nor the guidelines indicate how the likelihood terms should be combined. • Consequence assessments consider ecosystems and their constituent parts, people and their communities, all natural and physical resources, amenity values and aesthetic, cultural, economic, and social conditions. • There are no explicit social, economic or ecological analyses in the IRAs reviewed here. Economic and environmental impacts were assessed separately, but an overall judgement of the severity of consequences was provided, subsuming both impacts. • Guidelines suggest that when there is 'significant uncertainty', a precautionary approach may be adopted. There is no way of knowing when this approach was invoked, or how reliable each judgement is considered to be by the experts who made them. • The consequence assessments lack formal economic, social or environmental analysis. • Consequence assessment does not include time discounting and may underestimate consequences associated with entry and/or establishment. • It's not clear how probabilities assessed for a volume of trade expected in a year are scaled to account for longer periods. • Qualitative IRAs do not deal explicitly with uncertainty, assuming that natural variation and lack of knowledge are contained within the subjective intervals. There is no way of knowing how reliable each judgement is considered to be by the experts who made them.
USA	• The USDA plant PRAs use an additive scoring system to indicate the potential of a pest to establish, spread, and cause economic and environmental impacts. • In the plant IRAs, the probabilities of entry, establishment and spread are linked to a

	probability scale. • The point scoring system sums values representing probabilities, which is likely to produce counterintuitive and incorrect combinations of probabilities. • There are no explicit social, economic or ecological analyses in the IRAs reviewed here. • In the animal IRA, risks were assessed qualitatively and combined subjectively into an overall estimate of risk. • Neither the guidelines nor the plant or animal IRAs provide guidance on how to handle uncertainty. There is no way of knowing how reliable each judgement is considered to be by the experts who made them. • The consequence assessments lack formal economic, social or environmental analysis. • Consequence assessment does not include time discounting and may underestimate consequences associated with entry and/or establishment. • It's not clear how probabilities assessed for a volume of trade expected in a year are scaled to account for longer periods. • Qualitative IRAs do not deal explicitly with uncertainty, assuming that natural variation and lack of knowledge are contained within the subjective intervals. There is no way of knowing how reliable each judgement is considered to be by the experts who made them.

Table 6.4. Consistency of applications with domestic guidelines

Consistency	
Country	Evaluation
Australia	The national framework guidelines (IRA Handbook) provides an overview of administrative procedures and policy. Risk analysis method details appear in the IRAs themselves. The IRAs reviewed here were consistent with guidelines and implemented the technical detail as described in the introductions of the IRAs. There were some differences between the IRAs – they varied between quantitative to more qualitative assessments, reflecting an evolution in methods.
Canada	Guidelines suggest spatial analysis should be used to support spread estimates. Guidelines suggest IRAs are available on request, but our approaches the relevant agency did not result in access to animal IRAs. The plant PRAs we obtained are consistent with the local prescriptions for conducting a PRA.
New Zealand	Guidelines recommend scenario trees be used to show the pathways for the introduction of pests and diseases. These have not been applied in practice, although tree diagrams are employed. Guidelines recommend analytical techniques be used in consultation with experts in economics to complete detailed assessments of potential economic effects. The IRAs reviewed here did not employ these tools, and conclude with a broad summary indicating whether risks are negligible or non-negligible.
USA	Even though NAPPO guidelines provide example options to be considered when defining the acceptable risk, it is not clear if USDA uses these guidelines in implementing ALOP.

6.1 Approaches to ALOP

Beale *et al.* (2008) stated that no country has defined ALOP with any precision. None of the country guidelines reviewed above specify ALOP precisely (Table 6.1); Australia indicates that it is 'very low' but assessments against this standard are subjective. However, other countries avoid indicating their ALOP altogether. When economically and technically feasible alternatives for meeting ALOP are available, the least trade restrictive option must be chosen, although opinions about equivalence vary between nations (e.g., irradiation for phytosanitary purposes; Follet and Neven 2006).

Beale *et al.* (2008) also noted that many countries define ALOP in terms of measures taken to manage risk. This is apparent in the PRAs and IRAs published by New

Zealand, Canada and the USA (Table 6.1) where the specification of measures provide an operational definition of ALOP. The former two do not require risk management measures if the risk is 'negligible'. The USA typically does not specify measures if the risk is 'low'. The term negligible is not defined in the New Zealand protocol. Gascoine (2001) predicted that ALOP would be vaguely specified because appropriate data and understanding are unavailable and values are unavoidable in decisions.

It is possible to construct a system that would provide a quantifiable, verifiable standard for ALOP. Sgrillo (2002, undated) proposed that ALOP be expressed as the $\log_{10}$ of the *introduction period*, the expected time between two introductions of a pest or disease agent associated with a particular commodity. Of course, this relative risk would need to be combined with estimates of consequence.

Sgrillo (2002) begins with the ALOP, determines the consequences of an introduction of the pest, and 'calculates' the limit for the probability of entry, establishment and spread which cannot be exceeded. Sgrillo's general concepts are equivalent to the steps employed by Biosecurity New Zealand (2006a), Biosecurity Australia (2009) and the USDA (2000). These jurisdictions 'calculate' the probability of entry, establishment and spread, estimate consequences, combine likelihood and consequence to determine risk, and compare the resulting risk with ALOP. The system in Canada is different because it combines scores for establishment and spread with consequences before combining them with the likelihood of entry.

Bigsby (2001) suggested plotting economic impact against probability of introduction for a large sample of pests or products about which regulatory decisions have already been made. Pests and organisms for which a decision has been taken not to regulate form a curve that indicates acceptable risk. This would provide an empirical expression of each country's ALOP, and would allow the consistency of subsequent decisions to be evaluated. This approach would recognize that ALOP is '*an emergent property of a sequence of import risk analyses and decisions based on them'* (Burgman, in Beale *et al.* 2008).

6.2 Cumulative risk

In the US, Canada, Australia and New Zealand, each organism or disease is dealt with separately. As long as no individual pest or disease risk exceeds ALOP, measures are not required. However, even if each pest or disease is assessed individually and has its risk mitigated to meet ALOP, if there are multiple hazards, each of which has a low probability, there may be a significant aggregate probability that at least one of the many will occur (Aven and Renn 2009). For the sake of consistency, Bigsby (2001) suggested that commodity-based import risk assessments should estimate risk using,

$$R = \sum_{i=1}^{n} p_i C_i$$

where p_i is the probability of entry, establishment and spread of pest i, and C is the impact (cost) of pest i, if it spreads (Bigsby 2001). This is essentially the expression for expected (dis)utility from classical decision theory (French 1986) in which the expected value of a decision is the sum of the expected outcomes (likelihood x consequence) of each of its elements.

In a PRA initiated by a specific pathway (usually an imported commodity), IPPC (2009) suggests that the probability of pest entry should be evaluated for a pathway in question. Hence, computation of cumulative risks and costs associated with multiple pests

would give an appropriate, overall estimate of the risks. Despite the recognition of this issue in biosecurity literature and the availability of tools to deal with it, no country attempts to evaluate the cumulative risks associated with multiple pests that might be carried with a single commodity, or the risks of entry, establishment and spread of a single pest over many commodities and pathways.

One PRA reviewed here made reference to 'Probit 9', a standard used broadly in the USA and other jurisdictions after World War II. USDA (2007a) noted '*Currently, the United States allows entry of limes from Chile after treatment with soapy water and wax (USDA treatment schedule 102-b-1) (USDA-APHIS-PPQ, 2006b; USDA-APHIS-PPQ, 2006c). This treatment is applied to all citrus from Chile by default (Snell, W., 2006). It meets probit 9 requirements for controlling B. chilensis on limes (Gonzalez, 1997)…*' (p. 16). The standard requires that commodity treatments for quarantine pests, especially fruit flies, must kill or sterilize 99.9968 percent of the pests in a test of at least 100,000 individual pests. This approach has been criticized as being hyperconservative, ignoring a range of practices (i.e. a systems approach) that may mitigate risks in other ways, such as pre-shipment cultural practice, packing and shipping procedures, and distribution times and areas (Sgrillo 2002). Probit 9 would seem to exceed the onus of proof required by the SPS Agreement, particularly equivalence of alternative risk mitigation practices and procedures.

6.3 Consistency, harmonisation, transparency

Both the OIE and the IPPC (2007) suggest that national biosecurity organisations strive for consistency in PRAs. Consistency, the guidelines suggest, encourages non-discrimination, transparency, efficiency, and improved comparability between assessments. Consistency may be achieved through '*the elaboration of generic decision criteria and procedural steps, training of analysts, and review of draft PRAs*' (p. 14). The USDA (2000) has attempted to 'harmonize' plant protection and quarantine risk assessment procedures with guidelines provided by the IPPC (2007).

Beale *et al.* (2008) concluded that the different approaches to ALOP and different risk analysis criteria would lead to inconsistent decisions between and within countries. It is not possible to say if the decisions in the risk assessments reviewed above are consistent within or between countries, or not. Table 6.5 illustrates that processes vary substantially between countries (see also Table 6.1). IRAs can be difficult to find on the web, requires protracted procedures to obtain or may in fact be impossible to obtain. Appeals processes vary, although the risk analysis processes for all of the countries included in this review were available. However, if IRAs are not readily available or impossible to obtain, it severely limits or negates opportunities for information exchange and review.

Table 6.5 Comparison of aspects of transparency of risk analysis procedures

Country	Appeal mechanisms	Reports on the web[9]	Notification procedures	Enquiry points	Consultation processes

9 Obtaining IRAs for the US was not very straightforward; one has to get into the newsroom section of the website and then search for IRAs by year of publication. Obtaining IRAs for Canada was even more difficult, involving requests (by email) to the relevant authority.

Australia	30 days from the date of publication of the draft report, limited to process	Yes	Emails, website,	Biosecurity Australia	Specified in handbook
Canada	Not specified	No, on request	Not specified	CFIA	Not specified
NZ	6 weeks from the date of publication	Yes	Emails, website, paper	Biosecurity NZ	Specified in handbook
US	60 days from the date of publication	Yes	website	USDA-APHIS	Specified in handbook

In risk assessments, an element of transparency is to identify who was involved because it allows reviewers to assess relevant skills and makes the participants more responsible for the content (Burgman 2005). Earlier Australian IRAs list authors and reviewers (AQIS 1999). Biosecurity Australia (2004) acknowledges a range of participants. Recent animal IRAs list the names and expertise of the IRA teams including external technical participants (Biosecurity Australia 2008c, d). Canadian plant IRAs and recent Australian plant IRAs (Biosecurity Australia 2008a, b) do not identify individual contributors, in Australia as a precaution against potential actions by stakeholders against individual IRA team members. The IRAs produced by New Zealand list the individuals who authored or coordinated the documents, the technical advisers, and the people who provided internal and external peer review. Similarly, the USDA (2000) protocol and the individual IRAs list the authors and commentators of the documents and their qualifications.

In NZ IRAs, projects are initiated through the 'establishment' phase, which includes the development of a communication strategy. However, the details including the reasoning behind the development of the communication strategy, are not made public (e.g., Biosecurity New Zealand 2007, p. 3).

The structure and language of animal IRAs used by the OIE, Australian, New Zealand and Canadian are derived from the approach to risk assessment developed by Covello and Merkhofer (1993). The headings of this system (release, exposure, consequence, risk estimation) are broadly equivalent to those employed in the plant IRA frameworks, and the USDA's animal risk assessment framework (Tables 2.1, 3.1, 4.1, 5.1). This makes it relatively easy to evaluate the consistency of decision processes in the IRAs and to compare them between species groups and jurisdictions.

6.4 Dealing with uncertainty and variability

ISPM 2 (IPPC 2007) suggests that uncertainty should be taken into consideration when conducting PRAs. Specifically, IPPC (2007) recommends that '*the nature and degree of uncertainty in the analysis should be documented and communicated, and the use of expert judgement indicated. ... Documentation of uncertainty contributes to transparency and may also be used for identifying research needs or priorities*' (p. 13).

As noted in Section 1 above, it is helpful to classify uncertainty into two kinds; variability is naturally occurring variation that can be quantified but does not diminish with additional study and sampling. Incertitude is lack of knowledge, and it reduces as effort is expended to better understand systems and accumulate data (Burgman 2005). Biosecurity New Zealand (2006a) reflects these definitions, suggesting uncertainty may

be thought of as a measure of the incompleteness of one's knowledge or information about an unknown quantity.

The main sources of uncertainty in PRAs listed by ISPM 2 include missing, incomplete, inconsistent or conflicting data, natural variability of biological systems, subjectiveness of the analysis and sampling randomness. This list of uncertainties is incomplete (Roelofs 2009). For instance, the US and Canadian systems involve summation of scores where products may be more appropriate; this represents a form of model uncertainty. In addition, ISPM 2 pools natural variability of biological systems under the broad heading of uncertainty. Thus, ISPM 2 does not require a separate characterisation of variability (arising from nature) and incertitude (arising from a lack of knowledge).

The term 'uncertainty' is used in a variety of ways in the IRAs reviewed in this study, including:

a) To acknowledge a lack of accurate representation of the full complexity of the biological system under investigation, including all possible pathways.
b) To acknowledge general lack of information about a particular outcome or pathway.
c) To indicate specific uncertainty about accuracy or precision regarding information provided by experts or estimates obtained from data.
d) To allow for natural sampling variation in available data.

Interpretations (a)-(c) are used at some point by all countries, mainly by way of verbal acknowledgement and the claim that such uncertainty is accounted for by taking a 'conservative' approach to assessment of probability/likelihood/risk.

The Australian semi-quantitative method for animal IRAs (Biosecurity Australia 2004, 2008d) more formally incorporate (c) and (d) by sampling subjective and derived statistical distributions.

Biosecurity Australia and the USDA specify numerical intervals that correspond to linguistic interpretations of terms for likelihoods and provide rules for combining the implied probabilities. In contrast, Biosecurity New Zealand's method provides less precise definitions and does not indicate the rules for combining likelihoods.

This results in the potential for differences in the interpretation of risk concepts between jurisdictions. For example, the likelihoods of 'entry', 'exposure' and 'establishment' in New Zealand of squash bugs (*Leptoglossus gonagra*) on citrus fruit from Samoa were estimated to be very low, high and low, respectively (Biosecurity New Zealand 2008a, pp. 124-125). Potential consequences were estimated to be low. Risk estimation concluded the risks were non-negligible, New Zealand's ALOP was not satisfied and risk management measures were justified. If the same terms were applied in the Australian system, Tables 2.2 and 2.5 would result in a 'very low' risk, satisfying Australia's ALOP.

Similarly, the likelihoods of entry and establishment of fruit spotting bugs (*Amblypelta* spp.) on litchi fruit from Australia were both estimated to be very low. Potential consequences were estimated to be moderate. Risk estimation concluded the risks were non-negligible, New Zealand's ALOP was not satisfied and risk management measures were justified (Biosecurity New Zealand 2008b, pp. 54-55). If the same terms were applied in the Australian system, Tables 2.2 and 2.5 would result in a 'negligible' risk, satisfying Australia's ALOP.

It will be difficult for analysts to provide consistent assessments, and impossible for reviewers to evaluate consistency between decisions, if terms are not explicitly defined,

as is the case in New Zealand and Canadian risk assessments protocols. It would assist the transparency of biosecurity decisions if these terms were used in a standard way internationally. Countries would still have a right under the SPS Agreement to apply a level of protection appropriate for national circumstances.

The Canadian guidelines consider direct and indirect effects of pests and pathogens, consistent with IPPC and OIE guidelines, but the evaluation is structured differently to systems in Australia. The Canadian guidelines exclude indirect impacts the pest might have on potential trade, such as export significance. This issue is dealt with as a trade component of risk management. The Canadian guidelines recommend that the potential to have an effect on international or domestic trade should be highlighted but should not be included in the score. Other countries take this factor into account when assessing potential consequences, as do the applications of Canadian plant IRAs reviewed here. For example, the assessment of Phytoplasma noted '*Export markets for live trees or woody propagative material would be jeopardized by the presence of ESFYP'* (CFIA 2004, i). Canadian IRAs conclude with a discussion of the main sources of uncertainty in the analyses. For example, CFIA (2008b) notes the behavior of Swede midge on North American canola is largely unknown and that selection pressure may lead to Swede midge populations that adapt to management practices.

Biosecurity New Zealand (2006a) recommends a risk-averse approach to uncertainty. For example, the guidelines note that the outbreak of a disease or the spread of a pest occurs following a (usually) complex chain of events. There may be good information about some steps in a chain, and poor or no information about other steps. The recommendation is that '*the impact of these uncertainties on the overall estimate of risk needs to be carefully considered*'. When there is '*significant uncertainty*' in the estimated risk, '*a precautionary approach to managing risk may be adopted*' (p. 28).

As noted above, subjective, risk-averse judgements are susceptible to a range of individual, psychological and contextual biases, the levels of which will be uncontrolled. The rules for combining judgements identified above in the New Zealand system serve to reinforce the conservatism of judgements associated with individual steps. These biases will compound in analyses to generate outcomes that are hyperconservative to an unknown extent. Other countries similarly use 'conservative' estimates from time to time (see Section 6.6).

Sensitivity analysis can be used to explore the influence on the outputs of an analysis of changes in the variables in a study. Such an analysis may help to identify key variables that influence the risk estimate, investigate the consequences of likely adverse changes in the key factors of entry, establishment and spread, and identify actions that could mitigate possible adverse effects on the risk assessment.

None of the 'qualitative' reports evaluated here attempted any kind of sensitivity analysis to explore the implications of assumptions about things such as the efficacy of inspection systems, treatments, or pest prevalence, except vaguely where uncertainty is explained in relation to the available data and the identified information gaps. It is beyond the scope of this report to outline comprehensively how this may be done for the qualitative elements of these IRAs, but some the parts of such analyses may include;

- providing a range of judgements about risk levels associated with each step in the pathway for entry, establishment and spread;
- providing a range of estimates for consequences;
- evaluating and communicating the reliability of the expert judgements used in the reports; and

- exploring the implications of uncertainty for decisions about the requirements for or the kinds of mitigation measures.

If estimates are all 'central tendencies' or 'best guesses', then it is likely that at least some results of IRAs that are equivocal will appear unjustifiably certain. If judgements are a mixture of best guesses and conservative estimates, then outputs will be conservative, but the degree of conservatism will be unknown, even to those who conduct the analysis.

Currently, comprehensive and coherent treatments of uncertainty are lacking in IRAs. The convention in qualitative biosecurity risk assessments to ignore most elements of uncertainty is at odds with the aims in the IRA handbooks and guidelines to acknowledge uncertainty and incorporate it in the analysis and management decisions (e.g., ISPM 2, IPPC 2007). Ideally, estimates of likelihood and consequence under uncertainty should strive to be objective and risk neutral. Risk appetite should be expressed in the application of each country's ALOP, and not in the underlying assessments. If individual judgements are 'conservative' in the sense that they over-estimate risk, the ALOPs may be hyper-conservative and un-necessarily trade restrictive. Unfortunately, since this criticism can be leveled at any IRA that fails to address this issue, even valid and accurate assessments may be brought into disrepute.

To some extent, this general limitation may be due to lack of guidance in international standards. For example, while ISPM 2 suggests that addressing uncertainty is important, it does not specify which types of uncertainties could be important, nor does it provide examples illustrating different types of uncertainties that could arise in quantitative and qualitative models.

The exceptions to these issues were the animal IRAs developed by Biosecurity Australia (2004, 2008d). The method describes pathways of entry, establishment and spread, compartmentalises these pathways into steps that can be evaluated individually, uses a variety of sources of information to quantify the likelihood of the compartments, and combines these likelihoods in a transparent manner to obtain an overall assessment of risk.

As noted above, the chicken and pig meat IRAs (Biosecurity Australia 2004, 2008d) emphasised that 'team members' used their expert judgement to assess model output and evaluate inconsistencies between the outputs and expectations. Analysts provided explanations for inconsistencies. The conclusions represented the 'opinions' of the IRA team, 'after consideration of the output of the quantitative model and any other relevant material' (Biosecurity Australia 2008d). Standard, formal methods for quantifying the influence of subjective judgements in quantitative analyses have become available and may be useful in these circumstances (see Choy et al. 2009). Despite these caveats, the commendable features of this approach are also the source of most criticism. By its transparency, it is easier to comment on the pathways, components, treatment of information, method of quantification, choice of distributions and ranges, choice of thresholds, conversion between quantitative and qualitative scales, and interpretation of results.

This leads to two overall cautionary statements. First, it is important that the use of a (semi)quantitative approach does not give undue impression of the validity of the input information. Second, the complexity of the pathway approach and the corresponding quantification is constrained by the available information; where it is warranted, simpler pathways may lead to less uncertainty and less criticism. This review concludes that uncertainty and sensitivity analyses should be applied and documented, irrespective of the

style of the risk analysis or the degree of quantification. A summary of best practice in biosecurity risk analysis is provided below.

6.5 Peer review

Peer review is the process of critical, transparent evaluation of the factual basis and analytical rigour of an analysis by suitably qualified, independent people. The hallmark of peer review is that commentaries and critiques are reconciled and incorporated into revisions to the satisfaction of an independent 'editor'. All of the protocols and applications reviewed here make use of peer review to some extent, as recommended by ISPM 2 (IPPC 2007), although the peer review systems vary substantially between jurisdictions.

In the Canadian animal IRA guidelines (CFIA 2000), peer review is explicit. APFRAN selects the participants for peer review who may include scientific experts from the CFIA, Centres of Expertise, field epidemiologists, risk analysts, economists or biostatisticians. The comments received from the participants are incorporated into a revised risk assessment document. It is not clear, however, if all comments received are published, nor how disagreements between authors and reviewers are reconciled. The guidelines indicate that the consultative process may be curtailed due to 'trade-related time constraints'. It is not clear what this might mean in practice.

The USDA's IRA reports are reviewed by internal members of USDA and by a small group of experts from other organisations who provide an independent oversight. The names and affiliations of the reviewers are documented at the end of conclusions of the risk assessment. Biosecurity New Zealand relies heavily on review, by both internal analysts and by external (national and international) referees. It is not explicit how different opinions and criticisms are reconciled.

Biosecurity Australia has a highly structured review process. In addition to internal and external review, Biosecurity Australia uses the 'Eminent Scientists Group' to examine comment on draft 'expanded' IRAs. This group occasionally co-opts additional expertise or seeks advice from Biosecurity Australia or stakeholders. This provides an explicit mechanism for reconciling alternative opinions. All the commentaries received are published together with the revised reports.

6.6 Qualitative and quantitative risk assessments

An uncomfortable dichotomy has arisen in some biosecurity literature that implies that there are distinct 'qualitative' and 'quantitative' methods for risk analysis. In fact, all quantitative methods rely on subjective judgement to formulate models and estimate parameters. Likewise, all sound qualitative methods involve an ordering of risks and outcomes that are answerable to the fundamental rules of probability and formal logic. ACERA Project 0901 compares a range of approaches and their potential application in IRAs. In the applications of risk analysis reviewed here, a variety of quantitative and qualitative tools were employed, from subjective reasoning based on descriptions of biological systems, to point scoring systems, logical rules and Monte Carlo simulation. Thus, there is a continuum ranging from implicit to explicit formal reasoning, each element of which may be associated with tools that express inputs and results with varying degrees of numerical representation.

Biosecurity New Zealand (2006a) states that different methods of import risk assessment may be appropriate in different circumstances. The New Zealand guidelines argue that qualitative risk assessment (defined as 'a reasoned and logical discussion of the

relevant commodity factors and epidemiology of a hazard' where likelihood and consequences 'are expressed using non-numerical terms such as high, negligible or non-negligible') is suitable for the majority of risk assessments. Risk assessments that depend on non-numerical analysis are the most common type of assessment for routine IRA decision-making in all jurisdictions reviewed here. The example IRAs from Biosecurity New Zealand reviewed here avoid all numerical representations.

Biosecurity New Zealand (2006a) and the USDA (2000) note that 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.

The Canadian animal IRA guidelines (CFIA 2000) refer to quantitative risk assessment in the form of 'scenario assessment', a perspective developed by Kaplan (1981) in which analyses aim to quantify a), what can go wrong? (the 'scenarios'), b), how likely is that to happen? and c), if it does happen, what are the consequences? The damage (consequence) index may be multidimensional and include animal deaths, human and wildlife infection, environmental contamination and so on. Like the New Zealand protocols, the Canadian protocols argue that risk assessment methods should be flexible and that no single method is applicable in all cases. Unfortunately, no example applications were available.

Biosecurity New Zealand (2006a) objects to risk assessment approaches they class as 'semi-quantitative'. They note a common approach to combining various qualitative estimates is to assign numbers to them (in the form of probability ranges or scores), to produce a summary measure. Systems like this are employed by Australia, Canada and the US, in a variety of forms. Biosecurity New Zealand (2006a) is uncomfortable with this approach because numbers, ranges, weights and methods of combination are usually arbitrary and lack transparency. Biosecurity New Zealand claims that semi-quantitative assessments often give a misleading impression of objectivity and precision and that assigning numbers to subjective estimates does not result in a more objective assessment, '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.' (Biosecurity New Zealand 2006a, p. 27).

In contrast, Aven and Renn (2009) suggest that when data about occurrences are lacking, larger deviations arise among experts' subjective probability assignments and participants become more convinced that many unlikely causes could lead to the undesired result. In their opinion, this creates an imperative for including and characterizing uncertainty in the risk assessment process using tools other than subjective, qualitative assessment. They recommend semi-quantitative methods that include construction of case scenarios, analogies from other related fields, brainstorming and/or Delphi-type exercises.

Both these views on the reliability and utility of 'semi-quantitative' risk assessments compared to qualitative systems are presented without empirical or theoretical support. That is, neither opinion is supported by data or theory. Our view is that strident opinions regarding types of risk analysis create false methodological dichotomies. Most risk assessment methods involve a mixture of qualitative and

quantitative methods because generally it is not possible to quantify all sources of variability and uncertainty. An appropriate choice of tools will be determined by the decision context, data, skills, and time frames. As noted above, even protocols that rely entirely on linguistic representations of probability and consequence are answerable to the rules of arithmetic, probability and logic. Perhaps the most important general point to emerge from the reviews above is that all risk assessments should include a systematic consideration of both quantified and unquantified sources of variability and uncertainty to evaluate how they might affect the assessment outcome. It is beyond the scope of this report to outline exactly how this might be achieved in every circumstance. However, our experience is that the choice of any risk assessment tool does not preclude a thorough and transparent treatment of uncertainty and variability. Biosecurity risk assessments that omit them are incomplete.

6.7 Time and volume of trade

If other conditions remain the same, the overall likelihood of entry increases as time passes and the volume of trade increases. Most of the risk assessment guidelines reviewed here make reference to consideration of time and/or volume of trade, but none give specific guidance on how these considerations should be accommodated in biosecurity risk assessments. Ideally, time and volume should be treated explicitly.

The Canadian plant IRA guidelines do not make specific reference to volume or time. However, when estimating likelihood of entry, the Canadian protocol (CFIA 2007) recommends that analysts consider the 'frequency of shipments', and that 'low commodity volume' contributes to an assessment of low likelihood of entry. The Canadian animal IRA guidelines include volume, quantity, frequency and time-frames of commodity or activity among the factors 'considered' during risk initiation. The principles of risk assessment articulated in the animal IRA guidelines note that '*Generally the risk estimates increase with increasing volume or quantity of commodity imported*' (CFIA 2000, p. 33).

The time frame over which likelihoods of entry, establishment and spread are considered by Biosecurity New Zealand is not precisely specified in the guidelines or the individual applications. It is not clear if the volumes of trade are considered for a year, for a season of trade, or if they are considered at all, when computing risks.

USDA (2000) assesses the probability of entry and establishment based on the quantity of a commodity imported annually. The categorisation is coarse, namely,

- Low (1 point): < 10 containers/year
- Medium (2 points): 10 - 100 containers/year
- High (3 points): > 100 containers/year

Biosecurity Australia also considers the likelihood of introduction on the basis of the estimated volume of one year's trade. They reason that this value is relatively easy to estimate and allows for expert consideration of seasonal variations in pest presence, incidence and behavior, but not so long as to incorporate inaccuracies that may be associated with changes in diseases, animal factors and trade (Biosecurity Australia 2008c, p. 97).

Biosecurity Australia (2008c) argued that without a quantitative framework, it would be difficult to demonstrate 'transparently or consistently' the effect of projected volumes of trade on biosecurity risks. In contrast, Biosecurity Australia (2006a) claimed that the consideration of the likelihood of introduction and consequences takes into account events that might happen over a number of years even though only one year's

volume of trade is considered. The Handbook states that policy decisions based on the estimated volume of one year's trade '*are consistent with Australia's policy on appropriate level of protection and meet the Australian Government's requirement for ongoing quarantine protection*'. Thus, the period of trade for which the risk is acceptable is unspecified, but, as noted above, it is longer than a year. It's not clear in the Handbook or the individual IRAs how this scaling was achieved. An explanation of how longer time horizons were considered in the scaling of the risk matrix would make the system more transparent.

All of the jurisdictions reviewed here could estimate risk based on the volume of trade expected in a year. For longer time periods, it would seem straight forward to assume trade will remain unchanged, and to estimate consequences over the period using some function of net present value, using a standard discount rate (Waage and Mumford 2009). 'Risk-return' (Beale et al. 2008) or benefit/cost decisions could be better supported by specifying the expected time to establishment of the pest of disease. The notion of expected time between incursions was noted under 'Approaches to ALOP' above, but can only be evaluated if likelihoods are computed numerically, or are tied to explicit numerical intervals. Because of these issues, this review concludes that there are sound reasons for linking language-based likelihood estimates to quantitative values, and for stating explicitly the period over which risk are evaluated. This topic is explored in the following section.

6.8 Defining and estimating likelihood

The USDA (2000) and Biosecurity Australia link the words used to describe probabilities with numerical intervals (Tables 2.2 and 4.2). Both protocols emphasise that the intervals are a 'guide' to assist qualitative judgements.

The individual risk estimates for each step in the Australian protocols are combined using the logical matrices provided in the Tables in Section 2 above. These rules are generally consistent with probability arithmetic. However, there are some discrepancies. For example, if entry is rated as 'very low' = [0.05, 0.3], and establishment is rated as 'very low' = [0.05, 0.3], then the interval product for the combined likelihood is [0.0025, 0.09], partly overlapping the interval for 'very low'. The rules for combining the likelihood in Table 2.3 give an outcome of 'extremely low'. However, the overlap suggests that two categories, 'very low' and 'extremely low', are consistent with the data. The results should be presented as a range of categories, to preserve this uncertainty. The range could be carried through the chain of reasoning and presented to a decision maker, forming an important element in the ultimate decision.

The quantitative analyses for animal IRAs (Biosecurity Australia 2004, 2008d) noted that many of the simulation output distributions resembled strongly skewed (lognormal) distributions. These analyses used the median to represent risk because '*the median value ... provides a true reflection of the likelihood model from which the output distribution is derived*'. These analyses ignored the more extreme percentiles of the output distribution (e.g. the 95th or 99th percentile) because they '*should not be equated with commonly reported confidence limits. Rather, they represent the tails of the probability distribution, and can be considered to be somewhat arbitrary outliers. It would not be appropriate to cite such outliers as the outputs of a likelihood model*'. Other applications of quantitative risk analysis consider the tails of these distributions to be among the most important and potentially useful products of the analysis (Burgman

2005), because they represent the relatively high consequence, low probability outcomes that form the primary focus of most risk analyses.

Biosecurity New Zealand is less transparent in its use of language, using words associated with probability to convey meaning about the relative risks in assessments. However, the guidelines provide no link to explicit numerical intervals (Table 6.6). It is noteworthy that the terms employed by Biosecurity New Zealand (Table 6.1) are not ordered numerically. The ordering is not self-evident. For example, consider the terms 'insignificant', 'remote' and 'negligible'. The latter of these terms has statutory importance because its use defines New Zealand's ALOP. It is not clear which of these terms is larger than the others.

Table 6.6. Biosecurity New Zealand's (2006a) 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

The Canadian protocol adds scores for establishment and spread to scores for economic and environmental impact. As noted above, adding scores for terms that represent independent probabilities may lead to counter-intuitive or perverse results. For example, a pest with no chance of spreading could score 9 (high). This aspect of the system is discussed further below. The Canadian matrix for combining likelihoods and consequences of entry is equivalent to the Australian risk estimation matrix. However, the definitions of probability are different in the two jurisdictions. The Canadian terminology describing the rating scales is close to the descriptions used by New Zealand.

In the US applications, the steps in the entry and establishment pathway are estimated as independent probabilities. The guidelines stipulate '*The events … should be considered as a series of independent events that must all take place before a pest outbreak can occur, i.e., the estimates for one element should not affect estimates for other elements*' (USDA 2000, p. 10). In most formal treatments of probability, the joint probability of several independent steps is calculated from the product of their probabilities. The sense of doing this is illustrated by the fact that if one of the steps has zero probability, then the overall outcome should also have a probability of zero.

The US and Canadian systems rely on additive point systems. Some potential problems of point-scoring systems include the fact that the factors have different units of measurement, so direct addition is not feasible. To avoid this issue, the values are translated into unitless scores, but this translation depends on ensuring the scales are equivalent (that a score of 3 for one factor means the same thing as a score of 3 on another) (MacLeod and Baker, 2003). In addition, the final (unitless) score is difficult to compare between risk assessments and between jurisdictions because they mean different

things to different people. This makes it difficult to assess objectively the consistency of risk assessments. Lastly, despite the characterisation of the steps as (qualitative) probabilities and the suggestion that they should be thought of as independent, the scores for each step are added. Thus, an analyst could estimate survival during shipment to be (virtually) zero, yet the likelihood of entry might be rated as high. These and related issues are not discussed in the relevant guidelines.

The Canadian system does not seem to adhere to the rules of probability or to the ISPM definition of risk (Risk= Likelihood of Introduction and consequences; IPPC 2007). In the Canadian protocol, risk is defined as likelihood of introduction and consequences of introduction (CFIA, 2007a). The consequence of introduction is defined as 'Establishment potential + Spread potential + Environmental impacts + Economic impacts'. Adding scores for probability of establishment and spread to scores for impact makes this system inconsistent with the systems employed by the other three countries (Australia, New Zealand and USA).

This review concludes that the systems for assessing and combining likelihoods should be consistent with the rules of probability. The international guidelines supported by the IPPC and the OIE should provide simple frameworks for the development of risk assessment systems that avoid the worst pitfalls.

6.9 Estimating consequences

In all the protocols examined here, estimates of consequences are essentially unbounded in the sense that consequences are estimated as the loss of net present value at the point at which the pest or disease is fully established and spread, irrespective of how long it might take for the organism to spread. No jurisdictions attempt to discount consequences over time. This perspective is implied by recommendations for outputs of risk estimation in the Canadian animal IRA guidelines (CFIA 2000) that specify '*estimated numbers of herds, flocks, animals or people experiencing health impacts of various severities over time*' (p. 32). While it is consistent with the provisions of the SPS Agreement, the use of open-ended time frames for the evaluation of consequences is a kind of worst-case assumption. It could be made more concrete through the use of specific time horizons, estimates for rates of spread and economic models to discount impacts (Waage and Mumford 2009).

As noted above, protocols in all countries for estimating consequence consider separate criteria that deal with environmental, economic and social impacts. Also as noted above, Beale *et al.* (2008) were critical of the fact that Australian protocols do not use formal economic tools, and that consequence assessments were not clear about an appropriate impact measure such as the absolute net value of production at risk (in fact, no country deals with these issues adequately). This review of guidelines and examples has highlighted that formal economic, social and environmental impact assessment tools are rarely if ever employed in any jurisdiction.

In Australia, the evaluations are weighted by the maximum level of consequence for any of the criteria (i.e. the maximum severity of the individual criteria), and by the spatial extent of the impact (local, regional or national). The acceptability of impact on each criterion is judged independently. This structure is a simple means of reconciling different kinds of values. It avoids the need to weight criteria or to combine different measures of impact. All other jurisdictions arrive at a subjective judgement regarding the seriousness of impacts, following a qualitative description of their extent and severity, without specifying whether or how the criteria are combined or assessed against each other.

The Canadian guidelines note that the underlying assumptions behind the rating system for combining consequence factors (establishment, spread, economic and environmental impact) are that all four factors 'are equally important for all pests, thus allowing comparisons between pests'. This confounds biological 'means' (establishment and spread) with economic and environmental 'ends'. Furthermore, the application of differential weights would not preclude comparisons between pests.

As noted above, the SPS Agreement stipulates that measures should be least trade restrictive. The evaluations in all of the IRAs reviewed here were subjective and qualitative. The deployment of explicit tools for estimating consequences for social, economic and environmental could play an important role in the assessment of alternative treatments and biosecurity measures. The detailed examination of these topics is beyond the scope of this report.

There is no easy way to evaluate the reliability of impact estimates in any of the systems, or how the different social, economic and environmental factors were weighed in reaching a conclusion about the seriousness of potential consequences. The treatment of consequences is perhaps the least convincing aspect of IRAs internationally.

6.10 Conclusions

The results of this review suggest a broad framework for IRAs. It is beyond the scope of this report to outline a complete system in full detail, but it should have the following properties:

1. Biosecurity risk assessments should distinguish between sources of natural variability and incertitude. Recognition of their separate contributions will allow critical appraisal and planning for future work to focus on areas in which additional knowledge will reduce uncertainty and improve the effectiveness of additional measures and trade restrictions. It would improve biosecurity risk assessment generally to consider approaches that would encompass a more complete treatment of uncertainty and provide for a range of results.
2. Assessments should not be tied automatically to a particular style of analysis. A qualitative structure such as those applied in New Zealand, or to animals in the USA and Canada, could be enhanced by quantitative tools that support individual steps in the analysis, where data or the structure of the problem warrants it. More generally, opportunities exist to deploy tools such as interval arithmetic, fuzzy numbers, imprecise probabilities and Bayes nets to deal with the mixture of subjective judgement and data that characterize typical biosecurity decisions. These methods offer the potential to deal consistently with a variety of kinds of uncertainty, so that information on uncertainty is retained in the analysis and can assist in decision making. As yet there is little guidance on how these different approaches might perform in biosecurity risk assessments; although it is worth noting that none of these tools require data beyond those encountered in the risk assessments reviewed here.
3. Consideration of a broader range of risk assessment tools would, however, require differently structured reports, different approaches to gathering and interpreting data, and different approaches to drawing inferences about ALOP, all of which may have important consequences for international policy and biosecurity standards.
4. Analyses should provide clear specification of how time and volume of trade are accommodated.

5. All of the methods employ expert judgement to estimate likelihoods and consequences, and to reach a final decision on ALOP. The guidelines should recommend methods for eliciting judgements from experts, reconciling disagreements among experts, combining opinions from different experts, providing feedback to experts on their performance, carrying the uncertainties through chains of reasoning and presenting them transparently to decision makers.
6. The guidelines should take care to define as precisely as possible the terms used to express likelihood, so that the consistency of assessments can be critically evaluated.
7. The rules for combining likelihoods should be consistent with the rules of probability.
8. The guidelines should recommend formal, transparent economic, social and environmental impact assessment tools.
9. Measures of impact should take care to define the measure of impact and to discount time-dependent outcomes.
10. The guidelines should recommend methods for estimating the potential spatial extent of impact and the severity of the impact within the area occupied, suitable for the kinds of data routinely available in biosecurity risk assessments.
11. The guidelines should recommend and provide examples of how to present uncertainties in outcomes, together with best estimates.
12. Sensitivity analyses should be routine elements of risk assessments, for both the qualitative and quantitative elements of assessments
13. Analyses should be based on best estimates, together with appropriately defined and managed uncertainties. Analysts should avoid making 'conservative', precautionary or risk-averse judgements in the midst of an analysis.
14. The 'attitude' to uncertainty of the importing country could be expressed by its interpretation of the bounds on likelihood and consequence, relative to its ALOP.
15. Decisions about commodities or pathways should take into account the cumulative likelihoods and consequences of multiple species.

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