Guidelines for Import Risk Analysis

Draft September 2001

AGRICULTURE, FISHERIES AND FORESTRY - AUSTRALIA

Guidelines for Import Risk Analysis

Draft September 2001

Disclaimer

Biosecurity Australia has released this draft of the *Guidelines of Import Risk Analysis* for external comment and critique.

The document should not be divided, duplicated or cited without the permission of Biosecurity Australia.

All comments and requests for electronic or paper copies of the document should be directed to:

Dr David Wilson
General Manager
Ph: +61 02 6272 3619
David.Wilson@affa.gov.au

Dr Sam Beckett
Senior Veterinary Officer
Ph: +61 02 6272 3270
Sam.Beckett@affa.gov.au

Biosecurity Development and Evaluation
Biosecurity Australia
GPO Box 898, Canberra
ACT, 2601
AUSTRALIA

ISBN [Insert ISBN number]

CONTENTS

LIST OF TABLES

LIST OF FIGURES

GLOSSARY OF TERMS AND ABBREVIATIONS

ALOP	Appropriate level of protection
AQIS	Australian Quarantine and Inspection Service
AQRC	Australian Quarantine Review Committee
AUSVETPLAN	Australian Veterinary Emergency Plan
CSIRO	Commonwealth Scientific and Industrial Research Organisation
EA	Environment Australia
GATT	General Agreement on Tariffs and Trade
IPPC	International Plant Protection Convention
IRA	Import risk analysis
ISPM	International Standards for Phytosanitary Measures
OIE	Office International des Epizooties
OIE Aquatic Code	OIE International Aquatic Animal Health Code
OIE Code	OIE International Animal Health Code
PDI	Pest and disease information database
PRA	Pest risk analysis
RAP	Risk analysis panel
SPS	Sanitary and phytosanitary
SPS Agreement	WTO Agreement on the Application of Sanitary and Phytosanitary Measures
WTO	World Trade Organization

IMPORT RISK ANALYSIS

In these guidelines (the *Guidelines*), import risk analysis is the term used to cover the identification, assessment and management of risks associated with the importation of animals and animal-derived products, and plants and plant-derived products.

In this context, import risk refers to:

- the likelihood of a pest or disease entering, establishing or spreading in Australia
- the likelihood that harm will result to animal, plant and human life or health, and the environment
- the likely extent of that harm.

BACKGROUND

In 1996, the Australian Quarantine Review Committee (AQRC), chaired by Professor Malcolm Nairn, undertook an independent review of Australian animal and plant quarantine programs and made recommendations on the process of carrying out import risk analyses. The Government's response noted that '*... risk analysis is the foundation stone on which all quarantine policy and action must be built ...*', and agreed with the Review Committee's six principles that should apply to import risk analysis.

The Committee recommended that import risk analysis should be:

- conducted in a consultative framework
- a scientific process and therefore politically independent
- a transparent and open process
- consistent with both government policy and Australia's international obligations (under the World Trade Organization [WTO] Agreement on the Application of Sanitary and Phytosanitary Measures, or *SPS Agreement*)
- harmonised, through taking account of international standards, guidelines and recommendations
- subject to appeal on process.

The publication in 1998 of the *Handbook* on the *Import Risk Analysis Process* responded to recommendations of AQRC, and of other committees, that a more formal and consultative import risk analysis process should be developed. The *Handbook*[1] describes the administrative process Biosecurity Australia follows when conducting an import risk analysis. Experience since then has indicated that improvements could be made to the process and, in conjunction with the Quarantine and Exports Advisory Council (QEAC) and in consultation with stakeholders, AFFA has reviewed the process. A new edition of the *Handbook* (with an amended title to better reflect the content) will be published in late 2002.

[1] Available at http://www.aqis.gov.au/

The administrative framework is designed to ensure that the Government's biosecurity objectives are met, in that:

- there is a sound scientific basis for biosecurity policies
- importation is only permitted when the risks posed can be managed in a manner consistent with Australia's highly conservative approach to pest and disease risk
- stakeholders have had reasonable opportunities to contribute to the outcomes of the import risk analysis
- stakeholders are aware of the reasons for new or revised policies.

PURPOSE OF THESE GUIDELINES

The technical process of import risk analysis is carried out within the administrative framework described in the *Handbook*.

These *Guidelines* provide guidance on the different types of import risk analysis methods used by Biosecurity Australia. The *Guidelines* describe a structured approach to import risk analysis that is consistent with Australian government policy, the *Quarantine Act (1908)* and subordinate legislation, the requirements of the *SPS Agreement* and with the standards for import risk analysis developed by the Office International des Epizooties (OIE) and under the International Plant Protection Convention (IPPC).

The chapter on import risk analysis in the *OIE International Animal Health Code* (*OIE Code*) has been extensively revised to reflect recent changes in this field of veterinary epidemiology. The corresponding chapter in the *OIE International Aquatic Animal Health Code* (*OIE Aquatic Code*) is modelled on the *OIE Code*. For this reason, the *OIE Code* has been adopted in these *Guidelines* as the relevant standard for both terrestrial and aquatic animals, and their products.

The second IPPC International Standard for Phytosanitary Measures (*ISPM2: Guidelines for Pest Risk Analysis*) has been adapted to apply specifically to 'quarantine pests' (cf. 'regulated pests'). This text is available in a new and currently unnumbered ISPM titled *Pest Risk Analysis for Quarantine Pests*. The approach to import risk analysis recommended in *Pest Risk Analysis for Quarantine Pests* is similar to that which is described in the *OIE Code*. In these *Guidelines*, the unnumbered ISPM *Pest Risk Analysis for Quarantine Pests* was adopted as the relevant standard for plant import risk analyses for quarantine pests.

DOCUMENT TEMPLATES FOR IMPORT RISK ANALYSIS

These *Guidelines* refer to 'document templates' for the various reports that will be required when communicating the methods and results of import risk analyses. Document templates are fully formatted electronic files that contain both generic text (text that applies to most Biosecurity Australia reports) and instructions for new material that should be inserted by the risk analyst. The document templates should provide an efficient and consistent means by which Biosecurity Australia animal and plant import risk analyses may be carried out and reported.

There are three document templates for carrying out and reporting animal or plant import risk analyses — the *Technical Issues Paper*, the *Draft/Final IRA Report* and the *Summary Document*.

- *Technical Issues Paper*. This template provides the structure and generic text required for the *Technical Issues Paper*. In brief, the paper contains:

- preliminary text regarding Australia's domestic biosecurity policy and international obligations
- an overview of the method for import risk analysis and a more detailed description of the approach to hazard identification (animals and their products) or pest categorisation (plants and their products)
- a discussion of issues relevant to the commodity for which access has been requested.

- *Draft/Final IRA Report*. This template provides the structure and generic text required for both the *Draft IRA Report* and *Final IRA report*. The structure of this document is similar to that of the *Technical Issues Paper*, but it also contains:
  - a more detailed description of import risk analysis methodology
  - the results of each risk assessment
  - a discussion (where appropriate) of risk management.
- *Summary Document*. This template provides the structure and generic text required for an outline of the scope of the import risk analysis, the background issues and a summary of the technical content of the associated *IRA Report*. The *Summary Document* may be distributed to stakeholders in place of a full report, with the latter made available on request or as a download from the AFFA Internet site. This system is intended to minimise the volume of material distributed to stakeholders, without reducing Biosecurity Australia's commitment to enhanced stakeholder consultation.

Each of these document templates is designed to provide the framework and generic text for a 'stand-alone' document. Text that is the same in different documents either is written into the templates, or can be copied and pasted between them. This approach is intended to ensure that the template system remains efficient and easy for import risk analysis teams to manage.

Each of these document templates has also been customised to be applicable to either 'generic' (or global) import risk analyses, or for import risk analyses based on commodity sourced from a particular country or group of countries. The document templates are available on the AFFA intranet to Biosecurity Australia personnel (J:\BDE\IRA Guidelines and Document Templates). Those outside Biosecurity Australia may obtain copies of the document templates from Dr David Wilson (General Manager – Biosecurity Development and Evaluation, Biosecurity Australia, David.Wilson@affa.gov.au).

AUSTRALIA'S BIOSECURITY POLICY

Legislative framework

AFFA's objective is to adopt biosecurity policies that provide the health safeguards required by government policy in the least trade-restrictive way and that are, where appropriate, based on international standards. In developing and reviewing quarantine (or biosecurity) policies, disease risks associated with importations may be analysed using import risk analysis — a structured, transparent and science-based process.

The *Quarantine Act* and its subordinate legislation, including the *Quarantine Proclamation 1998* (QP 1998), are the legislative basis of human, animal and plant biosecurity in Australia. The *Quarantine Amendment Act 1999*, which commenced in June/July 2000, incorporates major changes to the *Quarantine Act* as recommended in the report of the AQRC.

Section 4 of the *Quarantine Act* defines the scope of quarantine as follows.

In this Act, quarantine includes, but is not limited to, measures:

- *for, or in relation to, the examination, exclusion, detention, observation, segregation, isolation, protection, treatment and regulation of vessels, installations, human beings, animals, plants or other goods or things*
- *having as their object the prevention or control of the introduction, establishment or spread of diseases or pests that will or could cause significant damage to human beings, animals, plants, other aspects of the environment or economic activities.*

Quarantine Risk

The concept of level of quarantine (or biosecurity) risk has been introduced as the basis of quarantine decision-making. When making decisions under the *Quarantine Act*, decision-makers must consider the level of quarantine risk and must take prescribed actions to manage the risk if it is unacceptably high. For example, Section 44C concerns the examination of goods on importation and requires quarantine officers to order goods into quarantine if they decide the level of quarantine risk is unacceptably high. Section 46A concerns approvals for goods ordered into quarantine, and requires consideration of the level of quarantine risk with regard to matters such as the proposed procedures and the construction and management of biosecurity premises. Section 5D of the *Quarantine Act* includes harm to the environment as a component of the level of quarantine risk.

Section 5D: level of quarantine risk

A reference in this Act to a level of quarantine risk is a reference to:

(a) the probability of:

(i) a disease or pest being introduced, established or spread in Australia or the Cocos Islands; and

(ii) the disease or pest causing harm to human beings, animals, plants, other aspects of the environment, or economic activities; and

(b) the probable extent of the harm.

Quarantine Proclamation

Subsection 13(1) of the *Quarantine Act* provides that the Governor-General in Executive Council may, by proclamation, prohibit the importation into Australia of any articles or things likely to introduce, establish or spread any disease or pest affecting people, animals or plants. The Governor-General may apply this power of prohibition generally or subject to any specified conditions or restrictions.

QP 1998 is the principal legal instrument used to control the importation into Australia of goods of quarantine (or biosecurity) interest. A wide range of goods is specified in *QP 1998* including animals, plants, animal and plant products, micro-organisms, and certain other goods which carry a high risk if uncontrolled importation is allowed — e.g. soil, water, vaccines, feeds.

For articles or things prohibited by proclamation, the Director of Animal and Plant Quarantine may permit entry of products on an unrestricted basis or subject to compliance with conditions, which are normally specified on a permit. An import risk analysis provides the scientific and technical

basis for biosecurity policies that determine whether an import may be permitted and, if so, the conditions to be applied.

The matters to be considered when deciding whether to issue a permit are set out in Section 70 of *QP 1998* as follows:

70 Things a Director of Quarantine must take into account when deciding whether to grant a permit for importation into Australia

(1) In deciding whether to grant a permit to import a thing into Australia or the Cocos Islands, or for the removal of a thing from the Protected Zone or the Torres Strait Special Quarantine Zone to the rest of Australia, a Director of Quarantine:

(a) must consider the level of quarantine risk if the permit were granted; and

(b) must consider whether, if the permit were granted, the imposition of conditions on it would be necessary to limit the level of quarantine risk to one that is acceptably low; and

(c) may take into account anything else that he or she knows that is relevant.

The matters include the level of quarantine risk (see above), whether the imposition of conditions would be necessary to limit the quarantine risk to a level that would be acceptably low, and anything else known to the decision maker to be relevant.

Environment

While protection of the natural and built environment has always been an objective of Australian quarantine policy and practice, recent amendments to the *Quarantine Act 1908* make explicit the responsibility of quarantine officers to consider impact on the environment when making decisions. In particular, the scope of quarantine (as described in Section 4 of the *Quarantine Act*), and the level of quarantine risk (as described in Section 5D of the *Quarantine Act*), include explicit reference to the environment.

Environment is defined in Section 5 of the *Quarantine Act* as:

> *... all aspects of the surroundings of human beings, whether natural surroundings or surroundings created by human beings themselves, and whether affecting them as individuals or in social groupings.*

When undertaking an import risk analysis, Biosecurity Australia fully takes into account the risk of harm to the environment to ensure that the biosecurity policies developed reflect the Australian Government's approach to risk management. This is achieved through the involvement of Environment Australia in decisions on the import risk analysis work program and, for particular import risk analyses, discussions on the scope, the likely risks, and the expertise which may be required to address those risks. Environment Australia may identify additional technical issues that it believes should be considered during an import risk analysis, and may nominate officers with relevant expertise who would be available to participate in the import risk analysis — as a member of the import risk analysis team or on a TWG.

These Guidelines address this responsibility to protection of the environment in detail, particularly in the discussion on consequence assessment.

Policy framework

The primary purpose of biosecurity is to protect Australia from the entry, establishment and spread of unwanted pests and diseases that may cause social, economic or environmental damage, while minimising the restrictions on the entry of agricultural commodities.

Due to Australia's unique and diverse fora and fauna and the value of its agricultural industries, successive Australian Governments have maintained a highly conservative but not a zero-risk approach to the management of biosecurity risks. This approach is evident in the strictness of all biosecurity-related activities, including policies on imported commodities, procedures at the border and operations against incursions of pests and diseases.

Recent inquiries into Australia's biosecurity regime have recognised that it is impossible in practice to operate a zero-risk biosecurity regime. In 1979, the Senate Standing Committee on Natural Resources stressed that there is no such thing as a zero-risk quarantine policy, and it believed that Australia's approach should be better described as '*scientific evaluation of acceptable risk*'. In 1988, the Lindsay review of Australian quarantine concluded that '*a no risk policy is untenable and undesirable and should be formally rejected*'. In 1996, the Senate Rural and Regional Affairs and Transport Committee was of the view that a zero-risk approach was unrealistic and untenable, and that its currency only demonstrated that the concepts of risk assessment and risk management were widely misunderstood. These themes were repeated in the AQRC report. In its 1997 response to that report, the Government confirmed a managed risk approach.

Import risk analysis provides the basis for considering import applications for the importation of animals and animal-derived products, and plants and plant-derived products. In keeping with the scope of the *Quarantine Act* and Australia's international obligations, only factors relevant to the evaluation of quarantine risk (i.e. the risk associated with the entry, establishment and spread of unwanted pests and diseases) are considered in the import risk analysis. The potential competitive economic impact of prospective imports is not within the scope of the import risk analysis process, and any discussion on industry support mechanisms would need to remain quite separate from the import risk analysis.

WTO AND IMPORT RISK ANALYSIS

One of the principal objectives in developing the administrative framework outlined in these *Guidelines* was to ensure that it complied with Australia's international rights and obligations.

These derive principally from the *SPS Agreement*, although other WTO Agreements (including the *Agreement on Technical Barriers to Trade* - the TBT Agreement) may be relevant in certain circumstances. Specific international guidelines on risk analysis developed under IPPC and by OIE are also relevant.

The *SPS Agreement* applies to measures designed to protect human, animal and plant life and health from pests and diseases, or a country from pests, and which may directly or indirectly affect international trade. It also recognises the right of WTO Member countries to determine the level of protection they deem appropriate and to take the necessary measures to achieve that protection. Sanitary (human and animal health) and phytosanitary (plant health) measures apply to trade in or movement of animal and plant based products within or between countries.

In the *SPS Agreement*, SPS measures are defined as any measures applied:

- *to protect animal or plant life or health within the territory of the Member from risks arising from the entry, establishment or spread of pests, diseases, disease-carrying organisms or disease-causing organisms*
- *to protect human or animal life or health within the territory of the Member from risks arising from additives, contaminants, toxins or disease-causing organisms in foods, beverages or feedstuffs*
- *to protect human life or health within the territory of the Member from risks arising from diseases carried by animals, plants or products thereof, or from the entry, establishment or spread of pests*
- *to prevent or limit other damage within the territory of the Member from the entry, establishment or spread of pests*.

The key provisions of the *SPS Agreement* are as follows:

- An importing country has the sovereign right to adopt measures to achieve the level of protection it deems appropriate (its appropriate level of protection, or ALOP) to protect human or animal life or health within its territory, but such a level of protection must be consistently applied in different situations.
- An SPS measure must be based on scientific principles and not be maintained without sufficient evidence.
- In applying SPS measures, an importing country must avoid arbitrary or unjustifiable distinctions in levels of protection, if such distinctions result in discrimination or a disguised restriction on international trade.
- An SPS measure must not be more trade restrictive than necessary to achieve an importing country's ALOP, taking into account technical and economic feasibility.
- An SPS measure should be based on an international standard, guideline or recommendation, where these exist, except to the extent that there is scientific justification for a more stringent measure which is necessary to achieve an importing country's ALOP.
- An SPS measure conforming to an international standard, guideline or recommendation is presumed to be necessary protect human, animal or plant life or health, and to be consistent with the *SPS Agreement*.
- Where an international standard, guideline or recommendation does not exist or where, in order to meet an importing country's ALOP, a measure needs to provide a higher level of protection than accorded by the relevant international standard, such a measure must be based on a risk assessment; the risk assessment must take into account available scientific evidence and relevant economic factors.
- When there is insufficient scientific evidence to complete a risk assessment, an importing country may adopt a provisional measure(s) by taking into account available pertinent information; additional information must be sought to allow a more objective assessment and the measure(s) reviewed within a reasonable period.
- An importing country must recognise the measures of other countries as equivalent, if it is objectively demonstrated that the measures meet the importing country's ALOP.

The rights and obligations in the *SPS Agreement* must be read as a whole. The articles must be interpreted in relation to each other. That is, the articles do not stand alone.

In many instances, the biosecurity policies Biosecurity Australia develops are based on the relevant international standards, guidelines and recommendations. In certain instances and in conformity with rights under the *SPS Agreement*, Australia has not adopted such international norms because

to do so would result in an unacceptably high level of risk of disease or pest entry and establishment. Instead, the policies are based on a risk analysis.

The text of the *SPS Agreement* can be found at the WTO Internet site.[2]

The following issues are discussed in greater detail:

- notification obligations
- use of international standards
- equivalence
- risk assessment
- ALOP
- consistency in risk management.

Notification obligations

The WTO SPS Committee has been established to oversee the implementation of the *SPS Agreement*, and to provide a forum for the discussion of any trade issues related to biosecurity policies. Like other WTO committees, all WTO Members have the right to participate in the work and decision making of the SPS Committee; decisions are taken by consensus. The SPS Committee has accepted, as observers, the Codex Alimentarius Commission (Codex), OIE and IPPC, as well as other international and regional intergovernmental organisations with activities in food safety, animal health and plant protection to maximise knowledge of and participation in its work.

The SPS Committee normally meets three times a year at the WTO headquarters in Geneva, Switzerland.

In addition to considering any specific trade concerns raised by governments, the *SPS Agreement* has set specific tasks for the Committee. One of these is to monitor the extent to which governments are using internationally developed standards as the basis for their requirements for imported products. Countries identify cases where the non-use, or non-existence, of an appropriate international standard is causing difficulties for international trade. After consideration by the SPS Committee, these concerns may be brought to the attention of the relevant standard-setting organisations.

Under the *SPS Agreement*, Members are required to notify WTO of new sanitary or phytosanitary regulations or modifications to existing regulations that are not substantially the same as the content of an international standard and that may have a significant effect on international trade. Australia notifies new measures and comments on draft policies proposed by other countries through the SPS Notification Point in AFFA.

International reference organisations and standards

The *SPS Agreement* has conferred new responsibilities on three international organisations by requiring WTO Members to harmonise their sanitary and phytosanitary measures on the standards, guidelines and recommendations produced by those organisations unless there is scientific justification for a more stringent measure.

The three international organisations are referenced in Annex A of the *SPS Agreement* as follows:

[2] Available at http://www.wto.org/english/docs_e/docs_e.htm

- *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*
- *for animal health and zoonoses, the standards, guidelines and recommendations developed under the auspices of the International Office of Epizootics*
- *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*

Office International des Epizooties

OIE, the world organisation for animal health, is an inter-governmental organisation created by the International Agreement of 25 January 1924, signed by 28 countries.

The objectives of OIE, laid out in 1924, continue to be valid:

- to keep member countries informed of the occurrence and course of significant animal diseases throughout the world, and of means of controlling these diseases
- to coordinate, at the international level, studies devoted to the surveillance and control of significant animal diseases
- to harmonise health standards covering trade in animals and animal products.

OIE currently comprises 155 member countries and operates under the authority of an International Committee formed by permanent delegates designated by the governments of all member countries.

The standards referenced in the *SPS Agreement* include the following OIE Codes and Manuals:

- the *OIE International Animal Health Code*, prepared by the International Animal Health Code Commission, contains standards, guidelines and recommendations designed to prevent the introduction of pests and diseases into the importing country during trade in animals, animal genetic material and animal products
- the *Manual of Standards for Diagnostic Tests and Vaccines*, prepared by the Standards Commission, lists laboratory diagnostic techniques and requirements for production and control of biological products (mainly vaccines)
- an *Aquatic Animal Health Code* and a *Diagnostic Manual for Aquatic Animal Diseases*, prepared by the Fish Diseases Commission. These are sister publications to the OIE Code and Manual above.

OIE has developed guidelines for risk analysis which recognise that the importation of animals and animal products may involve a degree of risk to the importing country. OIE supports risk analysis because it provides importing countries with an objective method of assessing risks associated with importation and of determining how those risks may be managed. It notes that analysis should be transparent so that the exporting country is provided with a clear and documented decision on the measures imposed on imports or the reasons for refusing to allow importation.

International Plant Protection Convention

IPPC is a multilateral treaty deposited with the Director-General of the Food and Agriculture Organization of the United Nations. IPPC provides a framework and forum for international

cooperation, standards harmonisation and information exchange on plant health in collaboration with regional and national plant protection organisations (RPPOs and NPPOs). Its prime purpose is to help prevent the spread and introduction of pests of plants and plant products and to promote measures for their control.

Currently, 111 governments are contracting parties to IPPC.

The New Revised Text of IPPC provides for the establishment of a Commission on Phytosanitary Measures to serve as IPPC's new governing body. Membership in the Commission is open to all contracting parties of IPPC. The Commission meets annually to establish priorities for standard-setting and harmonisation of phytosanitary measures in coordination with the IPPC Secretariat.

The functions of the Commission are to provide direction to the work program of the IPPC Secretariat and promote the full implementation of the objectives of the Convention and, in particular, to:

- review the state of plant protection in the world and the need for action to control the international spread of pests and control their introduction into endangered areas
- establish and review procedures for the development and adoption of international standards, and to adopt international standards
- establish rules and procedures for the resolution of disputes
- cooperate with other relevant international organisations.

The new IPPC and currently unnumbered ISPM (*Guidelines for Pest Risk Analysis*) adopts a similar approach to that of OIE and notes the importance of documenting all steps in the process.

Equivalence

Article 4 of the *SPS Agreement* states that:

> *Members shall accept the sanitary or phytosanitary measures of other Members as equivalent, even if these measures differ from their own or from those used by other Members trading in the same product, 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.*

Members must accept the SPS measures of other Members as equivalent to their own if the latter can demonstrate objectively that their measures provide the level of protection required by the importing country. Often there are several alternative measures that may either singly or in combination achieve ALOP (e.g. treatment, quarantine or increased inspection). In choosing among such alternatives, a Member should put in place measures that are no more trade-restrictive than required to achieve its health protection objectives, provided those measures are technically and economically feasible. In doing so, the importing country must remain open to approaches from exporting countries with regard to alternative measures that may meet its ALOP.

Risk assessment

Articles 5.1 to 5.3 of the *SPS Agreement* outline the requirements that Members should follow when carrying out an import risk assessment.

Article 5.1 provides a basic statement of the obligation:

> *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 organisations*

Annex A of the *SPS Agreement* contains two definitions of risk assessment; the following is the definition applicable to biosecurity assessments:

> *The evaluation of the likelihood of entry, establishment or spread of a pest or disease within the territory of an importing Member according to the sanitary or phytosanitary measures which might be applied, and of the associated potential biological and economic consequences*

On the basis of this definition, the Appellate Body examining Australia's appeal against the dispute settlement panel's finding on Australia's prohibition of imports of Canadian salmon considered that a risk assessment within the meaning of Article 5.1 must:

- identify the hazards whose entry, establishment or spread within its territory a Member wants to prevent, as well as the associated potential biological and economic consequences
- evaluate the likelihood of entry, establishment or spread of these hazards, as well as the associated potential biological and economic consequences
- evaluate the likelihood of entry, establishment or spread of these hazards according to the SPS measures that might be applied; measures which might be applied are those which reduce the risks to the appropriate level, with the aim of being least trade restrictive.

The Appellate Body believed that, for a risk assessment to fall within the meaning of Article 5.1 and the first definition in paragraph 4 of Annex A of the Agreement, it is not sufficient that it conclude that there is a 'possibility' of entry, establishment or spread of diseases and their associated biological and economic consequences. That is, an assessment must evaluate the 'likelihood' (the 'probability') of entry, establishment or spread of diseases and their associated biological and economic consequences. Furthermore, likelihood should be evaluated without and then with any SPS measures that might be required.

Article 5.2 outlines factors that should be considered when assessing the risks associated with a proposed importation. Specifically, it states that:

> *In the assessment of risks Members shall take into account available scientific evidence; relevant processes and production methods; relevant inspection, sampling and testing methods; prevalence of specific diseases or pests; existence of pest- or disease-free areas; relevant ecological or environmental conditions; and quarantine or other treatment*

This paragraph emphasises the need to consider a wide range of factors in both the importing and exporting country.

Article 5.3 describes the need to include a consequence assessment in a risk assessment, and lists dimensions that should be considered when assessing 'potential damage' arising from a disease or pest incursion. Specifically, it states that:

> *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 cost of control or eradication in the territory of the importing Member*

This list of 'relevant economic factors' may be viewed as the bare minimum that must be considered if an analysis is to comply with the terms of the *SPS Agreement*. In addition, both the *OIE Code* and IPPC standards for risk analysis have outlined factors that should be considered when assessing consequences. These two standards also stress the need to consider the 'likely magnitude' of consequences — that is, to base an assessment of consequences on the likelihood of various levels of damage in the importing country. Finally, Article 5.3 states that Members should consider '*... the relative cost-effectiveness of alternative approaches to limiting risks ...*'. This is an issue that should be explored during risk management. Among factors that may not be taken into account are those relating to import competition.

The environmental and ecological consequences of pest or disease introduction are legitimate considerations in a risk assessment. The *SPS Agreement* provides a basic right to take measures to protect animal or plant life or health (Article 2). In Annex A, 'animal' is defined to include fish and wild fauna; and 'plant' to include forests and wild flora.

Additional to the economic factors identified in Article 5.3, the definition of risk assessment in Annex A, paragraph 4 (' *... evaluation of the likelihood of entry, establishment or spread of a pest or disease … and of the associated potential biological and economic consequences ...*') provides for general consideration of the biological consequences, including those for the environment. The environment is included in paragraph 1(d), which states that an SPS measure is one that is applied to ' *... prevent or limit other damage to a country from the entry, establishment or spread of pests ...*'.

Article 5.7 provides for the use of precaution when information is insufficient. This paragraph states that:

> *In cases where relevant scientific evidence is insufficient, a Member may provisionally adopt sanitary or phytosanitary measures on the basis of available pertinent information, including that from the relevant international organizations as well as from sanitary or phytosanitary measures applied by other Members. In such circumstances, Members shall seek to obtain the additional information necessary for a more objective assessment of risk and review the sanitary or phytosanitary measure accordingly within a reasonable period of time.*

Members, in adopting provisional measures, must demonstrate that there is insufficient information for an objective assessment of the risk. The provisional measures must be based on available information including international standards and the approaches of other countries. Countries adopting provisional measures are obliged to identify the additional information required for a more objective assessment and to seek that information in a timely manner. The provisional measure must be reviewed within a reasonable period because such measures are assumed to be trade limiting and contrary to the interests of WTO agreements.

Appropriate level of protection

The *SPS Agreement* defines '*appropriate level of sanitary or phytosanitary protection*' as the level of protection deemed appropriate by the Member establishing a sanitary or phytosanitary measure to protect human, animal or plant life or health within its territory. The *SPS Agreement* notes that many Members also refer to this concept as the '*acceptable level of risk*'. In setting their ALOP, Members are to take into account the objective of minimising negative trade effects (Article 5.4).

Determination of Australia's ALOP is an issue for government in consultation with the community — it is not a prerogative of WTO. ALOP reflects government policy that is affected by community

expectations; it is a societal value judgement to which AFFA contributes by providing technical information and advice. It is important to note that the *SPS Agreement* does not require a Member to have a scientific basis for its ALOP determination.

ALOP can be illustrated using a *risk estimation matrix* (Table 1). The cells of this matrix describe the product of likelihood and consequences — termed 'risk'.

When interpreting the risk estimation matrix it should be remembered that although the descriptors for each axis are similar ('low', 'moderate', 'high', etc.), the vertical axis refers to *likelihood* and the horizontal axis refers to *consequences*.

One implication of this is that a 'negligible' probability combined with 'extreme' consequences, is not the same as an 'extreme' probability combined with 'negligible' consequences — that is, that the matrix is *not symmetrical*. Another implication is that 'risk' is expressed in the same units as are used to estimate consequences — that is, risk is *not* a likelihood.

Table 1 Risk estimation matrix

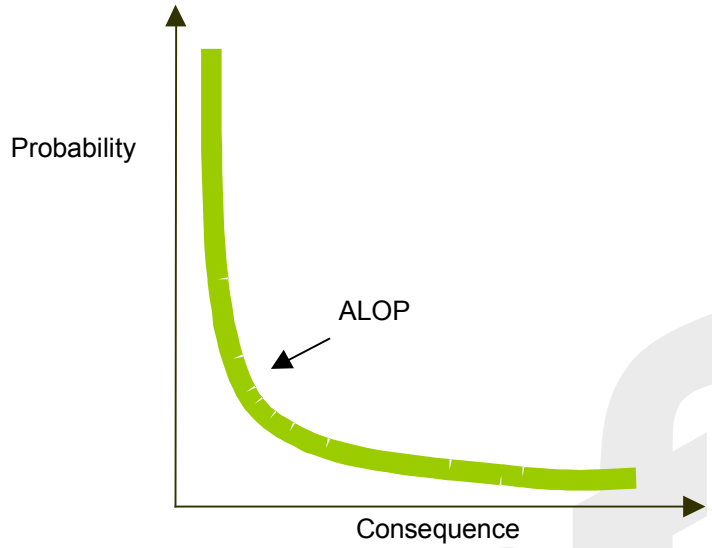
Likelihood of entry and exposure[3]	Negligible impact	Very low	Low	Moderate	High	Extreme impact
High likelihood	Negligible risk	Very low risk	Low risk	Moderate risk	High risk	Extreme risk
Moderate	Negligible risk	Very low risk	Low risk	Moderate risk	High risk	Extreme risk
Low	Negligible risk	Negligible 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 likelihood	Negligible risk	Negligible risk	Negligible risk	Negligible risk	Negligible risk	Very low risk

Consequences of entry and exposure

The band of cells in Table 1 marked 'very low risk' represents Australia's ALOP, or tolerance of loss. This band of cells represents an approximation of a continuous 'iso-risk curve' — a curve that will be asymptotic at the minimum level of consequences considered to be 'acceptable' (which, in Australia's case, is 'very low') and at a likelihood that tends toward zero. The principle of an iso-risk curve is illustrated in Figure 1.

[3] Read *entry, establishment and spread* for import risk analyses on plants or plant products

Figure 1 Theoretical iso-risk curve



Consistency in risk management

Article 5.5 states:

> *With the objective of achieving consistency in the application of the concept of appropriate level of sanitary or phytosanitary protection against risks to human life or health, or to animal and plant life or health, 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*

Members are obliged to avoid arbitrary or unjustifiable distinctions in the levels of protection applied in different situations, if such distinctions result in discrimination or a disguised restriction on international trade. This obligation reflects the objective of consistency in applying the concept of ALOP against risks to human, animal and plant life or health — that is, consistency in risk management. In other words, it is not open to a Member to arbitrarily vary its attitude to the acceptance of risk from one situation to another.

Consistency is achieved by using the risk estimation matrix (Table 1).

To support the carrying out of import risk analyses that are science-based, objective, defensible and transparent, OIE and IPPC standards each contains a standardised sequence of tasks or procedures. Collectively, these procedures constitute the respective 'international standards' for the conduct of import risk analyses for animal and plants and their products. In the first two sections of this discussion, the standards developed by OIE and IPPC are examined independently. In the final section, the two standards are compared in a summary table.

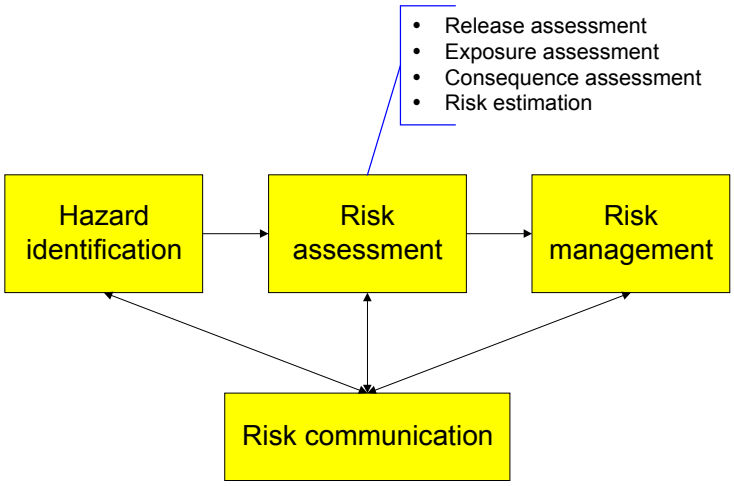
Note: Terminology adopted in these standards differs from that used in the *Australian/New Zealand Standards for Risk Analysis of Technological systems — Application Guide* (AS/NZS 3931:1998) and *Risk Management* (AS/NZS 4360:1999).[4]

The OIE and IPPC standards are those referenced by WTO for international trade, so it is appropriate for Biosecurity Australia to use that terminology. In stating this, it should also be recognised that the terminology for risk analysis adopted in the *SPS Agreement* is not entirely consistent with that in the *OIE Code* or IPPC standards. A tabulated comparison of the terms used by OIE and IPPC is given in Table 2.

OIE STANDARD FOR ANIMAL IMPORT RISK ANALYSIS

According to the *OIE Code*, the sequence of steps outlined in Figure 2 should be followed when carrying out an import risk analysis for an animal or animal product.

Figure 2 OIE approach to import risk analysis



[4] Available at http://www.standards.com.au/

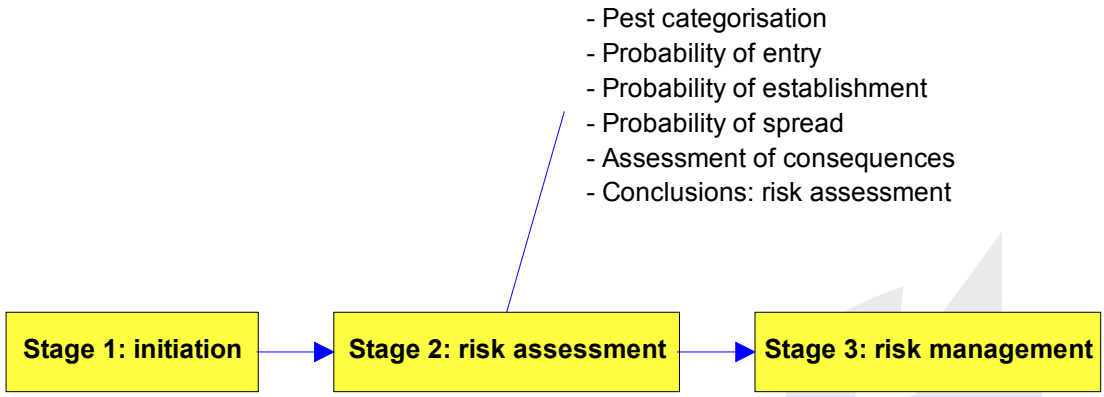
These steps are defined as follows in the *OIE Code*.

Hazard identification:	The process of identifying the pathogenic agents which could potentially be introduced in the commodity considered for importation.
Risk:	The likelihood of the occurrence and the likely magnitude of the consequences of an adverse event to animal or human health in the importing country during a specified time period.
Risk assessment:	The evaluation of the likelihood and the biological and economic consequences of entry, establishment or spread of a pathogenic agent within the territory of an importing country.
Release assessment:	A description of the biological pathways necessary for an importation activity to 'release' (that is, introduce) pathogenic agents into a particular environment, and an estimation of the probability (qualitative or quantitative) of the complete process occurring.
Exposure assessment:	A description of the biological pathways necessary for the exposure of animals and humans in the importing country to the hazards released from a given risk source, and an estimation of the probability of this occurring.
Consequence assessment:	A description of the potential consequences of a given exposure and an estimate of the likelihood that each will occur.
Risk estimation:	An integration of the results of the release assessment, exposure assessment and consequence assessment to produce an overall measure of the risk associated with each identified hazard.
Risk management:	The process of identifying, selecting and implementing measures that can be applied to reduce the level of risk.
Risk communication:	The process by which information and opinions regarding hazards and risks are gathered from potentially affected and interested parties during a risk analysis, and by which the results of the risk assessment and proposed risk management measures are communicated to the decision makers and interested parties in the importing and exporting countries.

IPPC STANDARD FOR PEST RISK ANALYSIS

According to the revised IPPC, the sequence of steps outlined below should be followed when carrying out a pest risk analysis.

Figure 3 IPPC approach to pest risk analysis



These steps are defined in the IPPC Standard as shown below:

Stage 1 (process initiation): Involves identifying the pest(s) and pathways that are of concern, and should be considered for risk analysis in relation to the identified PRA area.[5]

Stage 2 (risk assessment): Begins with the categorisation of individual pests to determine whether the criteria for a quarantine pest[6] are satisfied. Risk assessment continues with an evaluation of the probability of pest entry, establishment and spread, and of their potential economic consequences.

Stage 3 (risk management): Involves identifying management options for reducing the risks[7] identified at Stage 2. These are evaluated for efficacy, feasibility and impact in order to select those that are appropriate.

[5] A 'PRA area' is the area in relation to which a pest risk analysis is conducted — where an 'area' denotes an officially defined country, part of a country or all or parts of several countries.

[6] A 'quarantine pest' is a pest of potential economic importance to the area endangered and therefore not present there, or present but not widely distributed and being officially controlled. A 'pest' is any species, strain or biotype of plant or animal or any pathogenic agent, injurious to plants or plant products.

[7] 'Risk management' is planned if the unrestricted risk is considered 'unacceptable'. The acceptable level of risk may be expressed in several ways, including:

- reference to existing phytosanitary requirements
- indexed to estimated economic loss
- expressed on a scale of risk tolerance
- compared with the level of risk tolerated by other countries.

COMPARISON OF OIE AND IPPC STANDARDS

The major similarities and differences between the standards for import risk analysis provided by OIE and IPPC are summarised in Table 2 below.

Table 2 Comparison of OIE and IPPC standards for import risk analysis

OIE Code	IPPC Standard	Comments
Import risk analysis	Pest risk analysis	Differences in terminology only
-	Stage 1: Initiation	IPPC provides detailed descriptions of events that may lead to the initiation of an analysis. The OIE Code simply states that an import risk analysis should commence with a description of the commodity proposed for import and the likely annual volume of trade
Hazard identification	Pest categorisation	'Hazard identification' is a discrete preliminary procedure, whereas 'pest categorisation' is defined as an element of risk assessment. Aside from this, the two are very similar hazard/pest classification procedures
Release assessment	The probability of entry	'Release assessment' generally stops at the importing country's border, whereas the 'probability of entry' for quarantine pests stops at the 'endangered area' within the importing country
Exposure assessment	-	'Exposure assessment' describes events leading up to and including the exposure of susceptible animals. This does not have a direct equivalent in IPPC context, although steps in the distribution of the commodity in the importing country are considered when assessing the 'probability of entry'
-	The probability of establishment	The 'probability of establishment' consists of a comparison between biological factors in the source area and those in the immediate PRA area. The OIE Code incorporates the 'probability of establishment ' in the assessment of consequences
-	The probability of spread	The 'probability of spread' consists of a comparison between biological factors in the source area and those in the endangered area. The OIE Code incorporates the 'probability of spread' in the assessment of consequences
Consequence assessment	Assessment of economic consequences	The OIE approach requires that the likelihood of consequences occurring be considered in the assessment. As stated above, this equates to the IPPC description of the 'probability of establishment and spread'

OIE Code	IPPC Standard	Comments
Risk estimation	Conclusions — risk assessment	'Risk estimation' is not an explicit step in the IPPC framework — it is simply referred to as 'the conclusions of risk assessment'. Risk estimation is described in the OIE Code as the process of combining the likelihood and consequences of an event
Risk management	Pest risk management	Similar, except that ALOP does not appear to be as explicitly described by IPPC. Similarly, the delineation of option evaluation is not as explicitly outlined by IPPC
Risk communication	-	'Risk communication' is not explicitly described by IPPC as a component of the risk analysis process, although suggestions for the 'documentation of pest risk analysis' are briefly annotated

Import risk analysis for animals and animal products is based on the following procedures:

- hazard identification
- risk assessment, incorporating
  - release assessment
  - exposure assessment
  - consequence assessment
  - risk estimation
- risk management.

Risk communication will be carried out in accordance with the requirements for stakeholder consultation outlined in the *Handbook*.

HAZARD IDENTIFICATION

According to the *OIE Code*, hazard identification should be undertaken as a classification step, to identify pathogenic agents[8] that could be associated with the importation of a commodity. Agents thus classified are termed 'potential hazards'. The *OIE Code* states that, to be identified as a potential hazard, a pathogenic agent should comply with *all* of the following criteria:

- the pathogenic agent should be appropriate to the animal species to be imported, or from which the commodity is derived
- the pathogenic agent could produce adverse consequences in the importing country
- the pathogenic agent may be present in the exporting country[9]
- the pathogenic agent should not be present in the importing country. If present, the pathogenic agent should be associated with a notifiable disease, or should be subject to control or eradication measures.[10]

Hazard identification will begin with an initial list of pathogenic agents. For terrestrial animals, this list will include the causative agents for each of OIE List A and B diseases that are relevant to the species to be imported, or from which the commodity is derived.[11] For aquatic animals, the initial list will include the causative agents for diseases listed in the OIE Aquatic Code as either 'diseases notifiable to the OIE' or 'other significant diseases', and relevant to the species from which the commodity is derived. In either case, the initial list may be augmented through consultation with

[8] Or a clearly identified strain of a pathogenic agent

[9] The *OIE Code* states that ' *... the evaluation of the veterinary services, surveillance and control programs and zoning and regionalisation systems are important inputs for assessing the likelihood of hazards being present in the animal population of the importing country ...*'

[10] In this context, 'control or eradication measures' are taken to mean a compulsory control or eradication program.

[11] The *OIE Code* lists and describes 'diseases', rather than their causative pathogenic agents, whereas in undertaking a risk analysis, the 'potential hazard' is the pathogenic agent and not the disease syndrome with which it is associated.

experts and by reviewing the scientific literature, to include all pathogenic agents of concern to the importing country (with regard to a given import risk analysis).

Hazard identification is a categorisation procedure[12] that may be carried out and reported using a single table, with column headings representing the classification criteria described at the start of this section. If reasons for the inclusion or exclusion of particular pathogenic agents are not clear-cut, these agents should be retained on the list and examined using a formal risk assessment. An example of this principle is given in Table 3. The specific formats that should be used in an *Technical Issues Paper* or a *[Draft] IRA Report* are shown in their respective document templates.

[12] If reasons for the inclusion or exclusion or particular pathogenic agents are not clear-cut, these agents should be retained on the list and examined during risk assessment.

Table 3 Hazard identification — a categorisation step

Disease agent (disease)	Susceptible species	Adverse consequences in Australia (Yes / No)	Distribution	Potential hazard? (Yes / No)	Reasons for removal
Disease agent 1 (Disease 1)			*Australia*: *[Exp country]*:		
.			*Australia*: *[Exp country]*:		
.			*Australia*: *[Exp country]*:		
.			*Australia*: *[Exp country]*:		
Etc			*Australia*: *[Exp country]*:		

Finally, note that *the risk analysis should halt at the completion of hazard identification* if any of the following conditions apply:

- no potential hazard is identified
- the importing country elects to use risk management measures described in the *OIE Code* for all identified potential hazards
- the importing country decides not to apply risk management measures to hazards not addressed in the *OIE Code*.

RISK ASSESSMENT

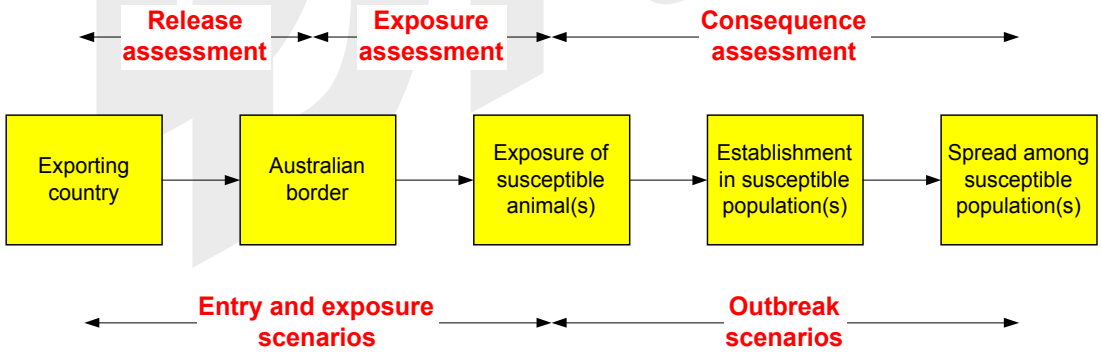
Risk assessment is defined in the *OIE Code* as:

> *An evaluation of the likelihood and the biological and economic consequences of entry, establishment or spread of a pathogenic agent within the territory of an importing country.*

The likelihood that a pathogenic agent will enter an importing country, and the likelihood that susceptible animals will be exposed to that agent, are determined through a 'release assessment' and an 'exposure assessment', respectively. The likelihood of establishment and spread, and biological and economic consequences of introducing a pathogenic agent, are determined through a 'consequence assessment'. The risk assessment for each identified agent concludes with 'risk estimation' — the combination of the likelihoods and consequences — and yields the 'unrestricted risk estimate'.

These components are illustrated in Figure 4.

Figure 4 The components of risk assessment



Release assessment

A release assessment comprises two distinct procedures:

- a description of scenarios
- an evaluation of likelihoods.

Description of scenarios

In the context of import risk analysis, a ‘scenario’ represents the ordered sequence of steps that lead to a particular outcome, or ‘event’, and should have a carefully stated ‘initiating step’ and ‘end point’.

The initiating step for a release scenario will vary among commodities, but will generally be the first discrete process associated with a commodity’s production or selection for export. The end point of a release scenario will be the initiating event of the subsequent exposure scenario, in either case defined as ‘the arrival in Australia of an infected or contaminated commodity’. The initiating step and end point of a release scenario are illustrated in Figure 4.

After the initiating event and the end point of a release scenario have been defined, the ‘steps’ that connect the two need to be identified. The level of detail required will vary among assessments, although the governing principle should be to represent adequately any relevant processes that may affect the likelihood of entry.

The *OIE Code* provides a list of factors or considerations that should be taken into account when identifying and describing the steps in a release scenario. These factors should also be considered when assigning likelihoods to the component steps, as will be described in the following section.

Factors contributing to release scenarios

Biological factors

- species, age and breed of animals
- agent predilection sites
- vaccination, testing, treatment and quarantine

Country factors

- incidence or prevalence
- evaluation of veterinary services, surveillance and control programs, and zoning systems, of the exporting country

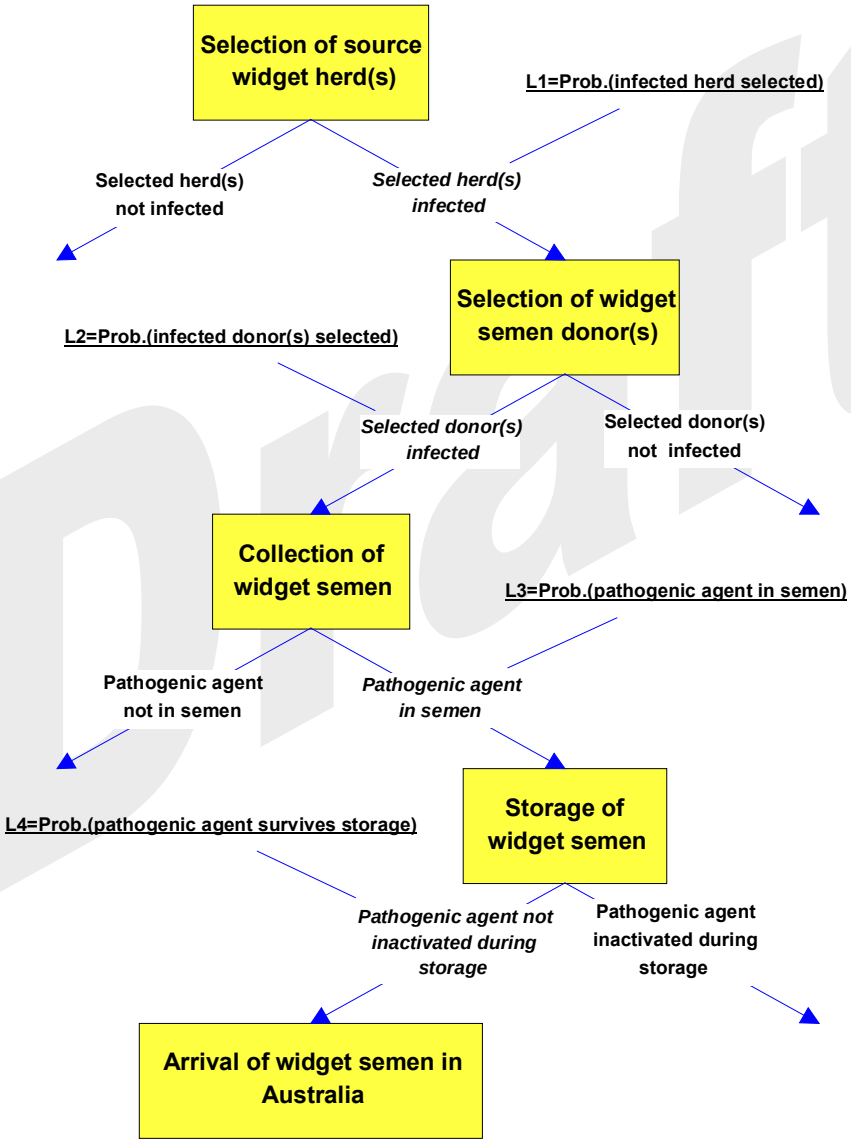
Commodity factors

- quantity of commodity to be imported
- ease of contamination
- effect of processing
- effect of storage and transport

Scenario diagrams, or ‘trees’, should be constructed to illustrate release scenarios and thus to adequately communicate the process of likelihood evaluation. The convention underlying this form of representation is that ‘events’ are described in boxes or ‘nodes’, whereas the probability or likelihood to be ascribed to each event is associated with the arrows emanating from its respective node.

A hypothetical example[13] of a release scenario is provided in Figure 5. In this example, the release scenario describes a series of four events (with likelihoods L_1–L_4) that *must* occur in order for contaminated 'widget semen'[14] to enter Australia. The initiating step is the selection of stud herds from which the donor widgets will be sourced, whereas the end point is, as always, the arrival in Australia of the contaminated commodity — in this case, semen.

Figure 5 A release scenario for the importation of widget semen



[13] This document contains numerous 'hypothetical' examples. These have been included for illustration, and are not intended to represent Australian policy concerning real commodities.

[14] The term 'widget' has been used throughout this document to avoid any unintended association with a 'real' commodity, or an existing or planned import risk analysis.

Evaluation of likelihood

In the second phase of the release assessment, likelihoods[15] are ascribed to each of the identified steps in the scenario. In some situations, it may subsequently be useful to combine these step-level likelihoods to estimate the overall likelihood of entry. Alternatively, it may be more appropriate to assign the likelihoods and to calculate the overall likelihood of entry *and* exposure at the close of the risk assessment (see, Risk Estimation). The method adopted will generally be determined by the inherent complexity of the release and exposure scenarios, and by the decision to carry out the release and exposure assessments 'qualitatively', 'semi-quantitatively', 'quantitatively' or using a mixture of these approaches.

According to the *OIE Code*, a qualitative assessment is one that is expressed in 'words', whereas a quantitative assessment produces a 'numerical estimate'. A definition for semi-quantitative likelihood evaluation is not given in the *OIE Code*. In these *Guidelines*, the definitions adopted are as follows:

- *Qualitative likelihood evaluation*. This is an evaluation in which likelihoods assigned to steps in scenarios (and/or to the overall result for a scenario) have been categorised according to an ordinal descriptive scale — e.g. 'low', 'moderate', 'high', etc. — and where no attempt has been made to equate descriptors with numeric values or scores
- *Semi-quantitative likelihood evaluation*. This is an evaluation in which likelihoods assigned to steps in scenarios (and/or to the overall result for a scenario) have been given numeric 'scores' (e.g. 1, 2, 3), or probabilities and/or probability intervals (e.g. $0 \rightarrow 0.0001$, $0.0001 \rightarrow 0.001$, $0.001 \rightarrow 0.01$, $0.01 \rightarrow 1$).[16]
- *Quantitative likelihood evaluation*. This is an evaluation in which likelihoods assigned to steps in scenarios (and/or to the overall result for a scenario) have been described in purely numeric terms — whether as 'deterministic' point estimates or as 'stochastic' probability distributions. The outcome of a purely deterministic quantitative model will be a single likelihood estimate. The outcome of a stochastic model will be a distribution of simulated values.

Each of the three approaches to likelihood evaluation has its advantages and constraints. Indeed, there will be some situations where one or other approach will be the most appropriate or, as suggested above, a combination of approaches may be required. For example, it may be that *qualitative* or *semi-quantitative* assessments of all identified hazards will be supported by *quantitative* assessments of one or more hazards considered of principal importance. Alternatively, it may be appropriate for the release assessment to be modelled *quantitatively* and the exposure assessment *qualitatively* or *semi-quantitatively*. Finally, particular 'steps' in either scenario may be modelled *quantitatively*, regardless of the approach adopted for the rest of the evaluation.[17]

The choice of approach to the evaluation of likelihood will depend on both technical and practical considerations. General recommendations are not appropriate. However, guidelines regarding the advantages, constraints and application of each approach may be useful, and are provided below.

---

[15] The term 'likelihood' has been used throughout this document to denote the 'chance' that a particular event will occur.

[16] Probability intervals do not include either '0' or '1'.

[17] Where the quantitative approach is used in conjunction with, or as a component of, a qualitative or semi-quantitative assessment, the numerical result should be expressed in the relevant categorical terms. The reverse — that is, the reporting of qualitative or semi-quantitative likelihood assessment in purely numerical terms — is not appropriate.

Qualitative likelihood evaluation

Qualitative likelihood evaluation is based on a descriptive ordinal scale — such as provided in Table 4.

Although the qualitative approach is conceptually simple, the descriptors themselves remain effectively 'undefined'. That is, it will be impossible to state precisely what is meant by a designation of, for example, 'low', because one person's understanding of 'the event would be unlikely to occur' (as described in Table 4) will be different to another's. This characteristic of qualitative likelihood evaluation may lead to inconsistency, both within and between import risk analyses.

Table 4 Nomenclature for qualitative likelihoods

Likelihood	Descriptive definition
High	The event would be very likely to occur
Moderate	The event would occur with an even probability
Low	The event would be unlikely to occur
Very low	The event would be very unlikely to occur
Extremely low	The event would be extremely unlikely to occur
Negligible	The event would almost certainly not occur

Qualitative likelihoods can be assigned to individual steps in scenarios, or to the probability that the entire scenario will occur.

If qualitative likelihoods have been assigned to individual steps in a scenario, then some form of 'combination rule' will be needed for calculating the probability that the entire scenario will occur. Rules can be displayed in various formats, but the most intuitive is a two-by-two tabular matrix, such as shown in Table 5.

The rules in the matrix are, by definition, arbitrary. This matrix was derived by combining the 'midpoints' of the corresponding *semi-quantitative* probability intervals (Table 7). The semi-quantitative method was adopted so that the two approaches (qualitative and semi-quantitative) yielded equivalent results and, if necessary or useful, so that evaluations could be carried out using a mixture of both. This method is discussed in further detail in the following section.

Table 5 A matrix of 'rules' for combining descriptive likelihoods

	High	Moderate	Low	V. low	E. low	Negligible
High	High	Moderate	Low	V. Low	E. Low	Negligible
Moderate		Low	Low	V. Low	E. Low	Negligible
Low			V. low	V. Low	E. Low	Negligible
V. low				E. Low	E. Low	Negligible
E. low					Negligible	Negligible
Negligible						Negligible

The procedure can be illustrated using the hypothetical widget semen example (Figure 5). In this example, each of the four steps has been assigned a likelihood. These likelihoods were subsequently combined using the 'rules' provided in Table 5.

Table 6 Qualitative evaluation of the widget semen scenario

Step	Qualitative descriptor	Product of likelihoods
L_1: Selection of an infected widget herd	Low	
L_2: Selection of an infected semen donor	Moderate ..... ➔	Low
L_3: Pathogenic agent present in semen	High ..... ➔	Low
L_4: Pathogenic agent survives storage and transport	V. Low ..... ➔	V. low

The result of the procedure is an estimate of the probability that the complete chain of events will occur — that is, 'the probability that imported widget semen will be infected on arrival'. In this hypothetical example, the probability that imported widget semen is infected is estimated to be 'very low'. Alternatively, it could be stated that it is 'very unlikely' that imported widget semen will be infected. The calculation of this probability would conclude a qualitative release assessment.

The *advantage* of this matrix-based qualitative approach is that a release scenario can be broken into its component steps and a descriptive likelihood assigned to each. This provides a simple means by which to improve the transparency of an assessment. The principal *disadvantage* is that the assessment will often lead to a conservative overestimate of the likelihood that would have been obtained had the scenario been evaluated using a quantitative or semi-quantitative approach. This is because the repeated application of any one of the rules in the matrix (Table 5) will lead to the same likelihood. For example, if two steps in a scenario were considered to have a 'low' likelihood of occurrence, then the product of these, as determined using the matrix, would be 'very low'. Unfortunately, the same result would be obtained if there were three, four, five, etc., steps

with a 'low' likelihood, and yet clearly the overall likelihood should be progressively lower in each case.

The seriousness of this problem will be determined by the number of steps in the scenario, and by the need for a given assessment to provide a precise and ultimately defensible estimate. Where the problem is considered to be severe, a practical 'solution' may be to assign a single likelihood to the entire release scenario, to do the same for the exposure scenario(s) (see Exposure Assessment), and to subsequently combine these using a *single* application of the qualitative combination rules (Table 5). The disadvantage of this approach is that the transparency afforded by the scenario-based assessment will, at least in part, be lost.

Finally, it will be shown (see Risk Estimation) that an important consideration in carrying out a release assessment is how each likelihood may be influenced by the volume of trade during a specified period. This issue is difficult to incorporate into a qualitative framework, because numeric manipulation of descriptive adjectives (at least beyond that used as the basis for combination rules) is likely to be criticised. One solution may be to state at the start of the risk assessment that *all* likelihoods have been assigned or derived under the implicit assumption that they refer to the volume of commodity likely to be imported in a given period. It is clear, however, that because estimates assigned on this basis will be more difficult to defend, the approach is likely to be problematic. A preferable solution for situations that require consideration of the effect of trade volume will be to provide a quantitative or semi-quantitative assessment, either as an embellishment of the qualitative assessment or in place of it. These approaches are outlined in the following discussions.

Semi-quantitative likelihood evaluation

There are two broad approaches to semi-quantitative likelihood evaluation. On one hand, the categories may be represented by scores (e.g. 1, 2, 3). This approach, however, rests on arbitrary rules governing the combination and interpretation of scores, and is not considered sufficiently robust. The alternative is to divide explicitly the 0–1 interval into a small number of mutually exclusive categories, or 'probability intervals'. These categories may subsequently be correlated with an equal number of descriptors, such that the analyst makes statements such as:

> *'We believe that the event will occur with an even probability — that is, we believe that the likelihood of the event may be as low as 'a' or as high as 'b''*

Biosecurity Australia has adopted probability intervals for semi-quantitative assessment that correlate directly with the qualitative descriptors discussed in the previous section. These ranges are shown in Table 7. When interpreting the table, it should also be noted that events described in risk assessment scenarios cannot be said to occur with a zero probability[18], and events that are 'almost certain' to occur may be modelled as certainties and thus assigned a likelihood of one.

[18] If an event were assigned a zero probability of occurring, then the scenario also would have a zero probability of occurring. Zero likelihood would in turn lead to zero risk, which is not a sensible result for an import risk analysis.

Table 7 Nomenclature for semi-quantitative likelihoods

Likelihood	Descriptive definition	Probability (P)
High	The event would be very likely to occur	Range = $0.7 \rightarrow 1$
Moderate	The event would occur with an even probability	Range = $0.3 \rightarrow 0.7$
Low	The event would be unlikely to occur	Range = $0.05 \rightarrow 0.3$
Very low	The event would be very unlikely to occur	Range = $0.001 \rightarrow 0.05$
Extremely low	The event would be extremely unlikely to occur	Range = $10^{-6} \rightarrow 0.001$
Negligible	The event would almost certainly not occur	Range = $0 \rightarrow 10^{-6}$

Semi-quantitative likelihoods may be combined using several approaches. The approach adopted by Biosecurity Australia is to convert each semi-quantitative likelihood into a Uniform probability distribution[19] whose parameters, or boundaries, are those described in Table 7. This is illustrated in Table 8.

Table 8 Probability distributions for semi-quantitative likelihoods

Likelihood	Probability interval	Probability distribution
High	Range = $0.7 \rightarrow 1$	P ~ Uniform (0.7, 1)
Moderate	Range = 0.3 – 0.7	P ~ Uniform (0.3, 0.7)
Low	Range = 0.05 – 0.3	P ~ Uniform (0.05, 0.3)
Very low	Range = 0.001 – 0.05	P ~ Uniform (0.001, 0.05)
Extremely low	Range = 10^{-6} – 0.001	P ~ Uniform (10^{-6}, 0.001)
Negligible	Range = $0 \leftarrow 10^{-6}$	P ~ Uniform (0, 10^{-6})

Uniform probability distributions may subsequently be simulated within a quantitative spreadsheet using software such as @RISK (Palisade Corporation). Simulation is complex, but it can be used to obtain 'samples' from a series of Uniform distributions with only a working knowledge of Microsoft Excel and a small number of pointers on the use of @Risk. This software contains excellent tutorials, as well as detailed hard-copy manuals. Very briefly, having opened @Risk within Excel, Uniform distributions are entered into individual cells in the place of point estimates, using the following syntax:

= RiskUniform(lower boundary, upper boundary)[20]

[19] A Uniform, or Rectangular, distribution has no 'curve' as such, because each value within its limits occurs with an equal probability.

[20] Note that there is no space between the words 'Risk' and 'Uniform', or before the opening bracket.

To maintain consistency amongst Biosecurity Australia assessments, simulations should be based on *1000 – 2000 iterations*, a *random number generator seed of 'one'*, *Latin hypercube sampling* and *no monitoring of convergence*. These options can be selected from @Risk's Simulation Settings dialogue box.

The semi-quantitative 'model' itself is defined by the relationships amongst spreadsheet cells. Such relationships will be identical for simulation exercises involving distributions, as for the situation where individual cells contain the more familiar point estimates. The difference between simulated spreadsheets and the simpler 'deterministic' approach is that the output will be a distribution, rather than a single value.

For risk assessment models based on semi-quantitative Uniform distributions, the output (when viewed as a probability density plot or histogram) will typically appear as a left-skewed bell-shaped distribution. This distribution should be interpreted by 'fitting' it to the most appropriate semi-quantitative category. The approach to fitting that has been adopted by Biosecurity Australia is to compare the fifth, 50^{th} (or median) and 95^{th} percentiles of the output distribution with the probability intervals in Table 7.

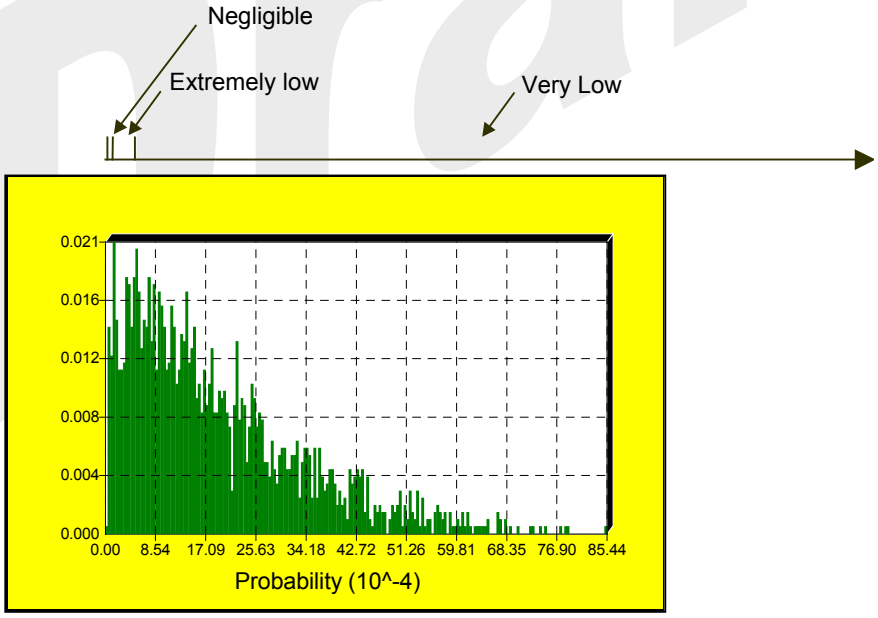
An example of this simulation-based semi-quantitative approach has been provided by extending the hypothetical widget semen scenario introduced in the previous discussion (Figure 5 and Table 9). In this example, the qualitative descriptors for step-level likelihoods are those presented in Table 6, although embellished using the appropriate Uniform probability distributions. The result of this is shown in Table 9.

The 'model' (in this case simply the product of each component likelihood) was run in @Risk / Microsoft Excel using the simulation settings described above. Statistics obtained from the simulation indicate that the fifth percentile for this release assessment is approximately 0.00017, the 50^{th} percentile (or median) approximately 0.0015 and the 95^{th} percentile approximately 0.0050. This suggests that although the distribution spans both the 'extremely low' and 'very low' intervals, the median value and, thus, more than half of the simulated values, are 'very low' (Figure 6). This output distribution was therefore classified as 'very low'.

Table 9 Semi-quantitative evaluation of the widget semen scenario

Step	Qualitative assessment	Semi-quantitative assessment
L_1: Selection of an infected widget herd	Low	P_1 ~ Uniform (0.05, 0.3)
L_2: Selection of an infected semen donors	Moderate	P_2 ~ Uniform (0.3, 0.7)
L_3: Pathogenic agent present in semen	High	P_3 ~ Uniform (0.7, 1)
L_4: Pathogenic agent survives storage and transport	V. low	P_4 ~ Uniform (0.001, 0.05)
Probability (P) that imported widget semen is infected	**V. Low**	Median ≡ 0.0015 5^{th} % ≡ 0.00017 95^{th} % ≡ 0.0050 **P ≡ V. low**

Figure 6 Interpretation of the simulation output from the widget semen scenario



The simulation-based semi-quantitative approach has four important advantages.

- By specifying (albeit arbitrary) probability intervals it will generally be possible to describe and interpret estimates of likelihood consistently. For example, if the definitions in Table 7 are adopted, analysts using the term 'moderate' will have indicated that they have estimated a given likelihood to fall 'somewhere between 0.3 and 0.7'. All readers would understand that this was the analysts' understanding of the said likelihood, and that all other likelihoods described as 'moderate' should be interpreted in the same way.

- The quantitative framework upon which this approach to semi-quantitative likelihood evaluation is based enables the effect of the volume of trade during a specified period to be considered explicitly. Volume of trade will be an important issue in most import risk analyses and, as stated in earlier discussions, cannot easily be incorporated into the simpler qualitative approach. The implications of volume of trade are discussed in further detail under *Risk Estimation*.
- The use of a spreadsheet model has the particular advantage that individual steps within the framework of a likelihood pathway can easily be considered. This scenario-based approach to likelihood evaluation is considered more transparent than a simple narrative description of relevant factors or events, and enables the relative importance of particular steps to be evaluated. Examination for relative importance is one form of sensitivity analysis, and can be used to identify steps for which information is most critical, or at which risk management might be most effective.
- The simulation-based approach provides a very simple and robust means by which the 'uncertainty' inherent in most import risk analyses can be represented and incorporated in the assessment process. That is, the Uniform distribution corresponding to each general statement about likelihood will be sampled randomly many times (1000–2000 iterations are recommended), thus providing an output distribution that represents all possible combinations of uncertain inputs.

Given these advantages, the principal constraint of the semi-quantitative approach is the need to place likelihoods confidently in one or other category. However, given that the categories at either end of the 0–1 interval are extreme and unlikely to be contentious, and that the central ('moderate') category broadly represents an 'even probability', this difficulty is unlikely to be serious. Where the likelihoods to be attributed to particular steps in a model are poorly understood and the analyst is uncomfortable with assigning semi-quantitative categories, sensitivity analysis might be used. As discussed above, sensitivity analysis will determine how important each step is to the overall likelihood. Important steps that are poorly understood or poorly documented in the literature can be modelled conservatively as 'one'. Alternatively, the simulation might be repeated using a range of reasonable and defensible inputs to examine the precise effect of the uncertainty.

Quantitative likelihood evaluation

Quantitative likelihood evaluation is a large and complex field, and comprehensive guidelines are beyond the scope of this document. The single important difference between *quantitative* and *semi-quantitative* likelihood evaluation (as discussed above) is that the latter is based on a predetermined set of likelihood intervals and their corresponding descriptive definitions. In contrast, where true quantitative likelihood evaluation is used, analysts will be free to model inputs using any point estimate or probability distribution. If the quantitative approach is adopted, care must be taken in the use of adjectives or verbal descriptors for likelihood so readers do not get the impression that the 'standardised' semi-quantitative intervals have been used.

Quantitative models that incorporate probability distributions are described as 'stochastic models'. As discussed above, stochastic models can be 'simulated' using software such as @Risk, and will produce an output distribution rather than a single 'deterministic' point estimate.

To illustrate the use of the quantitative approach, probability distributions were assigned to each of the steps in the hypothetical widget semen example, and the model simulated. The results of the simulation include summary statistics (of which the median, fifth percentile and the 95th percentile are reported in Table 10), a histogram (or probability density plot, Figure 7), a cumulative

histogram (or cumulative density plot, Figure 8) and the results of a sensitivity analysis (correlations and a tornado diagram, Figure 9).

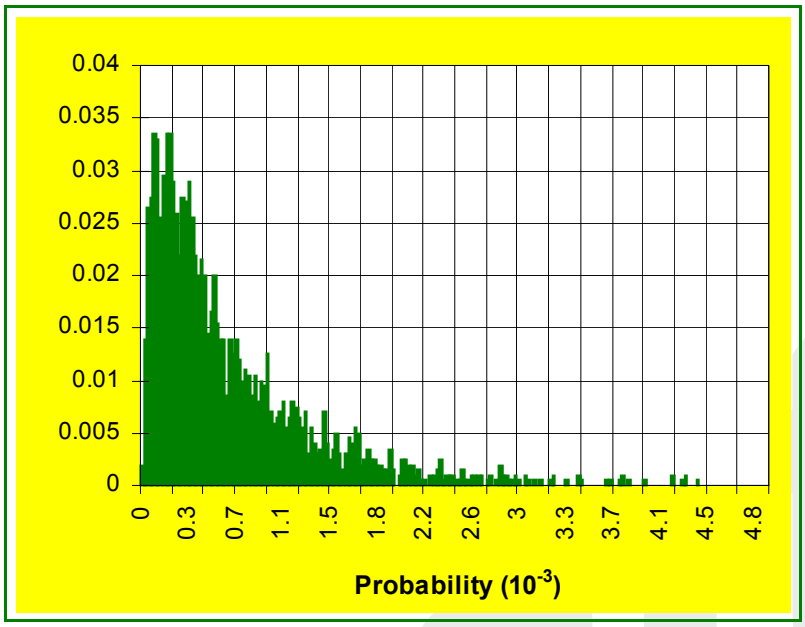
The output from a stochastic quantitative evaluation should be interpreted in the same manner as the output from a simulation-based semi-quantitative evaluation. That is, the distribution should be 'fitted' visually and by virtue of the distribution statistics to the most appropriate semi-quantitative interval. In the hypothetical widget semen example, this procedure led to the probability that imported widget semen is infected being classified as 'extremely low'.

Table 10 Quantitative evaluation of the widget semen release scenario

Step	Quantitative input
L_1: Selection of an infected widget herd	P_1 ~ Triangular (0.05, 0.1, 0.5)
L_2: Selection of an infected semen donors	P_2 ~ Uniform (0.1, 0.5)
L_3: Pathogenic agent present in semen	P_3 ~ Triangular (0.90, 0.95, 0.99)
L_4: Pathogenic agent survives storage and transport	P_4 ~ BetaPert (0.001, 0.005, 0.05)
Probability (P) that imported widget semen is infected	Median ≡ 0.0005
	5^{th} % ≡ 0.00008
	95^{th} % ≡ 0.002
	P ≡ E. low

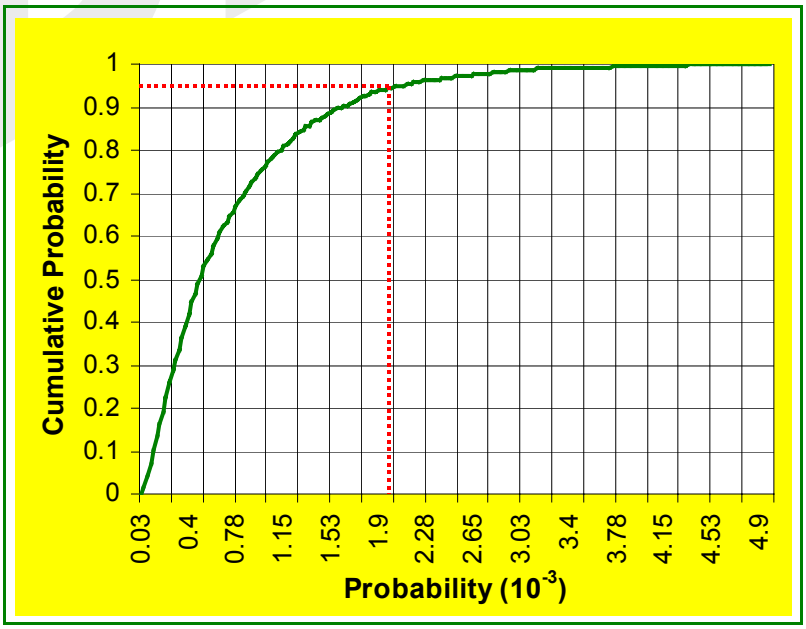
The histogram, or 'probability density plot', generated when this hypothetical example was simulated is shown in Figure 6. This plot will be useful for communicating the spread of simulated values, and the approximate 'shape' of the output distribution.

Figure 7 A probability density plot for the widget semen release assessment



Alternatively, the 'cumulative density plot' in Figure 8 illustrates the relative likelihood that the outcome will be at least as low as each value on the x-axis. For example, the 95th percentile is approximately 0.002, indicating that 95 per cent of simulated values were smaller than or equal to 0.002. On the semi-quantitative scale, a result of 0.002 would be classified as 'very low'.

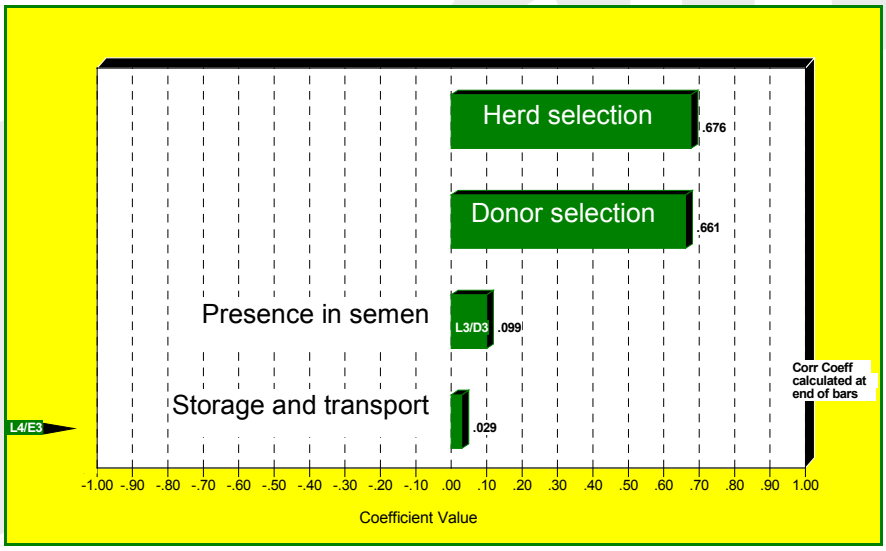
Figure 8 A cumulative density plot for the widget semen release scenario



In practice, many analysts choose to report the 95th percentile. It is probable that this trend has arisen as an extension of the convention in statistics whereby 0.05 is generally considered the benchmark for a 'significant' result. In fact, simulated percentiles are not equivalent (or even similar) to the 'confidence limits' reported in statistics and if, for example, a 95th percentile is to be reported, then the reason for taking this very conservative approach should be clearly stated. In the hypothetical widget semen example, reporting the 95th percentile in the place of the median (50th percentile) would raise the output probability from 'extremely low' to 'very low'.

One of the principal advantages of the quantitative approach to likelihood evaluation is the ability to carry out a *sensitivity analysis* and, thus, identify the most influential input variables. By knowing the most influential input variables, it may be possible to increase the efficiency of risk management, or to concentrate research in an area that will be maximally useful to any further analysis. A sensitivity analysis (Figure 9) on the hypothetical widget semen release assessment showed that 'the probability that an infected herd is selected', and 'the probability that an infected donor widget is selected', are the two most important variables. This information might be used to validate a decision to concentrate risk management on efforts to ensure that the source herd and donor widget were free from a given disease.

Figure 9 Sensitivity analysis for the widget semen release assessment



Another feature of the quantitative approach is the ability to model *correlations* between input variables. For example, there may be a correlation between the size of a herd and the prevalence of a given disease. This is the case for lameness in dairy cattle, where it has been shown that larger herds tend to have a higher prevalence of lame cows and heifers. By positively correlating these two variables in a quantitative model, it will be possible to ensure that higher simulated values of one occur in the same iteration as higher simulated values of the other. This will reduce 'unrealistic variability', although the variance, or spread, of the output will increase with positive correlation, and will better represent the biology of the scenario being modelled.

Quantitative modelling also allows the effect of the *volume of trade* during a given period on the likelihood of disease entry and/or exposure to be directly assessed. Whether this is carried out as a

component of the release and/or exposure assessment, or as a separate procedure at the completion of both release and exposure assessments, will depend on the particulars of each scenario.

The principal constraints of quantitative modelling are the required time and technical resources. In general, this will limit quantitative modelling to a small proportion of contentious or otherwise important analyses. Once the decision has been made to include quantitative modelling in an analysis, the interpretation of results may present a further quandary. Where a model is stochastic (includes simulated probability distributions) then the outcome will be a distribution. It will not be possible to report an entire distribution, so should the mean, median, 95th percentile, etc., be reported? As shown in the example discussed above, these values may be very different, and the decision to report the 95th percentile in place of the median, may alter a subsequent decision about the need for risk management.[21]

Quantitative models are further limited by the need for reasonable data or information, although most 'adequate' quantitative models are based on expert opinion, or extrapolation of results of very specific experiments. The use of epidemiological field data is relatively uncommon. Interpretation of expert opinion is beyond the scope of this document, but those adopting the quantitative approach should be familiar with, and use, currently available techniques.

The final (and perhaps most serious) limitation of quantitative modelling is that it will not generally be possible to arrive at a mathematical structure and a set of modelling assumptions that are beyond critique. That is, in creating a model, the analyst will always be abbreviating 'reality' — hopefully retaining most of the features of the 'real' scenario that would determine the real likelihood of the event in question. As quantitative models become more sophisticated, they also inevitably become more specific, and rely more heavily on specific assumptions. This may have ramifications for the acceptability of a quantitative model in an adversarial environment, because it will always be relatively easy for critics to cast doubt on the structure of a model and, therefore, the conclusions drawn from the assessment.

Conclusions: approaches to likelihood evaluation

Each modelling approach has advantages and constraints. Likewise, there is no single 'best approach' and, indeed, it will occasionally be sensible to combine approaches in a given assessment.

Whichever approach (or combination of approaches) is chosen, it should provide for the following:

- an assessment based on sound science
- an assessment that is structured and transparent
- an assessment that is internally consistent, and that can be repeated (with the same or a similar outcome) by another operator using the same framework and data
- an outcome that will support the estimation of 'risk' (a combination of likelihood and consequences)
- an outcome that will enable risk to be evaluated against the importing country's ALOP, or 'tolerance for loss'
- a framework within which the efficacy of risk management and the acceptability of a mitigated risk can be evaluated.

[21] As a rule, it is recommended that the 95th percentile of an output distribution be reported. This conservative policy is based on a recognition that all models are (at least to some extent) imperfect representations of reality.

Exposure assessment

An exposure assessment comprises two distinct procedures:

- a description of scenarios
- an evaluation of likelihood.

Description of scenarios

As was the case for release scenarios, exposure scenarios are based on initiation points, end points and the steps that link these 'events'. The initiation point for an exposure scenario will be the end point for the corresponding release scenario — that is, 'the arrival in Australia of an infected or contaminated commodity'. The end point, or end points, will represent 'the exposure of susceptible animals in Australia'.

The principal difference between release and exposure assessments is that exposure assessments are frequently more complicated. In general, exposure assessments will follow one of the three configurations shown below:

- a single exposure pathway leading to a single end point — as described for the release scenario
- multiple exposure pathways leading to a single end point
- multiple exposure pathways leading to multiple end points.

The first configuration is the simplest and, indeed, is structurally identical to the hypothetical release scenario described above. An example might be the importation of production animal semen, where the commodity is implanted directly into the recipient animal in the importing country. Here it is clear that the exposure scenario will be limited to the steps or procedures associated with the storage and transport of semen in Australia, any further processing, and the ability of the agent to infect the recipient.

The second configuration — multiple pathways leading to the same end point — is more complex, but might be illustrated by the importation of live production animals (cattle, sheep, pigs, etc.). Here, for example, susceptible animals in Australia could be exposed through direct contact with infected imported animals or indirectly through a vector, fomites, contaminated feed, etc. Each of these two alternatives would constitute a 'pathway', and should be considered as such in the assessment.

Finally, and most difficult to model, is the situation where there are several distinct groups, or species, of exposed animals. An example of this situation might be the importation of a meat product for human consumption, where discrete populations (e.g. domestic, feral or wild animals) could be exposed. The difference between this scenario and that described above is that the separate pathways lead to separate end points.

Once the initiation point and end point(s) of an exposure scenario(s) has been defined, it remains to identify the connecting 'steps'. The level of detail required at this stage will vary amongst assessments, although the governing principle should be to adequately represent processes that may affect the likelihood of exposure.

The *OIE Code* provides a list of factors that may be considered when identifying or describing the steps in exposure scenarios. These factors are not steps as such, but considerations that should be borne in mind when identifying and describing the scenarios. These factors should also be considered when assigning likelihoods to the component steps, as will be described in the following section (see, Evaluation of Likelihood).

Factors contributing to exposure scenarios

Biological factors

- properties of the agent

Country factors

- presence of potential vectors
- human and animal demographics
- customs and cultural practices
- geographical and environmental characteristics

Commodity factors

- quantity of commodity to be imported
- intended use of the imported animals or products
- disposal practices

As for release assessments, scenario diagrams or 'trees' should be constructed to illustrate scenarios and to communicate the process of likelihood evaluation. The principle behind this form of representation is that 'events' are described in boxes or 'nodes', whereas the probability or likelihood to be ascribed to each event is associated with the arrows emanating from its respective node.

An example of each of the three generalised configurations for exposure scenarios is shown in Figure 10 – Figure 12, respectively. Note that the initiation point is always 'the arrival in Australia of contaminated commodity', but that the scenarios that follow are determined by the nature of the imported commodity. These scenario diagrams will form the basis for likelihood evaluation, as described in the following section.

Figure 10 An exposure scenario for the importation of widget vaccine

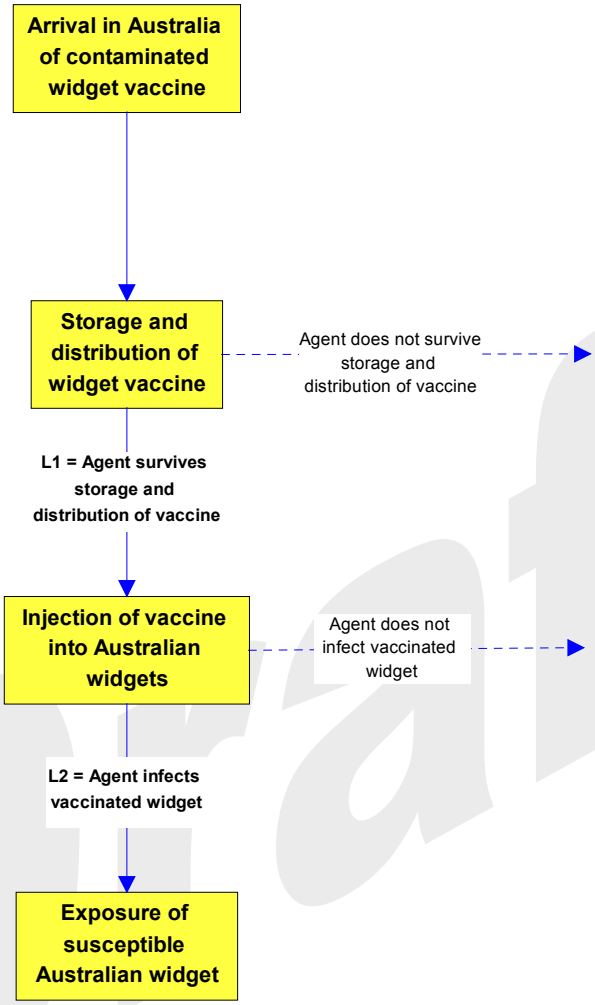


Figure 11 Exposure scenarios for the importation of live widgets

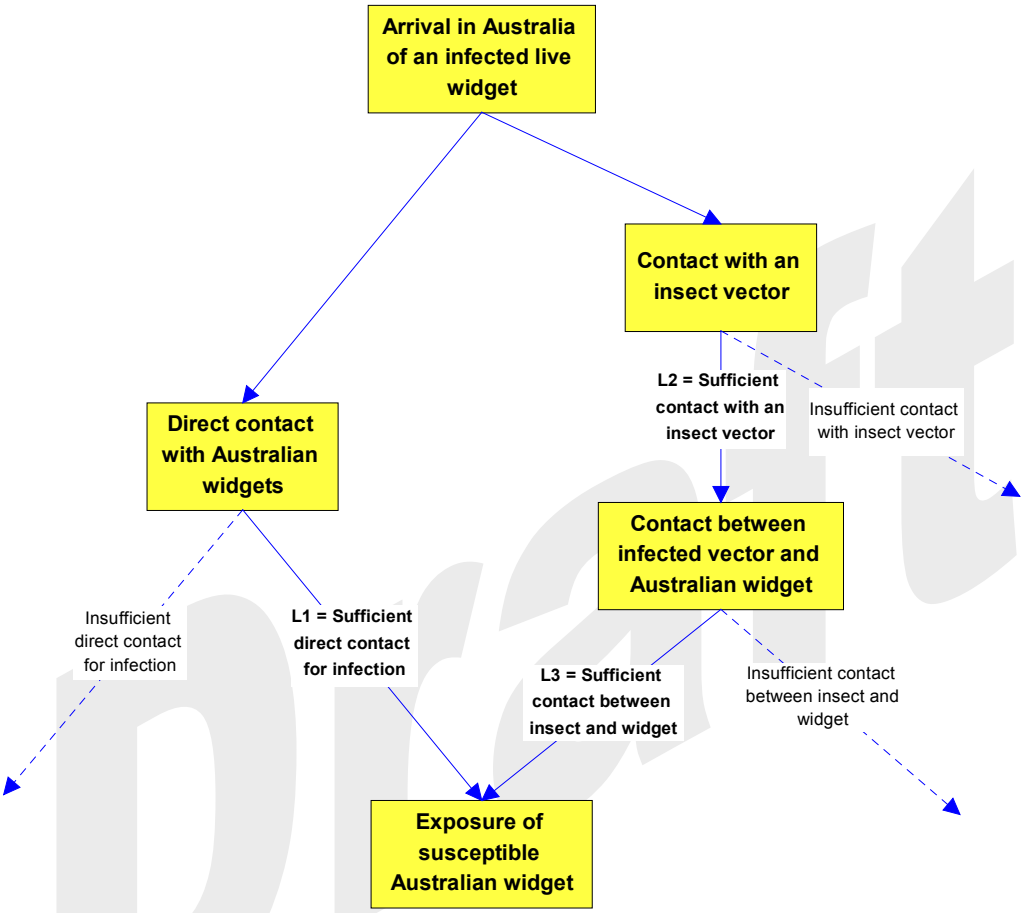
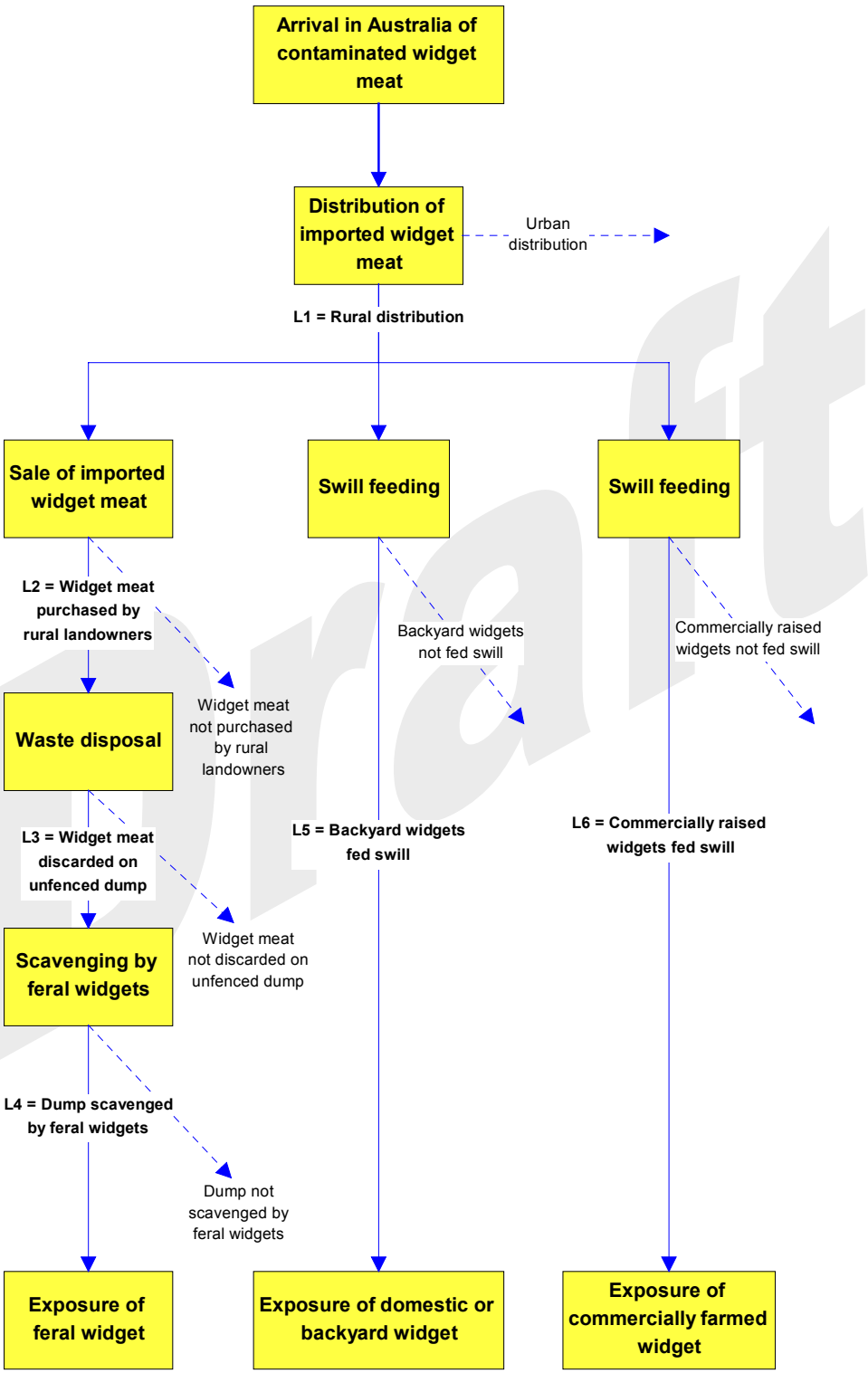


Figure 12 Exposure scenarios for the importation of widget meat[22]



[22] It is assumed in these entirely hypothetical exposure scenarios that widgets are only found in rural areas.

Evaluation of likelihood

In the second phase of the exposure assessment, likelihoods are ascribed to the steps in each identified exposure scenario. In some situations, it may subsequently be useful to combine these step-level likelihoods to estimate the overall likelihood of exposure. Alternatively, it may be more appropriate to assign the likelihoods to steps in scenarios, but to calculate the overall likelihood of entry *and* exposure at the close of the risk assessment (see, Risk Estimation). The approach adopted will generally be determined by the complexity of the exposure scenarios, and whether the exposure assessments are to be carried out 'qualitatively', 'semi-quantitatively' or 'quantitatively', or using a mixture of these approaches.

The principles of qualitative, semi-quantitative and quantitative likelihood evaluation have been described in the discussion of release assessment, and will not be reiterated except to state that the approach adopted should provide for the following:

- an assessment based on sound scientific principles
- an assessment that is structured and transparent
- an assessment that is internally consistent, and that can be repeated (with the same or a similar outcome) by another operator using the same framework and data
- an outcome that will support the estimation of 'risk' (a combination of likelihood and consequences)
- an outcome that will enable risk to be evaluated against Australia's ALOP, or tolerance for loss
- a framework within which the efficacy of risk management and the acceptability of a mitigated risk can be evaluated.

Likelihood evaluation for each of the three configurations of exposure scenarios will be discussed below.

Single scenario / single end point

This configuration is identical to that described in the discussion of release assessment — given this, it follows that the method for evaluating likelihood will also be identical.

Multiple scenarios / single end point

This configuration was illustrated using the hypothetical example of the importation of live widgets, as shown in Figure 11. The challenge with this configuration is to combine likelihoods ascribed to the separate steps in such a way as to convey the relative importance of each branch of the scenario diagram.

Two factors may influence the relative importance of a particular branch of the exposure scenario diagram. Firstly, it may be relevant to consider the relative 'volume' of commodity physically distributed to that pathway. For example, if the branch described direct contact between imported live animals and susceptible animals in Australia, then the proportion of live animals that would be distributed directly to recipient herds should be considered. The second factor affecting the importance of a branch will be the likelihoods assigned to individual steps. Examples of this might be the likelihood that unsuitable vectors in Australia would adapt to become competent hosts for an introduced agent, or the likelihood that a live zoo animal would escape and come into contact with susceptible domestic species. Either of these likelihoods might lead to the given path being considered relatively unimportant.

The relative importance of each branch of a scenario diagram is described in this document as the 'partial likelihood of exposure' (abbreviated as PLE in formulae and figures). Each partial likelihood of exposure can be derived using one of the three approaches (qualitative, semi-quantitative or quantitative) outlined in the discussion of release assessment. Because each branch of the exposure scenario represents a single linear series of steps or events, the method used to derive a partial likelihood of exposure will be identical to that described in the discussion of release assessment.

Once the partial likelihood of exposure has been derived, it remains to determine the overall likelihood of exposure (LE). This can be stated in several ways, but one that is logical in the quarantine context is:

> *the likelihood that exposure of susceptible animals will occur by at least one of the available pathways.*

Algebraically, this is equivalent to one minus (i.e. 'the complement of') the likelihood that exposure does not occur by any of the available pathways. The likelihood that exposure does not occur by *any* of the available pathways will be the product of the complement of each. The likelihood of exposure can best be described in the equation:

$$LE = 1 - (1 - PLE_1) \times (1 - PLE_2) \times (1 - PLE_3) \times ... (1 - PLE_n)$$

The approach adopted in applying the principle behind this equation will depend upon whether the partial likelihoods (PLE_1, PLE_2, …etc.) have been obtained using a qualitative, semi-quantitative or quantitative approach.

Where partial likelihoods have been evaluated *qualitatively*, decision rules for determining their 'complements' must be derived. When partial likelihoods have been obtained by using a matrix of decision rules (Table 6), and this matrix is based on the products of the midpoints of corresponding probability intervals, it is sensible to use the same approach to derive complements for the qualitative likelihoods (that is, to subtract their midpoints from one, and report the category in which the result falls).

The results of this procedure are shown in Table 11.

Table 11 Complements of qualitative likelihoods

Original qualitative likelihood		Complement
Term	*Descriptive definition*	
High	The event would be very likely to occur	Low
Moderate	The event would occur with an even probability	Moderate
Low	The event would be unlikely to occur	High
V. Low	The event would be very unlikely to occur	High
E. Low	The event would be extremely unlikely to occur	High
Negligible	The event would almost certainly not occur	High

After complements of the qualitative partial likelihoods of exposure have been obtained, they need to be inserted into the equation shown on the previous page. The multiplication of qualitative likelihoods will be done using the matrix described in the discussion of release assessment (Table 6). The complement of the final product will then be obtained by using the rules shown in Table 11. The result of this procedure will be a qualitative estimate for '*the likelihood that exposure of susceptible animals will occur by at least one of the branches or pathways described in the exposure scenario diagram*'.

Where the partial likelihoods ascribed to each branch of the exposure scenario have been derived *semi-quantitatively* (using the simulation-based approach) or *quantitatively*, the equation can simply be inserted into the mathematical logic of the quantitative model.

Multiple scenarios / multiple end points

This configuration is illustrated in the hypothetical example of the importation of widget meat, as shown in Figure 12. The distinguishing feature of this type of scenario is that it will *not* generally be desirable to combine the branches to derive an estimate for the overall likelihood of exposure. The reason for this will be discussed in further detail in the descriptions of consequence assessment and risk estimation but, in brief, hinges on the fact that the 'risk' associated with each distinct end point, or category of exposed animals, is not reliant on others and should be treated separately.

After partial likelihood of exposure for each branch of the scenario tree has been derived, the likelihood evaluation component of the exposure assessment will be complete. Whether assessments are carried out qualitatively, semi-quantitatively or quantitatively, the partial likelihoods can be derived in the same manner as described in the discussions above and the discussion of release assessment.

The result of an exposure assessment based on the multiple scenarios and multiple end points configuration will therefore be a series of partial likelihoods of exposure.

Conclusions: exposure assessment

Describing the scenario component of exposure assessment will frequently be more complicated than describing release assessments. Three general configurations have been identified and, in general, an exposure assessment can be fitted to one of these.

It should be noted, however, that this document is intended to provide 'guidelines', and not a definitive description of all possible forms of exposure assessment. It may, for example, be appropriate to construct an exposure scenario in which one of the more complicated configurations is 'nested' within the other. Where complications arise, it will be necessary to break the scenario down into its fundamental components (as would be attempted if it were an electrical wiring diagram) and address each using the principles described in this document.

Consequence assessment

According to the *OIE Code*, a consequence assessment should *describe the potential consequences of a given exposure, and estimate the probability of them occurring*.

The 'potential consequences of an exposure' may be accrued in several direct and indirect ways. These have collectively been termed 'consequence criteria', and are discussed below. The probability that a particular outcome will occur will be determined by factors associated with

'establishment' and 'spread' of the disease, given exposure of a susceptible animal(s). Estimation of the establishment and spread of disease is discussed under the heading 'consequence assessment scenarios'.

Criteria for assessing consequences

Criteria for assessing the consequences associated with a pest or disease are outlined in the relevant acts and agreements, and in the standards prepared by the relevant international organisations.

In particular:

- the *Quarantine Act* requires decision-makers to take into account the likelihood of harm being caused (to humans, animals, plants, other aspects of the environment, or economic activities) and the probable extent of the harm (Section 5D)
- the *SPS Agreement* states that:

  Members shall take into account as relevant economic factors; the potential damage in terms of loss of production or sales in the event of 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
- OIE and IPPC expand the 'relevant economic factors' described in the *SPS Agreement* to differentiate between the 'direct' and 'indirect' effects of a disease, and to provide examples of factors that will typically be relevant to an import risk analysis.

In each case, consequence assessments do not extend to considering the benefits or otherwise of trade in a given commodity, nor to the impact of import competition on industries or consumers in the importing country.

In these *Guidelines*, the criteria described by OIE and IPPC have been combined, to give an approach to consequence assessment that can be applied to animals and plants and their products.

This approach is outlined below.

Direct consequences

Direct harm to:

- animal or plant life, health or welfare (whether native or introduced species), including animal and plant production losses
- human life, health or welfare
- any other aspects of the environment not covered above (e.g. the physical environment or other life forms — microorganisms, etc.).

Indirect consequences

Indirect consequences are the costs resulting from natural or human processes associated with the incursion of a disease:

- new or modified eradication, control, surveillance/monitoring and compensation strategies/programs
- domestic trade or industry effects, including changes in consumer demand and effects on other industries supplying inputs to, or utilising outputs from, directly affected industries

- international trade effects, including loss of markets, meeting new technical requirements to enter/maintain markets and changes in international consumer demand
- indirect effects on the environment (see below), including biodiversity, endangered species, the integrity of ecosystems, reduced tourism, reduced rural and regional economic viability and loss of social amenity, and any 'side effects' of control measures.

A range of factors may be relevant to the consideration of harm to the environment, including those arising from the impact of the disease agent itself or from any treatments or procedures used to control it. The extent of harm should be evaluated taking into account the circumstances of the particular hazard using the schema that follows. Factors that should be considered include:

- all on-site and off-site impacts
- the geographical scope and magnitude of the impact
- the frequency and duration of the action causing the harm
- the total impact which can be attributed to that action over the entire geographic area affected, and over time (i.e. cumulative impact)
- any synergistic effect of hazards on impact
- reversibility of the impact
- the sensitivity of the receiving environment (recognised environmental features of high sensitivity)
- the degree of confidence with which the impacts of the action are known and understood.

The direct and indirect criteria described above collectively cover the *economic*, *environmental* and *social* effects of a disease. Given this, the criteria are also intended to be mutually exclusive — that is, an effect should not be assessed more than once. In particular, the direct effects of a disease on a native or wild species should be assessed under the criterion describing the '*animal or plant life, health or welfare*', whereas the indirect or 'flow-on' effects on the environment should be assessed under the last indirect criterion.

Consequence assessment scenarios

As stated above, a consequence assessment should include:

- an assessment of the criteria upon which a disease may impact (the 'consequence criteria' — as described)
- an evaluation of the *likely magnitude of consequences*, and the *likelihood that they will occur at any given magnitude.*

Ultimately, the establishment and spread component of a consequence assessment would be carried out as a discrete-event simulation exercise, using epidemiological parameters and the principles of economic modelling. This approach will not generally be practicable, and a simpler alternative is to identify and describe a small number of likely 'outbreak scenarios'. It should then be possible to estimate the relative likelihood that each scenario will occur (the likelihood of establishment and spread)[23], and the likely magnitude of the consequences in each case.

[23] In the context of import risk analysis, 'establishment' is taken to mean the establishment of a pathogenic agent within the exposed population/sub-population, whereas 'spread' implies the subsequent spread of the agent to other susceptible populations/sub-populations.

As an example, consider a consequence assessment for a disease associated with the importation of live production animals. It is evident that the optimal means by which to assess the possible impact of a disease introduced through live animals would be to construct a rigorous GIS-based discrete-event simulation model. This has been undertaken by several countries,[24] but is extremely costly and generally impractical for individual import risk analyses.

The alternative to a complex model is to consider a small number of likely 'outbreak scenarios'. For example, in the case of live animals these might include:

- disease does not establish within exposed population/sub-population
- disease establishes within exposed population/sub-population, but is identified and eradicated
- disease establishes within exposed population/sub-population and spreads to other populations before being eradicated
- disease establishes within exposed population/sub-population, spreads to other populations and becomes endemic in Australia.

After a small number of discrete outbreak scenarios have been identified and characterised, it will remain to determine:

- the likelihood that each will occur — that is, the 'partial likelihood of establishment and spread' (PLES) [25]
- the likely consequences according to each of the defined direct and indirect criteria (as discussed above).

The partial likelihood of establishment and spread can be estimated qualitatively, semi-quantitatively or quantitatively. Similarly, the consequences according to each direct and indirect criterion may be estimated using a purely economic scale, or using some form of non-economic (qualitative or semi-quantitative) scale. Some effects, such as change in commercial production, are relatively easy to measure. Others, such as change in social amenity or to biodiversity, are more difficult.

Direct and indirect consequences are estimated at each of four levels — local, district, regional and national. In this context, 'local', 'district', 'regional' and 'national' effects have been described as follows:[26]

Local: an aggregate of households or enterprises — e.g. 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, such as the 'North West Slopes and Plains' or 'Far North Queensland'

[24] For example, the InterSpread simulation model (a module within the disease control decision support system EpiMAN), is a tool developed in New Zealand for modelling contagious diseases and their economic consequences

[25] One of the outbreak scenarios listed has been described as 'disease does not establish'. When this scenario is included, the sum of all of the partial likelihoods of exposure and spread will equal one.

[26] When assessing the local, district, regional and national consequences, the frame of reference should be the impact of the disease on the community as a whole. This will often differ markedly from the effect of the disease on the local, district, regional or national population of directly affected parties.

Region: a geographically or geopolitically associated collection of districts — generally a state, although there may be exceptions with larger states such as Western Australia

National: Australia-wide

At each level, the quantum of impact is described as 'unlikely to be discernible', of 'minor significance', 'significant' or 'highly significant':

- an '*unlikely to be discernible*' impact is not usually distinguishable from normal day-to-day variation in the criterion
- an impact of '*minor significance*' is not expected to threaten economic viability, but would lead to a minor increase in mortality/morbidity or a minor decrease in production. For non-commercial factors, the impact is not expected to threaten the intrinsic 'value' of the criterion — though the value of the criterion would be considered as 'disturbed'. Effects would generally be reversible
- a '*significant*' impact would threaten economic viability through a moderate increase in mortality/morbidity, or a moderate decrease in production. For non-commercial factors, the intrinsic 'value' of the criterion would be considered as significantly diminished or threatened. Effects may not be reversible
- a '*highly significant*' impact would threaten economic viability through a large increase in mortality/morbidity, or a large decrease in production. For non-commercial factors, the intrinsic 'value' of the criterion would be considered as severely or irreversibly damaged.

When considering the extent of consequences of a disease, it will be important to consider the persistence of its effects. In general, where the effect is prolonged, as may be the case if it persists for several production cycles for production animals, or if regeneration of an ecosystem would take several generations, the consequences are considered to be greater. If the effect is not prolonged, then consequences are likely to be less serious. In either case, it may be necessary to place the disease into the next higher or lower level for that consequence criterion.

The consequences of the introduction, establishment and spread of a pest or disease are considered *for each consequence criterion* at the local, district, regional and national level. These four values are translated to a range (A–F) using the schema outlined in Table 12.

Table 12 The assessment of local, district, regional and national consequences

Impact score				
F	-	-	-	Highly significant
E	-	-	Highly significant	Significant
D	-	Highly significant	Significant	Minor
C	Highly significant	Significant	Minor	Unlikely to be discernible
B	Significant	Minor	Unlikely to be discernible	Unlikely to be discernible
A	Minor	Unlikely to be discernible	Unlikely to be discernible	Unlikely to be discernible
	Local	*District*	*Regional*	*National*
			Level	

After obtaining a measure of individual direct and indirect consequences of a disease, these need to be combined to estimate the overall consequences associated with an outbreak scenario. Intuitively, individual effects on each direct and indirect criterion should be summed, because these outcomes will be 'additive'. However, because the system is qualitative, true summation is not possible and the following rules have been developed to provide an approximate solution. The rules are mutually exclusive, and should be addressed in the order that they appear in the list. For example, *if the first set of conditions does not apply, the second set should be considered. If the second set does not apply, the third set should be considered* ..., and so forth until one of the rules applies:

1. Where any direct or indirect effect is 'F', the overall consequences associated with the outbreak scenario are considered to be 'extreme'.
2. Where more than one direct or indirect effect is 'E', the overall consequences associated with the outbreak scenario are considered to be 'extreme'.
3. Where a single direct or indirect effect is 'E' and each remaining direct or indirect effect is 'D', the overall consequences associated with the outbreak scenario are considered to be 'extreme'.
4. Where a single direct or indirect effect is 'E' and remaining direct and indirect effects are not unanimously 'D', the overall consequences associated with the outbreak scenario are considered to be 'high'.
5. Where all direct and indirect effects are 'D', the overall consequences associated with the outbreak scenario are considered to be 'high'.
6. Where one or more direct or indirect effect is 'D', the overall consequences associated with the outbreak scenario are considered to be 'moderate'.
7. Where all direct and indirect effects are 'C', the overall consequences associated with the outbreak scenario are considered to be 'moderate'.
8. Where one or more direct or indirect effect is 'C', the overall consequences associated with the outbreak scenario are considered to be 'low'.
9. Where all direct and indirect effects are 'B', the overall consequences associated with the outbreak scenario are considered to be 'low'.
10. Where one or more direct or indirect effect is 'B', the overall consequences associated with the outbreak scenario are considered to be 'very low'.

11. Where all direct and indirect effects are 'A', the overall consequences associated with the outbreak scenario are considered to be 'negligible'.

Having obtained an estimate of the consequences associated with each outbreak scenario, it remains to combine this with the likelihood that the scenario will occur and thus derive a scenario-specific measure of 'likely consequences', or 'risk'.

The matrix in Table 13 can be used to combine likelihood and consequences. By applying the table systematically, likely consequences can be derived for each identified outbreak scenario.

Table 13 Likely consequences: a combination of the likelihood of establishment and spread and its consequences

Probability of establishment and spread	Negligible	Very low	Low	Moderate	High	Extreme
High	Negligible	Very low	Low	Moderate	High	Extreme
Moderate	Negligible	Very low	Low	Moderate	High	Extreme
Low	Negligible	Negligible	Very low	Low	Moderate	High
V. Low	Negligible	Negligible	Negligible	Very low	Low	Moderate
E. Low	Negligible	Negligible	Negligible	Negligible	Very low	Low
Negligible	Negligible	Negligible	Negligible	Negligible	Negligible	Very low
	Negligible	*Very Low*	*Low*	*Moderate*	*High*	*Extreme*

Consequences of establishment and spread

After an estimate of the 'likely consequences' associated with each outbreak scenario has been obtained, remaining stages of the consequence assessment will depend on the complexity of the exposure scenario (see Exposure Assessment).

Note that although there is a huge range of possible exposure scenarios, there are only three basic 'configurations' (levels of complexity):

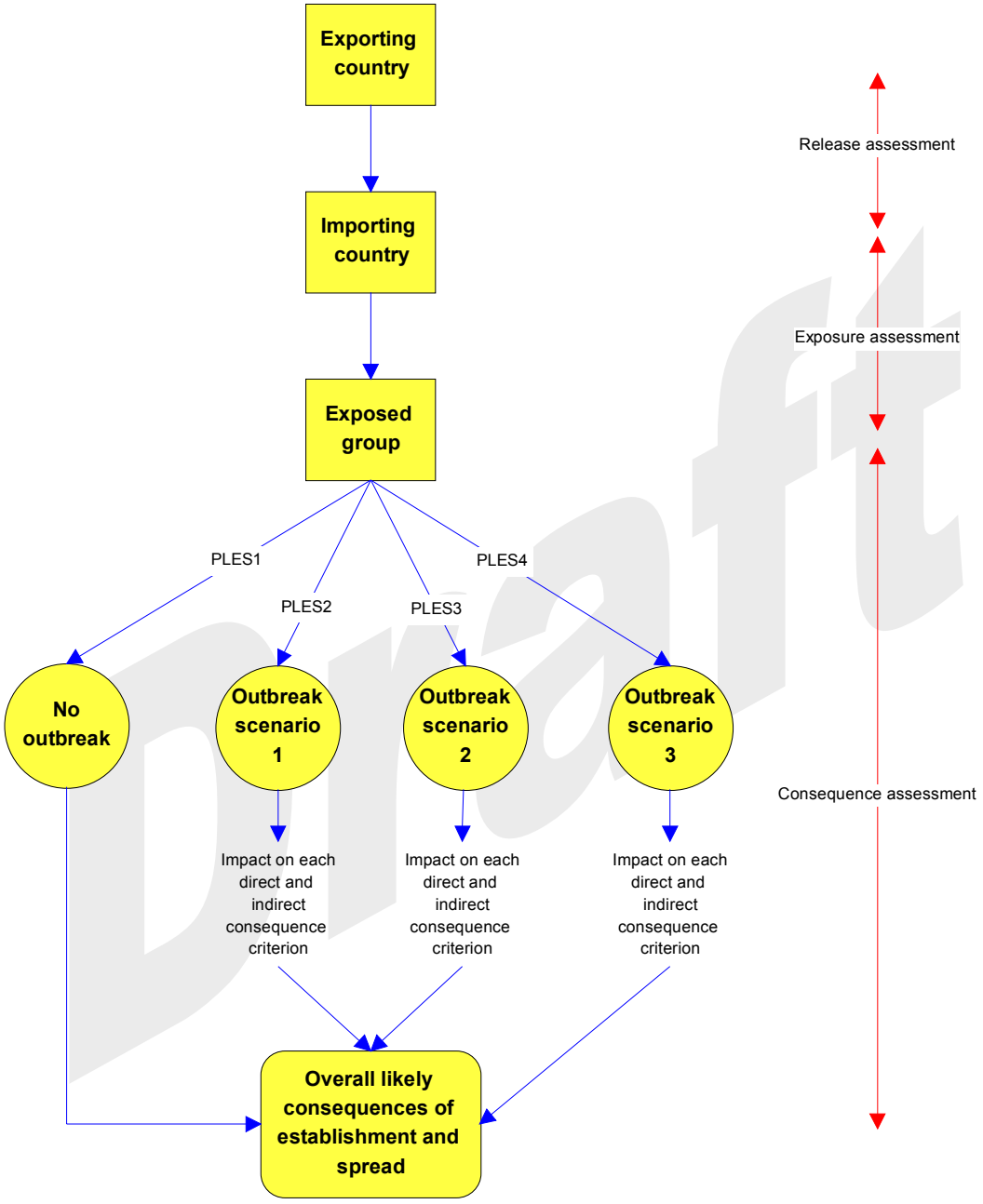
- a single exposure pathway leading to a single end point
- multiple exposure pathways leading to a single end point
- multiple exposure pathways leading to multiple end points.

With respect to consequence assessment and risk estimation (as discussed below), the important difference between these scenarios is whether or not there is a single 'end point', or group of exposed animals. Where there is only one important group of exposed animals (as was the case for the imported vaccine example) it is evident that there will also be a single set of 'outbreak scenarios'. Where there are several different groups of exposed animals (as in the imported widget meat example), each group will have its own set of outbreak scenarios.

Consequence assessment with a single group of exposed animals

Consequence assessment with a single group of exposed animals is illustrated in Figure 13.

Figure 13 Consequence assessment with a single exposed group



The likely consequences associated with each outbreak scenario has been described above, and it remains to 'sum' these across all identified scenarios to give an overall estimate — as described in the *OIE Code*.

Because the likely consequences associated with each of the outbreak scenarios will not have been derived quantitatively, these cannot be 'summed' in the usual sense. Instead, a system of eleven rules (similar to those described in the previous section) has been developed to provide a conservative approximation. These rules are mutually exclusive, and should be addressed in the

order that they appear in the list. For example, *if the first set of conditions does not apply, the second set should be considered. If the second set does not apply, the third set should be considered* ..., and so forth until one of the rules applies:

1. Where the likely consequences for any outbreak scenario are 'extreme', the overall likely consequences are also considered to be 'extreme'.
2. Where the likely consequences for more than one outbreak scenario are 'high', the overall likely consequences are considered to be 'extreme'.
3. Where the likely consequences for a single outbreak scenario are 'high' and the likely consequences for each remaining scenario are 'moderate', the overall likely consequences are considered to be 'extreme'.
4. Where the likely consequences for a single criterion are 'high' and the likely consequences for remaining criteria are not unanimously 'moderate', the overall likely consequences are considered to be 'high'.
5. Where the likely consequences for all criteria are 'moderate', the overall likely consequences are considered to be 'high'.
6. Where the likely consequences for one or more criteria are 'moderate', the overall likely consequences are considered to be 'moderate'.
7. Where the likely consequences for all criteria are 'low', the overall likely consequences are considered to be 'moderate'.
8. Where the likely consequences for one or more criteria are 'low', the overall likely consequences are considered to be 'low'.
9. Where the likely consequences for all criteria are 'very low', the overall likely consequences are considered to be 'low'.
10. Where the likely consequences for one or more criteria 'very low', the overall likely consequences are considered to be 'very low'.
11. Where the likely consequences for all criteria are 'negligible', the overall likely consequences are considered to be 'negligible'.

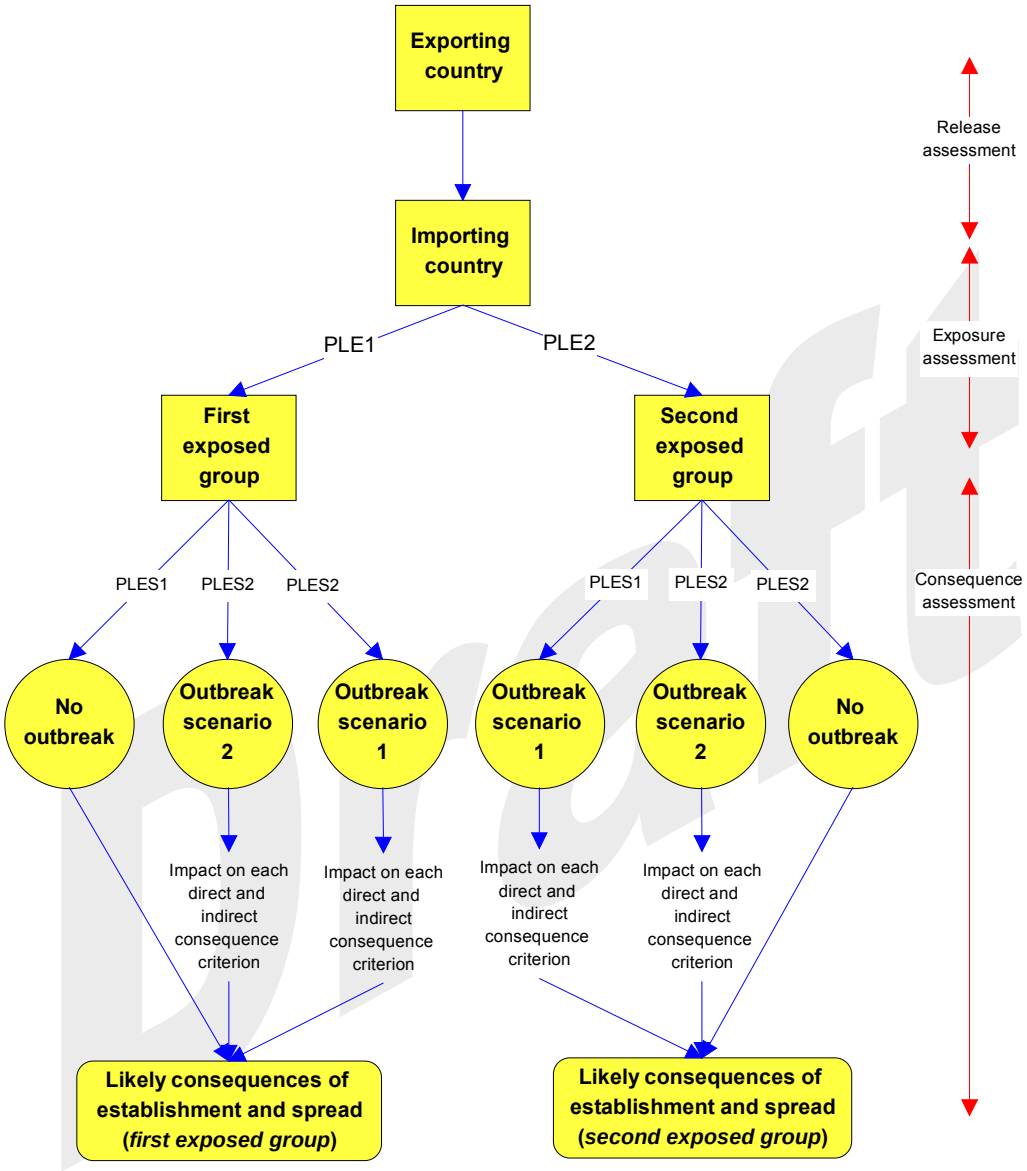
The result of the complete process will be a qualitative descriptive estimate for the likely consequences associated with the introduction of a particular disease into the importing country. This estimate will have been derived systematically and in a transparent manner, and will be based on a consideration of the effect that establishment and spread may have on the exposure of the single group of susceptible animals in the importing country.

Consequence assessment with more than one group of exposed animals

Consequence assessment with more than one exposed group is illustrated in Figure 14. The branches emanating from each of the exposed groups have the same structure as the assessment for single exposure groups described above.

One means by which consequence assessments can be carried out for these more complex exposure scenarios is to obtain a separate consequence assessment for each exposure branch in the manner described above. These separate estimates may then be combined with the release assessment and the relevant partial likelihood (as obtained during the exposure assessment). This procedure will be described in the following section.

Figure 14 Consequence assessment with more than one exposed group



Risk estimation

Risk estimation entails the integration of likelihood evaluation and consequence assessment, with the objective of deriving a measure of the 'risk' associated with each pathogenic agent. The procedure used to integrate the various components of the risk assessment will depend upon several factors, including:

- whether each component was obtained using a qualitative, semi-quantitative or quantitative approach
- whether one or more than one group of exposed animals was identified

- the manner in which the volume of trade during a specified period[27] is to be included in the assessment.

Although it is generally accepted that the volume of trade during a given period may have a marked effect on various likelihoods calculated or derived during a risk assessment, this aspect of import risk analysis remains relatively experimental. Where likelihoods obtained for the release and exposure assessment are calculated semi-quantitatively or quantitatively, the effect of trade volume can be assessed relatively easily. One approach to this would be to construct a separate module to determine the number of 'units' of a commodity that are likely to enter the importing country during a year, and to modify the likelihoods obtained for the release and exposure assessments accordingly. An alternative approach is to carry out release and exposure assessments in which the likelihoods assigned to particular steps are based on trade volume.

Where the release and/or exposure assessment has been carried out qualitatively, a practical approach will be needed. The adjustment of qualitative descriptors to accommodate the consideration of trade volume is not a technically ideal proposition. Given this, it is also imperative that the effect of trade volume be investigated and documented, because this may have a significant bearing on the importing country's decision to vary risk management measures, depending on the annual volume of imports.

One solution for qualitative assessments may be to state at the start of the risk assessment that *all* likelihoods have been assigned or derived under the implicit assumption that they refer to the volume of commodity likely to be imported in a given period. However, because estimates assigned on this basis will be more difficult to defend, the approach is likely to be problematic. A more preferable solution for situations that require consideration of the effect of trade volume would be to provide a quantitative or semi-quantitative assessment, either as an embellishment of the qualitative assessment or in place of it.

Incorporation of an assessment of the effect of trade volume is explained in further detail with reference to the two broad types of exposure assessment:

- risk estimation for assessments with a single identified exposure group
- risk estimation for assessments with more than one exposure group.

Risk estimation with a single identified exposure group

It was shown in the previous discussions that, where a single exposure group has been identified, the risk assessment would yield the following (qualitative, semi-quantitative or quantitative) results:

- the likelihood of entry
- the likelihood of exposure
- the likely magnitude of consequences.

In addition, it was explained that, where possible, trade volume should also be investigated and should be included in the process of risk estimation. Trade volume can be included in the release or exposure assessment, or examined at the completion of an assessment. The latter is considered more transparent. If trade volume is to be included at the completion of an assessment, it will be necessary to carry out the release and exposure assessments using a suitable 'basic unit'. For

[27] The *OIE Code* suggests that 1 year be adopted as period of time by which to evaluate the effect of a projected volume of trade.

example, if the commodity were 'live animals' then the individual animal would be a suitable basic unit. If the commodity is genetic material, then either an individual straw of semen or an individual embryo might be suitable. Alternatively, it may be more sensible to consider consignments of these commodities. Commodities for human consumption will generally be more complex, because they are invariably broken up or repackaged during the importation and/or exposure process.

After the most appropriate basic unit has been determined, the release and exposure assessments should be multiplied to give the likelihood of entry and exposure. Where both of the components have been estimated semi-quantitatively or quantitatively, this will be a mathematical procedure and can be incorporated in the spreadsheet model.[28] Where one or other components has been evaluated qualitatively, then it will be necessary to combine them by using the approaches described in the discussion of qualitative and semi-quantitative release and exposure assessment.

The likelihood of entry and exposure, once obtained, may be modified by considering trade volume. The appropriate result of this procedure will be a likelihood phrased as '*the likelihood that a given disease will be introduced at least once as a result of importing a given commodity for 1 year*'. Algebraically, this probability can be expressed as:

$$LEE_{annual} = 1 - (1 - LEE)^{VT}$$

where,

LEE_{annual}	is the annual likelihood of entry and exposure — that is, the likelihood that a given disease will be introduced as a result of importing the commodity for 1 year
LEE	is the likelihood of entry and exposure, expressed in terms of the chosen 'basic unit'
VT	is the volume of trade, expressed as the number of basic units imported during 1 year

After an estimate for the likelihood of entry has been obtained and expressed in units that reflect the likely trade volume, this can be combined with the assessment of consequences to derive a risk estimate. Where all components of the risk assessment are quantitative, this will simply be a mathematical procedure. In the more common situation where there are one or more qualitative elements, then a set of 'decision rules' will be required.

The risk estimation matrix shown in Table 14 provides one means by which decision rules can be intuitively displayed. The cells in the matrix represent 'expected loss' — that is, the combination of a measure of consequences and a measure of likelihood. Accordingly, risk will always be expressed in the same 'units' as consequences, and must be less than or equal to the original estimate of consequences.

[28] The mechanics of the model may be such that this step is more complex than simple 'multiplication'.

To illustrate by example:

If when tossing a coin, the likelihood of a head is 0.5 and the loss associated with it is $10, then the 'expected loss' or 'risk' will be expressed in dollars, and cannot be more than $10. In fact, the expected loss in this example is given by, $10 x 0.5 = $5.

A 2 x 2 risk estimation matrix could be drawn up for coin tossing. The purpose of the risk estimation matrix is thus to illustrate what is generally an intuitive relationship between 'likelihood' and 'consequences', and to formalise the rules that determine the result when specific values of each are combined.

If trade volume has been considered, the cells in the matrix (Table 14) represent 'the risk associated with the importation of a given commodity for 1 year'. Interpretation of the risk estimation matrix according to Australia's ALOP, or tolerance for loss, is discussed in the following section (see Risk Management).

Table 14 Risk estimation matrix

Likelihood of entry and exposure	Negligible impact	Very low	Low	Moderate	High	Extreme impact
High likelihood	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 likelihood	Negligible risk	Negligible risk	Negligible risk	Negligible risk	Negligible risk	Very low risk

Consequences of entry and exposure

Risk estimation with more than one exposure group

It was shown in earlier discussions that, where more than one exposure group has been identified, the risk assessment would yield the following qualitative, semi-quantitative or quantitative results:

- the likelihood of entry
- the partial likelihood of exposure for *each identified exposure group*
- the likely consequences for *each identified exposure group*.

As was the case for the more simple exposure scenarios, it may be necessary to add an assessment of trade volume to this list and to include it in the process of risk estimation. The role of the 'basic unit' in which a commodity is imported will be identical to that described above. Indeed, the only difference between risk estimation for single versus multiple exposure scenarios will be the manner in which the partial likelihoods of exposure are combined.

In the scenario diagram shown in Figure 14 there are essentially two distinct branches emanating from the two exposure groups and persisting through the assessment of consequences. This is sensible, because both consequence scenarios and the likely impact of a disease will most probably be different for each of the identified exposure groups. Accepting this, the risk estimation with multiple exposure scenarios will be carried out in two stages:

- an evaluation of the 'partial risk' associated with each branch of the exposure scenario
- the combination of partial risk for each exposure group to give an estimate of the 'overall risk' associated with the commodity.

The partial risk associated with each exposure group will be evaluated in essentially the same manner as described in the discussion of simple exposure pathways, the only difference being the replacement of the 'likelihood of exposure' with the 'partial likelihood of exposure'. Given this, the release assessment and each partial likelihood of exposure can be combined as described above, and the result modified to incorporate an estimate of the annual volume of trade. This likelihood can then be combined with the assessment of consequences to give the 'partial risk' associated with each exposure group. The process can be undertaken using the risk estimation matrix (Table 14).

After a partial risk estimate has been obtained for each of the identified groups of exposed animals, these can be combined to give an overall estimate of annual risk. Where the estimates are purely quantitative, this will be achieved mathematically. In the more common situation where at least one component is qualitative or semi-quantitative, and the qualitative or semi-quantitative terminology described throughout this document has been adopted, partial risks can be combined by applying the eleven decision rules shown below. These rules are mutually exclusive, and should therefore be addressed in the order that they appear in the list. For example, *if the first set of conditions does not apply, the second set should be considered. If the second set does not apply, the third set should be considered ...*, and so forth until one of the rules applies.

1. Where any one partial risk is 'extreme', the overall risk is also considered to be 'extreme'.
2. Where more than one partial risk is 'high', the overall risk is considered to be 'extreme'.
3. Where any one partial risk is 'high' and each remaining partial risk is 'moderate', the overall risk is considered to be 'extreme'.
4. Where a single partial risk is 'high' and the remaining partial risks are not unanimously 'high', the overall risk is considered to be 'high'.
5. Where all partial risks are 'moderate', the overall risk is considered to be 'high'.
6. Where one or more partial risks are 'moderate', the overall risk is considered to be 'moderate'.
7. Where all partial risks are 'low', the overall risk is considered to be 'moderate'.
8. Where one or more partial risks are 'low', the overall risk is considered to be 'low'.
9. Where all partial risks are 'very low', the overall risk is considered to be 'low'.
10. Where one or more partial risks are 'very low', the overall risk is considered to be 'very low'.
11. Where all partial risks are 'negligible', the overall risk is considered to be 'negligible'.

When trade volume has been considered, the result of the procedure will be an estimate of the risk associated with importing a given commodity for 1 year. Interpretation of this result according to Australia's ALOP, or tolerance for loss, is discussed in the following section.

RISK MANAGEMENT

Risk management describes the process of identifying and implementing measures to mitigate risks and so achieve the importing country's ALOP, or tolerance for loss, while ensuring that any negative effects on trade are minimised. As described previously in this document (see, Appropriate Level of Protection), ALOP is considered a societal value judgement that reflects the maximal risk (or expected loss) from a disease incursion that Australia considers 'acceptable'.

According to the *SPS Agreement*, Members should base risk management on a *consistent* level of acceptable risk. That is, a Member Country should exercise a single ALOP for animals/plants and their products (a separate ALOP may be applied to human health). This requirement means that the outcome of measures imposed on one commodity should not be more 'risk averse' or 'risk seeking' than the outcome of measures imposed on other commodities, whether from the same exporting country or different exporting countries.

To implement risk management appropriately, it is necessary to recognise the difference between 'unrestricted' and 'restricted' risk estimates. Unrestricted risk estimates are those derived in the complete absence of any risk management; or using only internationally accepted baseline risk management strategies (e.g. the International Embryo Transfer Society guidelines for embryo collection, handling and transfer, or ante- and post-mortem inspection of beef). In contrast, restricted or mitigated risk estimates are those derived when 'risk management' is applied.

The result of the 'risk assessment' for a given commodity (as described in the preceding section) will be a list of 'unrestricted risk estimates' corresponding to the list of identified hazards. These unrestricted risk estimates should each be compared with Australia's ALOP, which is shown in the risk estimation matrix (Table 14) as the band of cells associated with a 'very low' risk.

An unrestricted risk that is either 'negligible' or 'very low' meets Australia's ALOP and should be considered 'acceptable'. In this situation, risk management is not justified. Where an unrestricted risk is 'low', 'moderate', 'high' or 'extreme', however, risk management measures would need to be identified and applied and, for each of these, the restricted risk should be calculated. This process is termed 'option evaluation' in the *OIE Code*.

Where the restricted risk derived using a particular risk management measure (or combination of measures)[29] is 'very low', that measure(s) should be considered acceptable. Where the restricted risk derived using a particular risk management measure (or combination of measures) is 'negligible', the measure(s) *may* be considered unnecessarily trade-restrictive, and a reassessment of the measures imposed is justified (taking into account the availability and feasibility of alternative measures). Where possible, risk management measures that are overly restrictive on trade should either be rejected, or should be manipulated to be less trade-restrictive. The exception to this is the situation where production systems or other factors mean that 'overly trade-restrictive'

[29] In some situations, identified risk management measures will not reduce the risk to an acceptable level when applied individually. Here it will be necessary to investigate the efficacy of the feasible combinations of identified measures, or risk management 'strategies'. This process is considered an extension of 'option evaluation', and should be carried out in the same manner as is used to evaluate individual measures.

risk management measures are more easily accommodated by the exporting country than less restrictive alternatives. The range of alternative risk management measures may in some situations be limited. Where this is the case, it may be necessary to specify measures that result in a level of risk lower than Australia's ALOP, and to justify this with a transparent statement describing the limitation.

It is possible that some quarantine treatments will cause harm to the environment. Quarantine treatments should not be authorised unless any potential harm to the environment has been assessed. This includes harm from residues. Relevant considerations could include local legal requirements, manufacturer's advice on usage and national or international standards. Decision-makers should be satisfied that appropriate precautions to protect the environment would be used when the treatment is conducted.

The iterative process of risk management leads to a set of acceptable measures or strategies for each identified hazard for which the unrestricted risk is considered higher than Australia's ALOP. These measures or strategies will reduce risk to a level that is considered acceptable. Where measures or strategies that reduce the risk associated with a particular hazard to an acceptable level cannot be identified, permission to import the relevant commodity will be denied.

The conduct and documentation of import risk analysis for plants and plant-derived commodities should follow three discrete stages:

- Stage 1: Initiation of the pest risk analysis (PRA)
- Stage 2: Risk assessment
  - pest categorisation
  - probability of entry, establishment and spread
  - assessment of consequences
  - conclusions: estimation of risk
- Stage 3: Risk management

Risk communication will be carried out in accordance with the requirements for stakeholder consultation outlined in the *Handbook*.

STAGE 1: INITIATION OF THE PRA

According to IPPC, the aim of the initiation stage is to identify the objectives of the PRA — in particular, to define the initiation point[30] and the PRA area.[31] Typical initiation points for the PRA process include:

- the identification of a pathway that presents a potential pest hazard
- the identification of a pathway that may require regulation
- the review or revision of phytosanitary policies and priorities.

Each of these is outlined individually. From Biosecurity Australia's perspective, however, the identification of a new pathway will be the most common and important means by which a PRA is initiated.

PRA initiated by a pathway

In the context of PRA, a 'pathway' is a route or means by which a pest might enter the PRA area. IPPC describes three common scenarios in which identification of a pathway may lead to the initiation of a PRA:

- international trade is initiated in a new commodity or a commodity from a new point of origin
- new plant species are imported for selection and scientific research purposes
- a pathway other than commodity import is identified (natural spread, mail, garbage, passenger baggage, etc.).

Having identified the pathway, a list of pests may be generated by any combination of official sources, databases, literature sources or expert opinion. At this stage, all pests associated with the species of plant to be imported should be listed. Those that are relevant to the particular part of the

[30] The 'initiation point' describes the purpose or context in which the PRA was initiated.

[31] The 'PRA area' is the area in relation to which a PRA is conducted, where an 'area' is further defined by IPPC as an officially defined country, part of a country or all or part of several countries.

plant that constitutes the commodity may then be retained for inclusion in the risk assessment. This procedure will be carried out in an appendix, and the final list of pests reported at the conclusion of Stage 1.

Alternatively, if no potential quarantine pests are identified for the new pathway, then the PRA may stop at this point.

PRA initiated by a pest

According to IPPC, a PRA may be initiated by a pest in one of the following situations:

- an emergency arises on discovery of an established infestation, or an outbreak of a new pest within a PRA area
- an emergency arises on interception of a new pest on an imported commodity
- a new pest risk is identified by scientific research
- a pest is introduced into an area
- a pest is reported to be more damaging in an area other than its area of origin
- a particular pest is repeatedly intercepted.

PRA initiated by a policy

A PRA may be initiated by one of the following policy-related scenarios:

- a national policy decision is taken to review phytosanitary regulations, requirements or operations
- a proposal made by another country or by an international organisation is reviewed
- a new treatment system, process or new information impacts on an earlier decision
- a dispute arises on phytosanitary measures.

STAGE 2: RISK ASSESSMENT

Risk assessment describes the process of identifying pests of quarantine (or biosecurity) concern and estimating the risk (the probability of introduction and spread and the magnitude of the likely consequences) associated with each.

According to IPPC, risk assessment should be carried out and reported in the following steps:

- pest categorisation
- assessment of probability of entry[32], establishment[33] and spread[34]
- assessment of potential consequences[35] (including environmental impacts).

[32] 'Entry' describes the movement of a pest into an area where it is not yet present or present but not widely distributed and being officially controlled. This phase of risk assessment will be carried out on quarantine pests, so it follows that an area denotes an endangered area.

[33] 'Establishment' describes the perpetuation, for the near future, of a pest within an area after entry.

[34] 'Spread' describes the expansion of a geographical distribution of a pest within an area.

Pest categorisation

Pest categorisation is a classification phase to group pests identified in Stage 1 (*Initiation of the PRA process*) as either 'quarantine pests', or not. The objective of pest categorisation is, therefore, to screen a large and frequently unmanageable list of potential quarantine pests, before the more in-depth examinations within the risk assessment proper.

It was stated in earlier that, according to IPPC, a 'quarantine pest' is *a pest of potential economic importance to the area endangered thereby and not yet present there, or present but not widely distributed and being officially controlled*. Likewise, an 'endangered area' was cited as *an area where ecological factors favour the establishment of a pest whose presence in the area will result in economically important loss.*

On the basis of these definitions, pest categorisation has been summarised by IPPC as a screening procedure based on the five criteria outlined below:

- *Identity of the pest*. The identity of the pest should be clearly defined to ensure that the assessment is being performed on a distinct organism, and that biological and other information used in the assessment is relevant to the organism in question. If this is not possible because the causal agent of particular symptoms has not yet been fully identified, then it should have been shown to produce consistent symptoms and to be transmissible.

  The taxonomic unit for the pest is generally species. The use of a higher or lower taxonomic level should be supported by scientifically sound rationale. For levels below the species, this should include evidence demonstrating that factors such as differences in virulence, host range or vector relationships are significant enough to affect phytosanitary status.

  Where a vector is involved, the vector may also be considered a pest to the extent that it is associated with the causal organism and is required for transmission of the pest.
- *Presence or absence in the endangered area*. The pest should be absent from all or part of the endangered area.
- *Regulatory status*. If the pest is present but not widely distributed in the PRA area, it should be under official control or be expected to be under official control in the near future.
- *Potential for establishment and spread in the PRA area*. Evidence should be available to support the conclusion that the pest could become established or spread in the PRA area. The PRA area should have ecological/climatic conditions including those in protected conditions suitable for the establishment and spread of the pest where relevant, host species (or near relatives), alternate hosts and vectors should be present in the PRA area.
- *Potential for economic consequences in the endangered area*. There should be clear indication that the pest is likely to have an unacceptable economic impact (including environmental impact) in the PRA area.

For administrative purposes, pest categorisation should be carried out as follows:

---

[35] IPPC ISPM No 2 and the currently unnumbered ISPM (*Pest Risk Analysis for Quarantine Pests*) use the term 'economic consequences'. Except in the situation where either economic impact or economic viability is specifically of interest, the word 'economic' has been deleted from all headings, text and definitions. This action has been taken because it was believed that the impact of a pest would often be accrued in areas that cannot practically be evaluated through a traditional 'economics' approach. In particular, this would include the impact of a pest on the environment, on ecosystems, on biodiversity, etc.

Initially it will be important to provide a categorised list of pests[36] that are present in the exporting country, and either absent in the PRA area, or present but not widely distributed and under official control. Each pest on this list will then be examined for relevance to the particular commodity.[37] This information will be derived from several sources, including the plant health authorities in the exporting country and state plant health authorities in Australia. It may also be necessary to consult with experts on the plant species from which a given commodity was derived. If there is doubt or contention regarding the distribution or occurrence of a given pest, then a conservative approach should be taken and this pest retained on the list of potential quarantine pests. A table supporting the list should be included as an appendix to the *[Draft] IRA Report* (see, Document Templates). Information in this table should be referenced accordingly.

The *second stage* of pest categorisation hinges on categorising the potential for each listed pest (as identified above) to become established in the PRA area, and the severity of the consequences. Establishment potential should be classified as 'feasible' or 'not feasible', whereas consequences are simply 'significant' or 'not significant'. References (or at least one reference) to substantiate this information should be provided, although it should be stressed that the objective of pest categorisation is to facilitate a preliminary screening process. This process rests on clear classification (i.e. feasible/not feasible and significant/not significant) and *where classification is equivocal, the pest should be retained in the risk assessment for a more thorough and transparent evaluation*. This second stage of pest categorisation should also be tabulated (see *[Draft] IRA Report*).

The result of the two stages of pest categorisation will be a list of quarantine pests relevant to the import risk analysis. These pests will subsequently be subjected to more in-depth assessments of the probability of introduction (entry and establishment) and spread, and an evaluation of the magnitude of likely consequences. Considered together, these assessments and evaluations constitute a 'risk assessment' for each relevant quarantine pest.

Data-sheets[38] for relevant quarantine pests should be included in an appendix to the PRA (see *[Draft] IRA Report*). This information will be used to support the risk assessments.

Probability of introduction and spread[39]

According to IPPC, the probability of 'introduction' for a quarantine pest represents an amalgamation of the probability of 'entry' and the probability of 'establishment', as a result of trade in a particular commodity. The probability of entry is subsequently obtained by considering the 'importation' and 'distribution' pathway(s) for the commodity (see below) and the likelihood that a given pest will remain viable and undetected as each of the component steps is completed. The probability of establishment and the probability of spread are obtained by examining

[36] This list may be categorised phylogenetically, or by any other transparent and logical system.

[37] A pest is considered relevant to a commodity if it is (or may be) associated with the specific part of a plant, or plant product, to be imported.

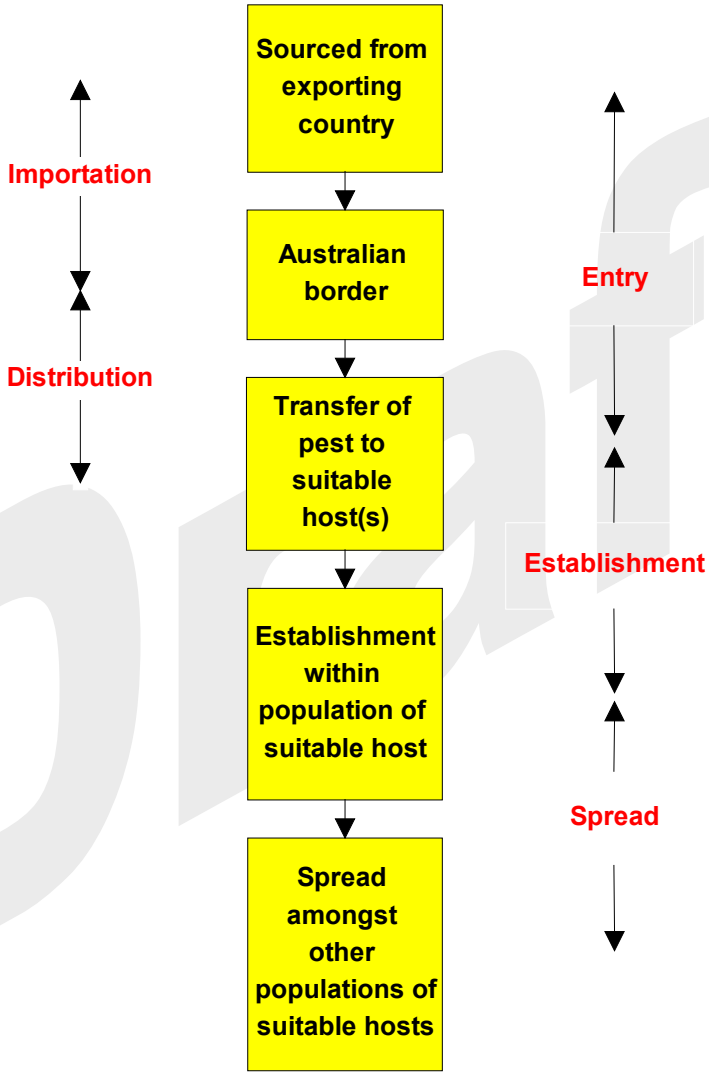
[38] A 'pest data-sheet' is the term given to the pest-specific report of biological and occurrence information generated from the Pest and Diseases Information (PDI) database.

[39] There appear to be contradictions amongst IPPC definitions and statements involving the 'probability of introduction' and the 'probability of spread'. The contradictions appear in various forms in both ISPM 2 and the ISPM titled *Pest Risk Analysis for Quarantine Pests*. In view of this, Biosecurity Australia has adopted the definitions and descriptions cited in this internal document as the standard for all Biosecurity Australia import risk analyses.

biological and other factors in the PRA area that may influence a pest's ability to become established and subsequently spread amongst populations of susceptible hosts.

Stages in the introduction and spread of a pest are illustrated schematically in Figure 15.

Figure 15 Stages in the entry, establishment and spread of a pest



Probability of entry

The probability of entry describes the probability that a quarantine pest will enter Australia as a result of trade in a given commodity, be distributed in a viable state to an endangered area and subsequently be transferred to a suitable host.

The probability of entry may be divided for administrative purposes into the following components:[40]

- *the probability of importation*: the probability that a pest will arrive in Australia when a given commodity is imported
- *the probability of distribution*: the probability that the pest will be distributed (as a result of the processing, sale or disposal of the commodity) to the endangered area, and subsequently be transferred to a suitable host.

Probability of importation

The probability of importation is estimated in two steps:

- the description of biological pathways, or 'scenarios'
- an evaluation of likelihood.

Description of scenarios

In the context of import risk analysis, a 'scenario' represents the ordered sequence of steps that lead to a particular outcome, or 'event', and should have a carefully stated 'initiating step' and 'end point'.

The initiating step for an importation scenario will vary amongst commodities, but will generally be the first discrete process associated with a commodity's production or selection for export. The end point of an importation scenario will be the initiating event of the subsequent distribution scenario, in either case defined as 'the arrival in Australia of commodity contaminated with a quarantine pest'.[41] The initiating step and end point of an importation scenario are illustrated in Figure 15.

After the initiating event and end point of an importation scenario have been defined, the 'steps' that connect the two need to be identified. The level of detail required will vary among assessments, although the governing principle should be to represent adequately any relevant processes that may affect the probability of importation.

IPPC identifies factors (see below) that should be considered when identifying and describing the steps in an importation pathway.[42] Often it will be useful to break these factors into specific events, thus creating a pathway that more closely represents events in the importation of the given commodity.

- *Association of the pest with the pathway at its origin*. The prevalence of the pest in the source area; the occurrence of the pest in a life stage associated with the commodity, containers or conveyances; the volume and frequency of movement along the pathway; seasonal timing of movements; pest management; cultural or commercial procedures applied at the point of origin (application of plant protection products, handling, culling, roguing, grading)

[40] It is important to note that, in breaking down the probability of entry into these two components, Biosecurity Australia has not altered the original meaning. The two components have been identified and separated to enable onshore and offshore pathways to be described individually.

[41] In the context of a PRA, 'arrival in Australia' is taken to imply the arrival of contaminated commodity at the point of entry, whether this is an airport, a shipping port or an Australian quarantine station.

[42] IPPC also describes the need to consider the probability of transfer of a pest to a suitable host. In these *Guidelines*, this issue is considered within the discussion of the probability of distribution

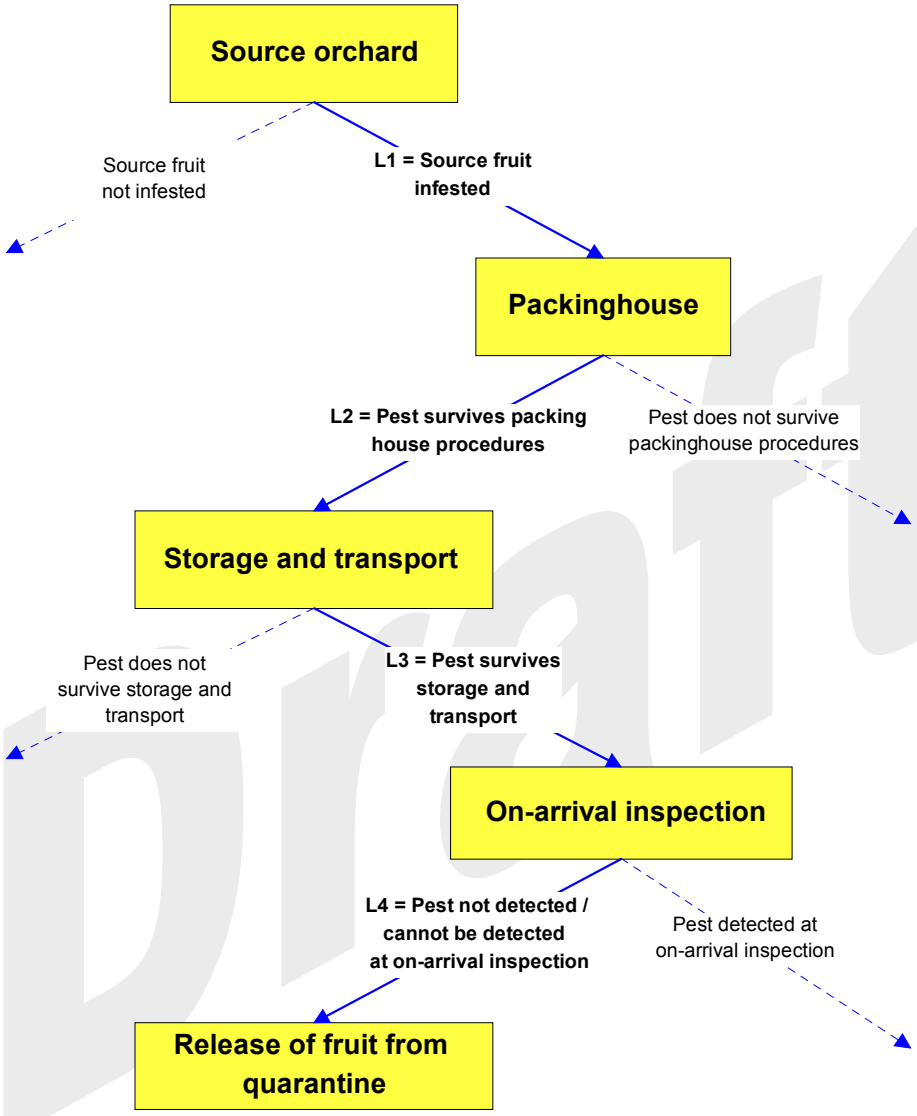
- *Survival of the pest during transport or storage*. The speed and conditions of transport and duration of the life cycle of the pest in relation to time in transport and storage; vulnerability of the life-stages during transport or storage; prevalence of pest likely to be associated with a consignment; commercial procedures (e.g. refrigeration) applied to consignments in the country of origin, country of destination, or in transport or storage.
- *Survival of the pest given any existing pest management procedures*. An evaluation of existing pest management procedures (including phytosanitary procedures) applied to consignments against other pests from origin to end-use should be evaluated for effectiveness against the pest in question. The probability that the pest will go undetected during inspection or survive other existing phytosanitary procedures should be estimated.

Whether the steps suggested by IPPC are adopted directly or are modified, the importation pathway should be illustrated schematically as a scenario diagram, or 'scenario tree'. The convention underlying this form of representation is that 'events' are described in boxes or 'nodes', whereas the probability or likelihood to be ascribed to each event is associated with the arrows emanating from its respective node.

A hypothetical example[43] of a scenario tree is provided in Figure 16. In this (albeit simplified) example, the importation scenario describes a series of four events (with likelihoods L_1–L_4) that *must* occur for fruit contaminated with a pest to enter Australia. The initiating step is the selection of orchards from which the fruit will be sourced, whereas the end point is, as always, the arrival in Australia of the contaminated commodity — in this example, fruit.

[43] This document contains numerous 'hypothetical' examples. These have been included for illustration, and are not intended to represent Australian policy concerning real commodities.

Figure 16 A scenario diagram for the importation of fruit



Evaluation of likelihood

In the second phase of the assessment of the probability of importation, likelihoods[44] are ascribed to each of the identified steps in the scenario. The likelihood associated with each step in the hypothetical importation scenario for fruit is shown in Figure 16 as L_1 to L_4. In the more general context of an importation scenario, these represent the likelihood that the commodity (or its source plant) will remain contaminated with a given pest after the completion of that step. This may reflect (for example) the likelihood that contaminated plants or commodity units will be selected,

[44] The term 'likelihood' has been used throughout this document to denote the 'chance' that a particular event will occur.

that screening procedures will fail to detect infestation, or that routine treatments will fail to inactivate a given pest.

The estimates assigned to the component steps in importation scenarios may be 'qualitative', 'semi-quantitative' or 'quantitative'. The following definitions for qualitative, semi-quantitative and quantitative likelihood evaluation have been adopted throughout this document:

- *Qualitative likelihood evaluation.* This is an evaluation in which likelihoods assigned to steps in scenarios (and/or to the overall result for a scenario) have been categorised according to an ordinal descriptive scale — e.g. 'low', 'moderate', 'high', etc. — and where no attempt has been made to equate descriptors with numeric values or scores
- *Semi-quantitative likelihood evaluation*. This is an evaluation in which likelihoods assigned to steps in scenarios (and/or to the overall result for a scenario) have been given numeric 'scores' (e.g. 1, 2, 3), or probabilities and/or probability intervals (e.g. $0 \rightarrow 0.0001$, $0.0001 \rightarrow 0.001$, $0.001 \rightarrow 0.01$, $0.01 \rightarrow 1$).[45]
- *Quantitative likelihood evaluation*. This is an evaluation in which likelihoods assigned to steps in scenarios (and/or to the overall result for a scenario) have been described in purely numeric terms — whether as 'deterministic' point estimates or as 'stochastic' probability distributions. The outcome of a purely deterministic quantitative model will be a single likelihood estimate. The outcome of a stochastic model will be a distribution of simulated values.

Each of the three approaches to likelihood evaluation has its advantages and constraints. Indeed, there will be some situations where one or other approach will be the most appropriate or, as suggested above, a combination of approaches may be required. For example, it may be that *qualitative* or *semi-quantitative* assessments of all identified quarantine pests will be supported by *quantitative* assessments of one or more pests considered of principal importance. Alternatively, it may be appropriate for the importation pathway to be modelled *quantitatively* and the distribution pathway to be modelled either *qualitatively* or *semi-quantitatively*. Finally, particular 'steps' in either scenario may be modelled *quantitatively*, regardless of the approach adopted for the rest of the evaluation.[46]

The choice of approach to the evaluation of likelihood will depend on both technical and practical considerations. General recommendations are not appropriate. However, guidelines regarding the advantages, constraints and application of each approach may be useful, and are provided below.

Qualitative likelihood evaluation

Qualitative likelihood evaluation is based on a descriptive ordinal scale, such as is provided in Table 15.

Although the qualitative approach is conceptually simple, the descriptors themselves remain effectively 'undefined'. That is, it will be impossible to state precisely what is meant by a designation of, for example, 'low', because one person's understanding of 'the event would be unlikely to occur' (as described in Table 15) will be different to another's. This characteristic of

[45] Probability intervals do not include either '0' or '1'.

[46] Where the quantitative approach is used in conjunction with, or as a component of, a qualitative or semi-quantitative assessment, the numerical result should be expressed in the relevant categorical terms. The reverse — that is, the reporting of qualitative or semi-quantitative likelihood assessment in purely numerical terms — is not appropriate.

qualitative likelihood evaluation may lead to inconsistency, both within and between import risk analyses.

Table 15 Nomenclature for qualitative likelihoods

Likelihood	Descriptive definition
High	The event would be very likely to occur
Moderate	The event would occur with an even probability
Low	The event would be unlikely to occur
Very low	The event would be very unlikely to occur
Extremely low	The event would be extremely unlikely to occur
Negligible	The event would almost certainly not occur

Qualitative likelihoods can be assigned to individual steps in scenarios, or to the probability that the entire scenario will occur.

If qualitative likelihoods have been assigned to individual steps in a scenario, then some form of 'combination rule' will be needed for calculating the probability that the entire scenario will occur. Rules can be displayed in various formats, but the most intuitive is a two-by-two tabular matrix, such as shown in Table 16.

The rules in the matrix are, by definition, arbitrary. This was derived by combining the 'midpoints' of the corresponding *semi-quantitative* probability intervals (Table 18). The semi-quantitative method was adopted so that the two approaches (qualitative and semi-quantitative) yielded equivalent results and, if necessary or useful, so that evaluations could be carried out using a mixture of both. The method is discussed in further detail in the following section.

Table 16 A matrix of 'rules' for combining descriptive likelihoods

	High	**Moderate**	**Low**	**V. low**	**E. low**	**Negligible**
High	High	Moderate	Low	V. Low	E. Low	Negligible
Moderate		Low	Low	V. Low	E. Low	Negligible
Low			V. low	V. Low	E. Low	Negligible
V. low				E. Low	E. Low	Negligible
E. low					Negligible	Negligible
Negligible						Negligible

The procedure can be illustrated using the hypothetical example of imported fruit (Figure 16). In this example, each of the four steps has been assigned a likelihood. These likelihoods have subsequently been combined using the 'rules' provided in Table 16.

Table 17 Qualitative evaluation of the imported fruit scenario

Step	Qualitative descriptor	Product of likelihoods
L_1: Source fruit infested	Low	
L_2: Pest is not detected / survives packinghouse procedures	Moderate ..... ➔	Low
L_3: Pest survives storage and transport	High ..... ➔	Low
L_4: Pest not detected during routine AQIS on-arrival inspection	V. Low ..... ➔	V. Low

The result of the procedure is an estimate of the probability that the complete chain of events will occur — that is, 'the probability that imported fruit will be infested on arrival'. In this hypothetical example, the probability that imported fruit is infested is estimated to be 'very low'. Alternatively, it could be stated that it is 'very unlikely' that imported fruit will be infested. The calculation of this probability would conclude a qualitative assessment of the probability of importation.

The *advantage* of this matrix-based qualitative approach is that an importation scenario can be broken into its component steps and a descriptive likelihood assigned to each. This provides a simple means by which to improve the transparency of an assessment. The principal *disadvantage* is that the assessment will often lead to a conservative overestimate of the likelihood that would have been obtained had the scenario been evaluated using a quantitative or semi-quantitative approach. This is because the repeated application of any one of the rules in the matrix (Table 16) will lead to the same likelihood. For example, if two steps in a scenario were considered to have a 'low' likelihood of occurrence, then the product of these, as determined using the matrix, would be 'very low'. Unfortunately, the same result would be obtained if there were three, four, five, etc., steps with a 'low' likelihood, and yet clearly the overall likelihood should be progressively lower in each case.

The seriousness of this problem will be determined by the number of steps in the scenario, and by the need for a given assessment to provide a precise and ultimately defensible estimate. Where the problem is considered to be severe, a practical 'solution' may be to assign a single likelihood to the entire importation scenario, to do the same for the distribution scenario(s) (see Probability of Distribution), and to subsequently combine these using a *single* application of the qualitative combination rules (Table 16). The disadvantage of this approach is that the transparency afforded by the scenario-based assessment will, at least in part, be lost.

Finally, it will be shown (see Risk Estimation) that an important consideration in carrying out an assessment of the probability of importation is how each likelihood may be influenced by the volume of trade during a specified period. This issue is difficult to incorporate into a qualitative framework, because numeric manipulation of descriptive adjectives (at least beyond that used as the basis for combination rules) is likely to be criticised. One solution may be to state at the start of the risk assessment that *all* likelihoods have been assigned or derived under the implicit assumption that they refer to the volume of commodity likely to be imported in a given period. It is clear, however, that because estimates assigned on this basis will be more difficult to defend, the approach is likely to be problematic. A preferable solution for situations that require consideration

of the effect of trade volume will be to provide a quantitative or semi-quantitative assessment, either as an embellishment of the qualitative assessment or in place of it. These approaches are outlined in the following discussions.

Semi-quantitative likelihood evaluation

There are two broad approaches to semi-quantitative likelihood evaluation. On one hand, the categories may be represented by scores (e.g. 1, 2, 3). This approach, however, rests on arbitrary rules governing the combination and interpretation of scores, and is not considered sufficiently robust. The alternative is to divide explicitly the 0–1 interval into a small number of mutually exclusive categories, or 'probability intervals'. These categories may subsequently be correlated with an equal number of descriptors, such that the analyst makes statements such as:

> *'We believe that the event will occur with an even probability — that is, we believe that the likelihood of the event may be as low as 'a' or as high as 'b''.*

Biosecurity Australia has adopted probability intervals for semi-quantitative assessment that correlate directly with the qualitative descriptors discussed in the previous section. These ranges are shown in Table 18. When interpreting the table it should also be noted that events described in risk assessment scenarios cannot be said to occur with a zero probability,[47] and that events 'almost certain' to occur may be modelled as certainties and thus assigned a likelihood of one.

Table 18 Nomenclature for semi-quantitative likelihoods

Likelihood	Descriptive definition	Probability (P)
High	The event would be very likely to occur	Range = $0.7 \rightarrow 1$
Moderate	The event would occur with an even probability	Range = $0.3 \rightarrow 0.7$
Low	The event would be unlikely to occur	Range = $0.05 \rightarrow 0.3$
Very low	The event would be very unlikely to occur	Range = $0.001 \rightarrow 0.05$
Extremely low	The event would be extremely unlikely to occur	Range = $10^{-6} \rightarrow 0.001$
Negligible	The event would almost certainly not occur	Range = $0 \rightarrow 10^{-6}$

Semi-quantitative likelihoods may be combined using several approaches. The approach adopted by Biosecurity Australia is to convert each semi-quantitative likelihood into a Uniform probability distribution[48] whose parameters, or boundaries, are those described in Table 18. This is illustrated in Table 19.

[47] If an event were assigned a zero probability of occurring, then the scenario also would have a zero probability of occurring. Zero likelihood would in turn lead to zero risk, which is not a sensible result for an import risk analysis.

[48] A Uniform, or Rectangular, distribution has no 'curve' as such, because each value within its limits occurs with an equal probability.

Table 19 Probability distributions for semi-quantitative likelihoods

Likelihood	Probability interval	Probability distribution
High	Range = 0.7 $\rightarrow$ 1	P ~ Uniform (0.7, 1)
Moderate	Range = 0.3 – 0.7	P ~ Uniform (0.3, 0.7)
Low	Range = 0.05 – 0.3	P ~ Uniform (0.05, 0.3)
Very low	Range = 0.001 – 0.05	P ~ Uniform (0.001, 0.05)
Extremely low	Range = 10^{-6} – 0.001	P ~ Uniform (10^{-6}, 0.001)
Negligible	Range = 0 $\leftarrow$ 10^{-6}	P ~ Uniform (0, 10^{-6})

Uniform probability distributions may subsequently be simulated within a quantitative spreadsheet using software such as @RISK (Palisade Corporation). Simulation is complex, but it can be used to obtain 'samples' from a series of Uniform distributions with only a working knowledge of Microsoft Excel and a small number of pointers on the use of @Risk. This software contains excellent tutorials, as well as detailed hard-copy manuals. Very briefly, having opened @Risk within Excel, Uniform distributions are entered into individual cells in the place of point estimates, using the following syntax:

= RiskUniform(lower boundary, upper boundary)[49]

To maintain consistency amongst Biosecurity Australia assessments, simulations should be based on *1000 – 2000 iterations*, a *random number generator seed of 'one'*, *Latin hypercube sampling* and *no monitoring of convergence*. These options can be selected from @Risk's Simulation Settings dialogue box.

The semi-quantitative 'model' itself is defined by the relationships amongst spreadsheet cells. Such relationships will be identical for simulation exercises involving distributions, as for the situation where individual cells contain the more familiar point estimates. The difference between simulated spreadsheets and the simpler 'deterministic' approach is that the output will be a distribution, rather than a single value.

For risk assessment models based on semi-quantitative Uniform distributions, the output (when viewed as a probability density plot or histogram) will typically appear as a left-skewed bell-shaped distribution. This distribution should be interpreted by 'fitting' it to the most appropriate semi-quantitative category. The approach to fitting that has been adopted by Biosecurity Australia is to compare the fifth, 50th (or median) and 95th percentiles of the output distribution with the probability intervals in Table 18.

An example of this simulation-based semi-quantitative approach has been provided by extending the hypothetical fruit importation scenario introduced in the previous discussion (Figure 16 and Table 17). In this example, the qualitative descriptors for step-level likelihoods are those presented in Table 18, although embellished using the appropriate Uniform probability distributions. The result of this is shown in Table 19.

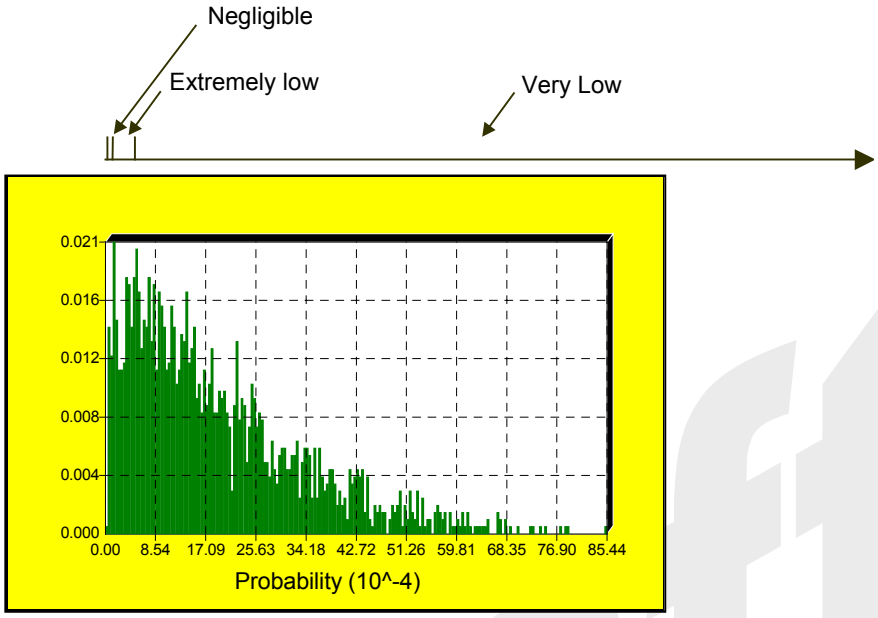
[49] Note that there is no space between the words 'Risk' and 'Uniform', or before the opening bracket.

The 'model' (in this case simply the product of each component likelihood) was run in @Risk / Microsoft Excel using the simulation settings described above. Statistics obtained from the simulation indicate that the fifth percentile for this release assessment is approximately 0.00017, the 50th percentile (or median) approximately 0.0015 and the 95th percentile approximately 0.0050. This suggests that although the distribution spans both the 'extremely low' and 'very low' intervals, the median value and, thus, more than half of the simulated values, are 'very low' (Figure 17). This output distribution was therefore classified as 'very low'.

Table 20 Semi-quantitative evaluation of the imported fruit scenario

Step	Qualitative assessment	Semi-quantitative assessment
L_1: Source fruit infested	Low	P_1 ~ Uniform (0.05, 0.3)
L_2: Pest is not detected / survives packinghouse procedures	Moderate	P_2 ~ Uniform (0.3, 0.7)
L_3: Pest survives storage and transport	High	P_3 ~ Uniform (0.7, 1)
L_4: Pest not detected during routine AQIS on-arrival inspection	V. low	P_4 ~ Uniform (0.001, 0.05)
Probability (P) that imported fruit is infested	**V. Low**	Median ≡ 0.0015 5th % ≡ 0.00017 95th % ≡ 0.0050 **P ≡ V. low**

Figure 17 Interpretation of the simulation output from the imported fruit scenario



The simulation-based semi-quantitative approach has four important advantages.

- By specifying (albeit arbitrary) probability intervals it will generally be possible to describe and interpret estimates of likelihood consistently. For example, if the definitions in Table 18are adopted, analysts using the term ‘moderate’ will have indicated that they have estimated a given likelihood to fall ‘somewhere between 0.3 and 0.7’. All readers would understand that this was the analysts’ understanding of the said likelihood, and that all other likelihoods described as ‘moderate’ should be interpreted in the same way.
- The quantitative framework upon which this approach to semi-quantitative likelihood evaluation is based enables the effect of the volume of trade during a specified period to be considered explicitly. Volume of trade will be an important issue in most import risk analyses and, as stated in earlier discussions, cannot easily be incorporated into the simpler qualitative approach. The implications of volume of trade are discussed in further detail under *Risk Estimation*.
- The use of a spreadsheet model has the particular advantage that individual steps within the framework of a likelihood pathway can easily be considered. This scenario-based approach to likelihood evaluation is considered more transparent than a simple narrative description of relevant factors or events, and enables the relative importance of particular steps to be evaluated. Examination for relative importance is one form of sensitivity analysis, and can be used to identify steps for which information is most critical, or at which risk management might be most effective.
- The simulation-based approach provides a very simple and robust means by which the ‘uncertainty’ inherent in most import risk analyses can be represented and incorporated in the assessment process. That is, the Uniform distribution corresponding to each general statement about likelihood will be sampled randomly many times (1000–2000 iterations are recommended), thus providing an output distribution that represents all possible combinations of uncertain inputs.

Given these advantages, the principal constraint of the semi-quantitative approach is the need to place likelihoods confidently in one or other category. However, given that the categories at either end of the 0–1 interval are extreme and unlikely to be contentious, and that the central ('moderate') category broadly represents an 'even probability', this difficulty is unlikely to be serious. Where the likelihoods to be attributed to particular steps in a model are poorly understood and the analyst is uncomfortable with assigning semi-quantitative categories, sensitivity analysis might be used. As discussed above, sensitivity analysis will determine how important each step is to the overall likelihood. Important steps that are poorly understood or poorly documented in the literature can be modelled conservatively as 'one'. Alternatively, the simulation might be repeated using a range of reasonable and defensible inputs to examine the precise effect of the uncertainty.

Quantitative likelihood evaluation

Quantitative likelihood evaluation is a large and complex field, and comprehensive guidelines are beyond the scope of this document. The single important difference between *quantitative* and *semi-quantitative* likelihood evaluation (as discussed above) is that the latter is based on a predetermined set of likelihood intervals and their corresponding descriptive definitions. In contrast, where true quantitative likelihood evaluation is used, analysts will be free to model inputs using any point estimate or probability distribution. If the quantitative approach is adopted, care must be taken in the use of adjectives or verbal descriptors for likelihood so that readers do not get the impression that the 'standardised' semi-quantitative intervals have been used.

Quantitative models that incorporate probability distributions are described as 'stochastic models'. As discussed above, stochastic models can be 'simulated' using software such as @Risk, and will produce an output distribution rather than a single 'deterministic' point estimate.

To illustrate the use of the quantitative approach, probability distributions were assigned to each of the steps in the hypothetical fruit example, and the model simulated. The results of the simulation include summary statistics (of which the median, fifth percentile and the 95th percentile are reported in Table 21), a histogram (or probability density plot, Figure 18), a cumulative histogram (or cumulative density plot, Figure 19) and the results of a sensitivity analysis (correlations and a tornado diagram, Figure 20).

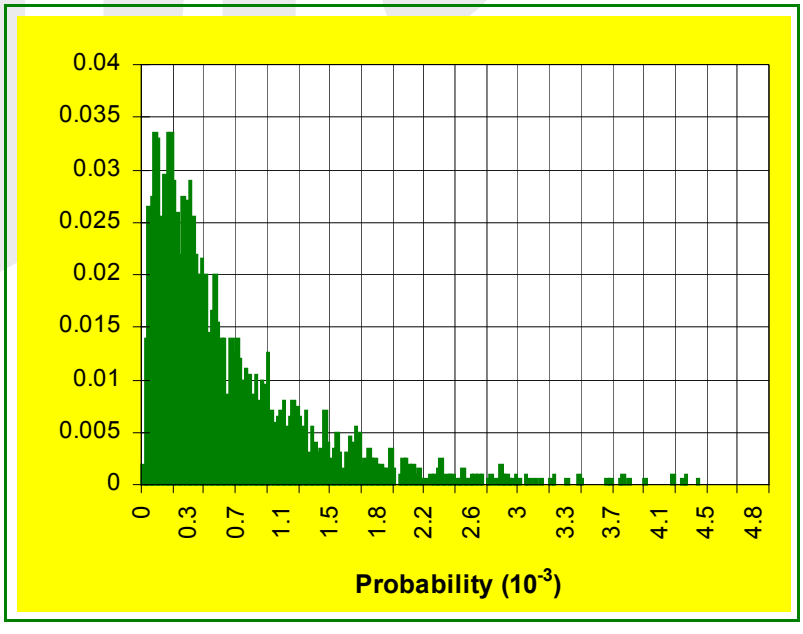
The output from a stochastic quantitative evaluation should be interpreted in the same manner as the output from a simulation-based semi-quantitative evaluation. That is, the distribution should be 'fitted' visually and by virtue of the distribution statistics to the most appropriate semi-quantitative interval and midpoint. In the hypothetical fruit example, the probability that imported fruit would be infested was classified as 'extremely low' using this procedure.

Table 21 Quantitative evaluation of the fruit importation pathway

Step	Quantitative input
L_1: Source fruit infested	P_1 ~ Triangular (0.05, 0.1, 0.5)
L_2: Pest is not detected / survives packinghouse procedures	P_2 ~ Uniform (0.1, 0.5)
L_3: Pest survives storage and transport	P_3 ~ Triangular (0.90, 0.95, 0.99)
L_4: Pest not detected during routine AQIS on-arrival inspection	P_4 ~ BetaPert (0.001, 0.005, 0.05)
Probability (P) that imported fruit is infested	Median ≡ 0.0005
	5^{th} % ≡ 0.00008
	95^{th} % ≡ 0.002
	P ≡ E. low

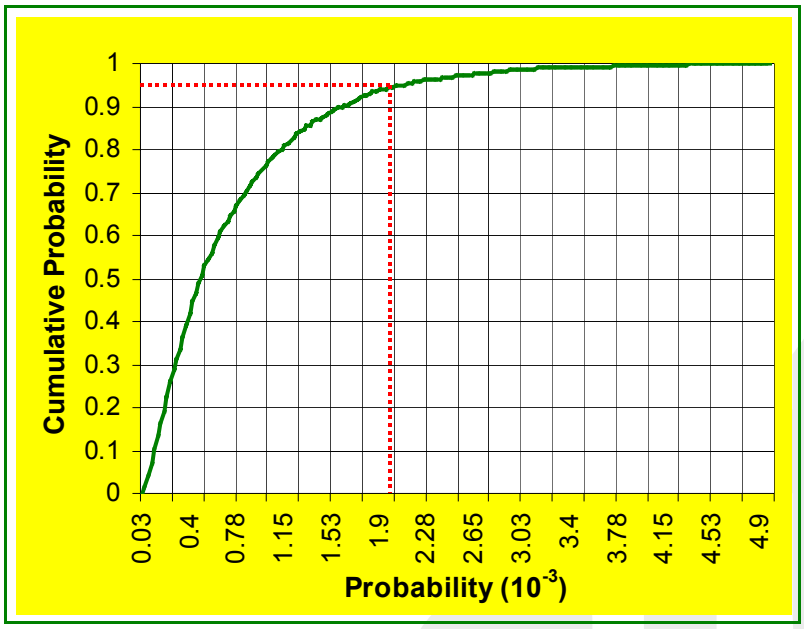
The histogram, or 'probability density plot', generated when this hypothetical example was simulated is shown in Figure 18. This plot will be useful for communicating the spread of simulated values, and the approximate 'shape' of the output distribution.

Figure 18 A probability density plot for the fruit importation pathway



Alternatively, the 'cumulative density plot' in Figure 19 illustrates the relative likelihood that the outcome will be at least as low as each value on the x-axis. For example, the 95^{th} percentile is approximately 0.002, indicating that 95 per cent of simulated values were smaller than or equal to 0.002. On the semi-quantitative scale, a result of 0.002 would be classified as 'very low'.

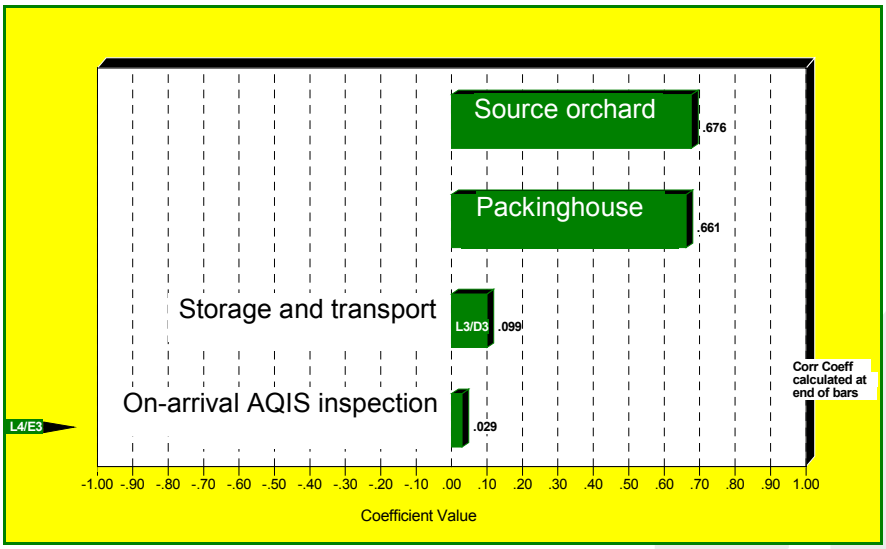
Figure 19 A cumulative density probability plot for the fruit importation pathway



In practice, many analysts choose to report the 95th percentile. It is probable that this trend has arisen as an extension of the convention in statistics whereby 0.05 is generally considered the benchmark for a 'significant' result. In fact, simulated percentiles are not equivalent (or even similar) to the 'confidence limits' reported in statistics and if, for example, a 95th percentile is to be reported, then the reason for taking this very conservative approach should be clearly stated. In the hypothetical fruit example, reporting the 95th percentile in the place of the median (50th percentile) would raise the output probability from 'extremely low' to 'very low'.

One of the principal advantages of the quantitative approach to likelihood evaluation is the ability to carry out a *sensitivity analysis* and, thus, identify the most influential input variables. By knowing the most influential input variables, it may be possible to increase the efficiency of risk management, or to concentrate research in an area that will be maximally useful to any further analysis. A sensitivity analysis (Figure 20) on the hypothetical fruit importation pathway showed that 'the probability that an infested source crop is selected', and 'the probability that pest is not detected or destroyed as a result of packinghouse procedures', are the two most important variables. This information might be used to validate a decision to concentrate risk management on efforts to ensure that the source crop was free from a given pest, or that the packinghouse procedures were optimally efficient.

Figure 20 Sensitivity analysis for the fruit importation pathway



Another feature of the quantitative approach is the ability to model *correlations* between input variables. For example, there may be a correlation between 'the size of a crop' and 'the prevalence of a given pest'. By positively correlating these two variables in a quantitative model, it will be possible to ensure that higher simulated values of one occur in the same iteration as higher simulated values of the other. This will reduce unrealistic variability, and will better represent the biology of the scenario being modelled.

Quantitative modelling also allows the effect of the *volume of trade* during a given period on the likelihood of pest entry to be directly assessed. Whether this is carried out while assessing the probability of importation, or as a separate procedure at the completion of the assessment of the probability of importation and distribution, will depend on the particulars of each scenario.

The principal constraints of quantitative modelling are the required time and technical resources. In general, this will limit quantitative modelling to a small proportion of contentious or otherwise important analyses. Once the decision has been made to include quantitative modelling in an analysis, interpretation of results may present a further quandary. Where a model is stochastic (includes simulated probability distributions), the outcome will be a distribution. It will not be possible to report an entire distribution, so should the mean, median, 95th percentile, etc., be reported? As shown in the example discussed above, these values may be very different, and the decision to report the 95th percentile in place of the median, may alter a subsequent decision about the need for risk management.[50]

Quantitative models are further limited by the need for reasonable data or information, although most 'adequate' quantitative models are based on expert opinion, or extrapolation of results of very specific experiments. The use of epidemiological field data is relatively uncommon. Interpretation of expert opinion is beyond the scope of this document, but those adopting the quantitative approach should be familiar with, and use, currently available techniques.

[50] As a rule, it is recommended that the 95th percentile of an output distribution be reported. This conservative policy is based on a recognition that all models are (at least to some extent) imperfect representations of reality.

The final (and perhaps most serious) limitation of quantitative modelling is that it will not generally be possible to arrive at a mathematical structure and a set of modelling assumptions that are beyond critique. That is, in creating a model, the analyst will always be abbreviating 'reality' — hopefully retaining most of the features of the 'real' scenario that would determine the real likelihood of the event in question. As quantitative models become more sophisticated they also inevitably become more specific, and rely more heavily on specific assumptions. This may have ramifications for the acceptability of a quantitative model in an adversarial environment, because it will always be relatively easy for critics to cast doubt on the structure of a model and, therefore, the conclusions drawn from the assessment.

Conclusions: approaches to likelihood evaluation

Each modelling approach has advantages and constraints. Likewise, there is no single 'best approach' and, indeed, it will often be sensible to combine approaches in a given assessment.

Whichever approach (or combination of approaches) is chosen, it should provide for the following:

- an assessment based on sound science
- an assessment that is structured and transparent
- an assessment that is internally consistent, and that can be repeated (with the same or a similar outcome) by another operator using the same framework and data
- an outcome that will support the estimation of 'risk' (a combination of likelihood and consequences)
- an outcome that will enable risk to be evaluated against the importing country's ALOP, or 'tolerance for loss'
- a framework within which the efficacy of risk management and the acceptability of a mitigated risk can be evaluated.

Probability of distribution

This is the probability that a pest that has entered Australia with the importation of a given commodity will be distributed (as a result of the processing, sale or disposal of the commodity) to the endangered area, and subsequently be transferred to a suitable host.

The probability of distribution should be derived in a manner similar to that described for the probability of importation — that is, by undertaking a description of scenarios and an evaluation of likelihood.

When describing scenarios and assigning likelihoods, IPPC suggests that the following factors be considered:

- dispersal mechanisms, including vectors to allow movement from the pathway to a suitable host
- whether the imported commodity is to be sent to few or many destination points in the PRA area
- proximity of entry, transit and destination points to suitable hosts
- time of year at which import takes place
- intended use of the commodity (e.g. planting, processing and consumption)
- risks from by-products and waste.

Some uses are associated with a much higher probability of introduction (e.g. planting) than others (e.g. processing). Thus the probability associated with any growth, processing, or disposal of the commodity in the vicinity of suitable hosts should also be considered.

Description of scenarios

As for the assessment of the probability of importation, distribution scenarios are based on initiation points, end points and the steps that link these 'events'. The initiation point for a distribution scenario will be the end point for the corresponding importation scenario — that is, 'the arrival in Australia of an infested or contaminated commodity'. The end point, or end points, will represent the transfer of the pest to a suitable host(s) within Australia.

The principal difference between the probability of importation and the probability of distribution is that the derivation of the latter is frequently more complicated. Given this, distribution scenarios will generally follow one of the three configurations:

- a single 'distribution pathway' leading to a single end point — as described for the probability of importation
- multiple distribution pathways leading to a single end point
- multiple distribution pathways leading to multiple end points.

The *first* case is the simplest and, indeed, is identical in structure to the importation scenario. An example of this configuration might be the distribution pathway for the importation of fruit (Figure 21), where pests might be distributed to a suitable host (e.g. susceptible fruit trees in Australia) through the disposal of fruit waste.

The *second* case, which is more complex, can be illustrated by the (once again hypothetical) importation of grain for stockfeed (Figure 22). Here there is likely to be a single category of 'suitable host' — that is, cereal crops within Australia — but more than one route by which pests could be distributed to that host. For example, pests might remain associated with the stockfeed and be distributed directly to farms that both graze animals and grow cereal crops. Alternatively, vehicles might become contaminated with a pest, and thus inadvertently distribute it to a cereal crop. Each of these alternatives would constitute a 'pathway', and should be considered as such in the assessment.

Finally, and most difficult to model, is the situation where there are several distinct categories of suitable host. An example of this might be the importation of a plant-based commodity for human consumption (Figure 23) where there may be, for each relevant pest, several suitable hosts within Australia. One (hypothetical) illustration of this may be the importation of unprocessed mushroom-based products. Here, the categories of suitable hosts could include native mushroom populations, farmed mushroom populations and any 'other susceptible species' that may be affected by pests of mushrooms or hitchhiker pests. The difference between this scenario and that described above (the importation of grain) is that the separate pathways lead to separate end points.

After the initiation point and end point(s) of a distribution scenario(s) has been defined, the connecting 'steps' need to be identified. The level of detail required will vary amongst assessments, although the governing principle should be to represent adequately any relevant processes that may affect the probability of distribution.

As for the assessment of the probability of importation, scenario diagrams or 'trees' should be constructed to illustrate distribution scenarios and to communicate the process of likelihood evaluation. The principle behind this form of representation is that 'events' are described in boxes

or ‘nodes’, whereas the probability or likelihood to be ascribed to each event is illustrated using arrows emanating from its respective node.

An example of each of the three generalised configurations for distribution scenarios is shown in Figure 21 – Figure 23, respectively. Note that the initiation point is always ‘the arrival in Australia of infested or contaminated commodity’, but that the scenarios that follow are determined by the nature of the imported commodity. These scenario diagrams will form the basis for likelihood evaluation, as described in the following section.

Figure 21 A distribution scenario for the importation of fruit

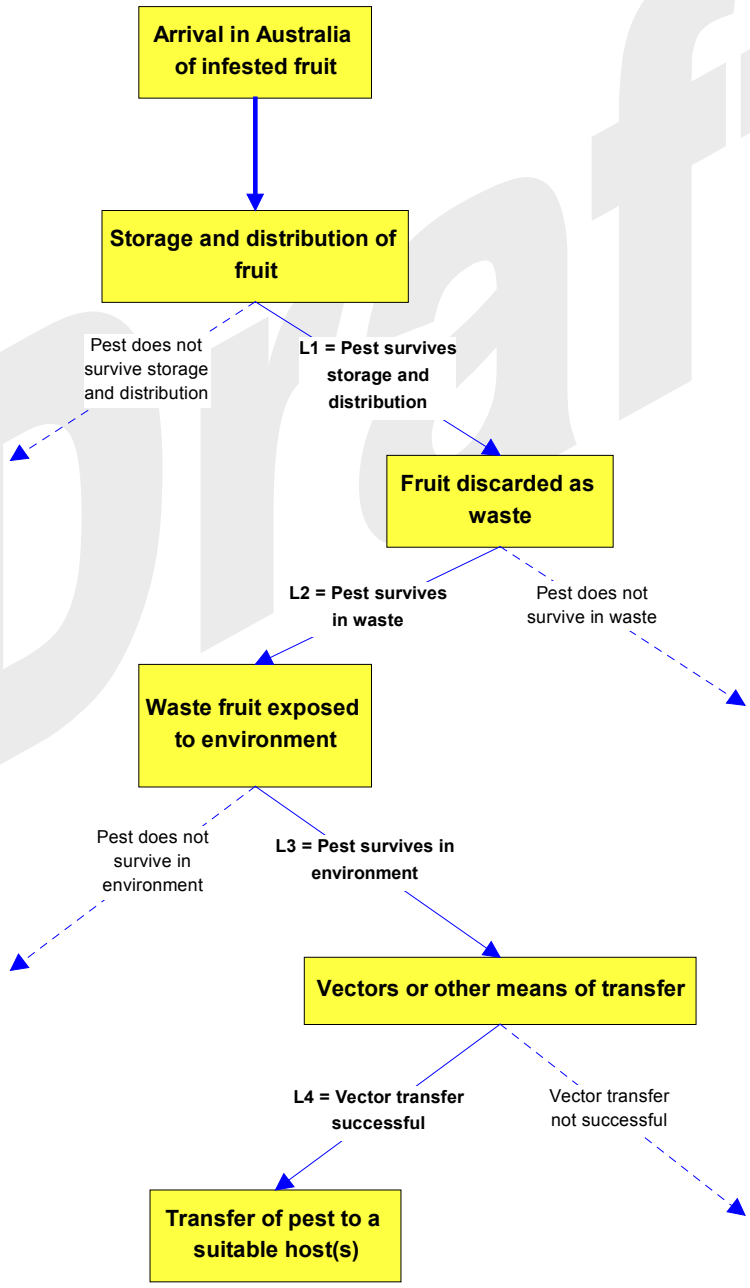


Figure 22 Distribution scenarios for imported grain for stock feed

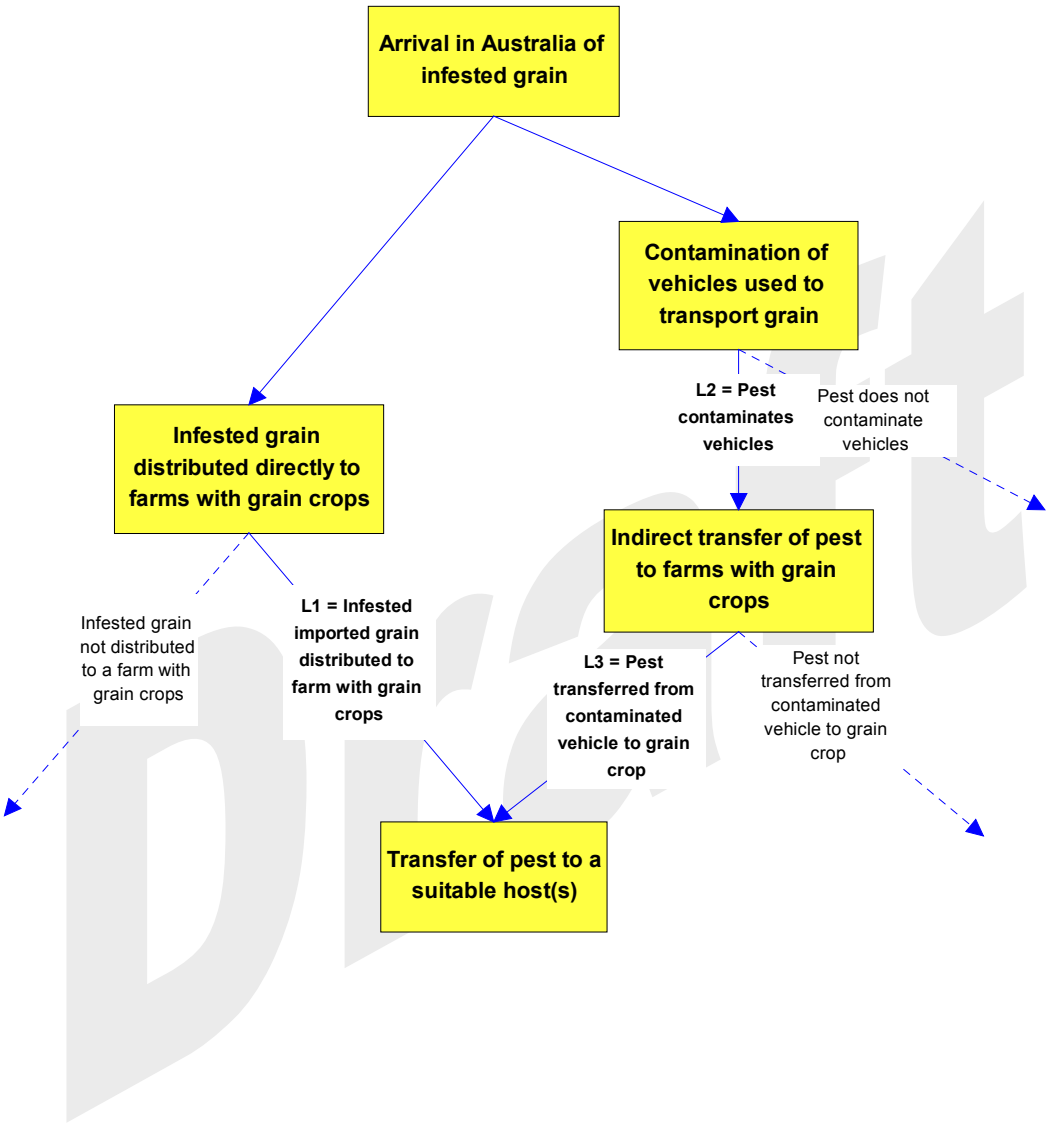
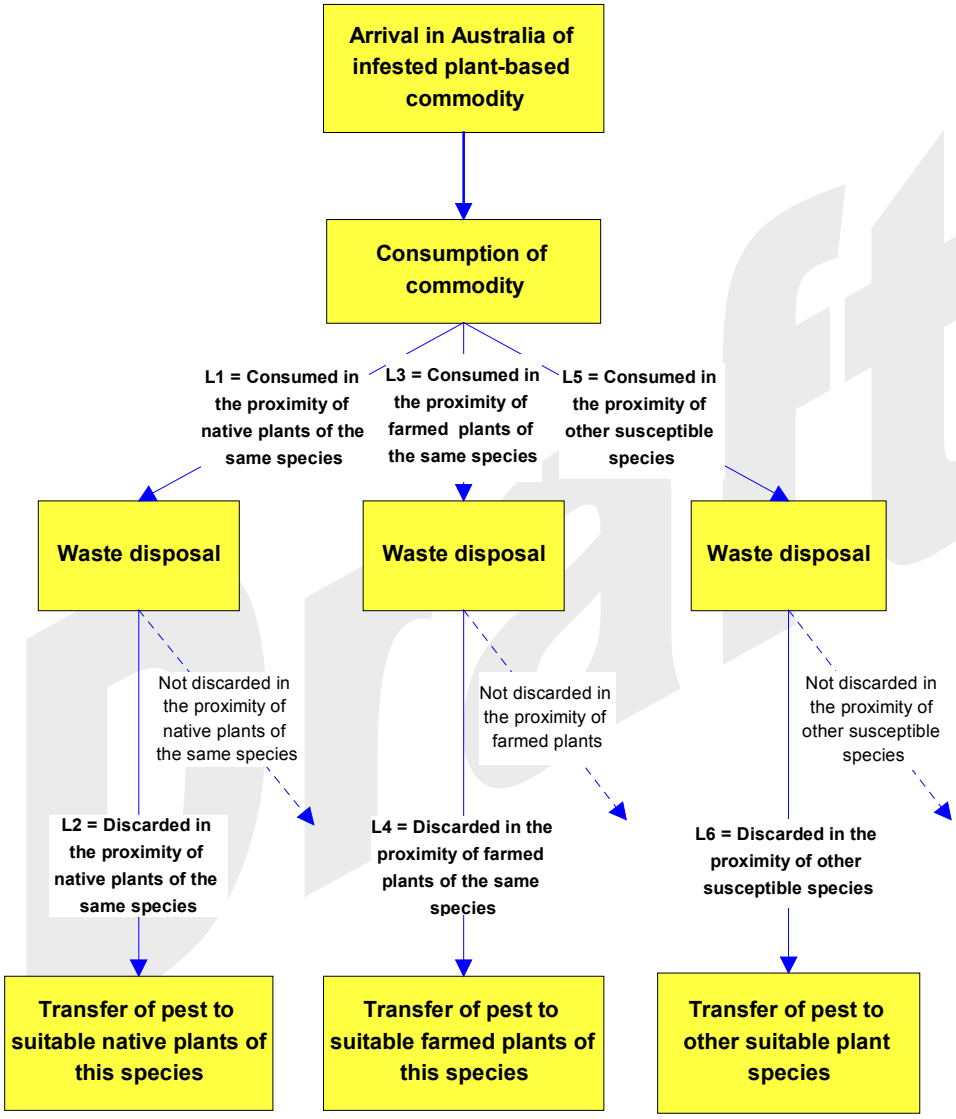


Figure 23 Distribution scenario for the importation of plant-based commodity for human consumption



Evaluation of likelihood

In the second phase of the assessment of the probability of distribution, likelihoods are ascribed to the steps in each identified distribution scenario. These will generally represent either the probability that a unit of the commodity (or a part thereof) will remain contaminated with viable pest after the completion of the given step, or the probability that a pest will independently complete a given step.

Likelihood evaluation for each of the three configurations of distribution pathway will be discussed in turn.

Single scenario / single end point

This configuration (Figure 21) is identical to that described in the discussion of release assessment — given this, it follows that likelihood evaluation will also be identical.

Multiple scenarios / single end point

This configuration was illustrated using the example of the (hypothetical) importation of grain for stockfeed, as shown in Figure 22. The challenge with multiple scenarios and single end points is to combine likelihoods ascribed to the separate steps in such a way as to convey the relative importance of each branch of the scenario diagram.

Two factors may influence the relative importance of a particular branch of the distribution scenario diagram. Firstly, it may be relevant to consider the relative 'volume' of commodity physically distributed to that pathway. For example, if the branch described direct contact between imported grain and the suitable host(s), then the proportion of grain that would be distributed to this pathway should be considered. The second factor affecting the importance of a branch will be the likelihoods assigned to individual steps. Examples of this might be the likelihood that a vehicle will become infested with a pest, or that the vehicle will subsequently be used to distribute grain to a suitable host(s). Either of these likelihoods might lead to the given path being considered relatively unimportant.

The relative importance of each branch of a scenario diagram is described in this document as the 'partial probability of distribution' (PPD). Each partial probability of distribution can be derived using one of the three approaches (qualitative, semi-quantitative or quantitative) outlined in the discussion of the probability of importation. Because each branch of the distribution scenario represents a single linear series of steps or events, the method used to derive a partial probability of distribution will be identical to that described in the discussion of the probability of importation.

Once the partial probability of distribution has been derived, it remains to determine the overall probability of distribution (PD). This can be stated in several ways, but one that is logical in the quarantine context is:

> *the likelihood that transfer of the pest to a suitable host(s) will occur by at least one of the available pathways.*

Algebraically, this is equivalent to one minus (i.e. 'the complement of') the likelihood that transfer does not occur through any of the available pathways. The likelihood that transfer does not occur by *any* of the available pathways will be the product of the complement of each. The probability of distribution thus can best be described in the equation:

$$PD = 1 - (1 - PPD_1) \times (1 - PPD_2) \times (1 - PPD_3) \times ... (1 - PPD_n)$$

The approach adopted in applying the principle behind this equation will depend upon whether the partial probabilities (PDP_1, PDP_2, …etc.) have been obtained using a qualitative, semi-quantitative or quantitative approach.

Where partial probabilities have been evaluated *qualitatively*, decision rules for determining their 'complements' must be derived. When partial probabilities have been obtained by using a matrix of decision rules (Table 16), and this matrix is based on the products of the midpoints of corresponding probability intervals, it would appear to be sensible to use the same approach to derive complements for the qualitative likelihoods (that is, to subtract their midpoints from one, and report the category in which the result falls).

The results of this procedure are shown in Table 22.

Table 22 Complements of qualitative likelihoods

Original qualitative likelihood		Complement
Term	*Descriptive definition*	
High	The event would be very likely to occur	Low
Moderate	The event would occur with an even probability	Moderate
Low	The event would be unlikely to occur	High
V. Low	The event would be very unlikely to occur	High
E. Low	The event would be extremely unlikely to occur	High
Negligible	The event would almost certainly not occur	High

After the complements of qualitative partial probabilities of distribution have been obtained, they need to be inserted into the equation shown on the previous page. The multiplication of qualitative probabilities will be carried out using the matrix described in the discussion of the probability of importation (Table 16). The complement of the final product will then be obtained by using the rules shown in Table 22. The result of this procedure will be a qualitative estimate for '*the likelihood that transfer of pest to a suitable host(s) will occur through at least one of the branches or pathways described in the distribution scenario diagram*'.

Where the partial likelihoods ascribed to each branch of the distribution scenario have been derived *semi-quantitatively* (using the simulation-based approach) or *quantitatively*, the equation can simply be inserted into the mathematical logic of the quantitative model.

Multiple scenarios / multiple end points

This configuration was illustrated using the hypothetical example of the importation of a plant-based commodity for human consumption, as shown in Figure 23. The distinguishing feature of this type of scenario is that it will *not* generally be desirable to combine the branches to derive an estimate for the overall probability of distribution. The reason for this will be discussed in further detail in descriptions of the assessment of consequences and of risk estimation but in brief, hinges on the fact that the 'risk' associated with each distinct end point, or category of suitable host, is not reliant on other risks and should be treated separately.

After the partial probability of distribution for each branch of the scenario tree has been derived, the assessment of the probability of distribution will be complete. Whether the evaluations are carried out qualitatively, semi-quantitatively or quantitatively, partial likelihoods can be derived in the same manner as described in the discussions above, and in the discussion of the probability of importation.

The result of this phase of an assessment based on the multiple distribution scenarios and multiple end points will therefore be a series of partial probabilities of distribution.

Conclusions: probability of distribution

Describing the scenario component of the assessment of the probability of distribution will frequently be more complicated than describing scenarios for assessing the probability of importation. Three general configurations have been identified and, in general, the assessment of the probability of distribution can be fitted to one of these.

It should be noted, however, that this document is intended to provide 'guidelines', and not a definitive description of all possible distribution scenarios. It may, for example, be appropriate to construct a scenario in which one of the more complicated configurations was 'nested' within the other. Where complications arise, it will be necessary to break the scenario down into its fundamental components and address each using the principles described in this document.

Probability of establishment

Where there is a single category of suitable host(s), then there will also be a single estimated probability of establishment. Conversely, where more than one category of suitable host can be identified, it will be necessary to determine the probability of establishment for each.

According to IPPC, the probability of establishment should be based on a comparative assessment of factors in the source area and PRA area considered pertinent to the ability of a pest to survive and propagate. Examples of these factors include:

- *The availability, quantity and distribution of hosts in the PRA area*: factors to consider are; whether hosts and alternate hosts are present and how abundant or widely distributed they may be; whether hosts and alternate hosts occur within sufficient geographic proximity to allow the pest to complete its life cycle; whether there are other plant species, which could prove to be suitable hosts in the absence of the usual host species; whether a vector, if needed for dispersal of the pest, is already present in the PRA area or likely to be introduced; whether another vector species occurs in the PRA area.

  The taxonomic level at which hosts are considered should normally be the 'species'. The use of higher or lower taxonomic levels should be justified by scientifically sound rationale
- *Suitability of the environment*: factors in the environment (e.g. suitability of climate, soil, pest and host competition) that are critical to the development of the pest, its host and if applicable its vector, and to their ability to survive periods of climatic stress and complete their life cycles, should be identified. It should be noted that the environment is likely to have different effects on the pest, its host and its vector. This needs to be recognised in determining whether the interaction between these organisms in the area of origin is maintained in the PRA area to the benefit or detriment of the pest. The probability of establishment in a protected environment (e.g. in glasshouses) should also be considered. Climatic modelling systems may be used to compare climatic data on the known distribution of a pest with that in the PRA area
- *Potential for adaptation of the pest*: whether the species is polymorphic, and the degree to which the pest has demonstrated the ability to adapt to conditions such as those in the PRA area should be considered (e.g. host-specific races or races adapted to a wider range of habitats or to new hosts). This genotypic and phenotypic variability facilitates a pest's ability to withstand environmental fluctuations, to adapt to a wider range of habitats, to develop pesticide resistance and to overcome host resistance
- *Reproductive strategy of the pest*: characteristics which enable the pest to reproduce effectively in the new environment — e.g. pathogenesis, self-crossing, duration of life cycle, number of generations per year, the presence of a resting stage, etc.

- *Method of pest survival*: if possible, the threshold population that is required for establishment should be estimated
- *Cultural practices and control measures*: Where applicable, practices employed during the cultivation/production of the host crops should be compared to determine if there are differences in such practices between the PRA area and the origin of the pest that may influence its ability to establish. Pest control programs or natural enemies already in the PRA area which reduce the probability of establishment may be considered. Pests for which control is not feasible should be considered to present a greater risk than those for which treatment is easily accomplished. The availability (or lack) of suitable methods for eradication should also be considered.

Technical information to support the assessment of the probability of establishment should be derived from the data-sheet for each quarantine pest, and from an assessment of the relevant factors in the area of origin and the PRA area. In contrast to the probability of entry (and its two components), the probability of establishment will not typically result from a structured 'scenario' of events, or pathway. That is, the probability of establishment will generally be derived from expert opinion based on a single comparative evaluation of the factors described above.

The probability of establishment may be expressed in qualitative, semi-quantitative or quantitative terms. In each case, the relevant principles for qualitative, semi-quantitative or quantitative likelihood evaluation described in the discussion of the probability of importation can be applied.

Probability of spread

Where there is a single category of suitable host(s), then there will also be a single probability of spread. Conversely, where several categories of suitable host(s) have been identified, it will be necessary to determine the probability of spread for each.

According to IPPC, the probability of spread should be based on a comparison of biological information derived from the source area and PRA area, and information regarding the probability of establishment for a pest. This information can be integrated using expert opinion and by considering case histories. As for the probability of establishment, the probability of spread will be derived in a single step. This contrasts with the scenario-based approach adopted when estimating the probability of entry.

Factors that may be considered when evaluating case histories include:

- suitability of the natural and/or managed environment for natural spread of the pest
- presence of natural barriers
- potential for movement with commodities or conveyances
- intended use of the commodity
- potential vectors of the pest in the PRA area
- potential natural enemies of the pest in the PRA area.

It is important to note that information regarding the spread of the pest may also be used to estimate how rapidly the pest's potential importance may be expressed in the PRA area. This will be particularly pertinent where there is potential for a pest to spread into an area of higher importance. The probability of spread will also be important in evaluating the feasibility of pest containment.

The probability of spread may be expressed in qualitative, semi-quantitative or quantitative terms. In each case, the relevant principles for qualitative, semi-quantitative or quantitative likelihood evaluation described in the discussion of the probability of importation can be applied.

Conclusions: probability of introduction and spread

The probability of introduction and spread describes a combination of the probabilities of entry, establishment and spread. Where distribution scenarios culminate in a single end point (the transfer of a pest to a single category of suitable host), it will generally be appropriate to combine the likelihood estimates for importation, distribution, establishment and spread, and arrive at an overall estimate of the probability for introduction and spread. The method by which individual likelihoods are combined will depend on whether each is qualitative, semi-quantitative or quantitative, or a whether the different likelihoods have been expressed using more than one of these approaches. The principles for obtaining qualitative, semi-quantitative or quantitative estimates can be applied to obtain an estimate for introduction and spread.

Where distribution scenarios culminate in more than one end point (the transfer of a pest to more than one category of suitable host), it will not generally be appropriate to derive a single estimate for the probability of introduction and spread. This is sensible, because the probabilities of establishment and spread will generally be quite different for different categories of suitable host. It is also important to reiterate that the consequences of establishment and spread are likely to differ between categories of host, and that the likelihoods pertaining to these consequences should be kept separate to enable the calculation of separate risk estimates (see Risk estimation).

Consequences

The approach to the assessment of consequences will be determined largely by whether one, or more than one, category of suitable host(s) has been identified during the assessment of the probability of distribution:

- Where there is a *single category of suitable host*, there will generally be a single estimate for the probability of distribution, the probability of establishment and the probability of spread, and a single estimate of the consequences associated with the transfer of a pest to that host.
- Where there is *more than a single category of suitable host*, each will have a probability of distribution, a probability of establishment and a probability of spread, and each will have an estimate of the consequences given the transfer of a pest to that host. These individual assessments will subsequently be combined at the close of the risk assessment, to derive an overall estimate for the 'risk' that should be attributed to the commodity.

Whether a single assessment of consequences, or multiple assessments, will be required, each should be based on:

- a description of the directions in which consequences may be accrued — the so-called 'consequence criteria'
- a transparent system for assessing the likely consequences of a pest on each criterion, and subsequently combining these across all criteria to provide an overall estimate.

Criteria for assessing consequences

Criteria for assessing the consequences associated with a pest or disease are outlined in the relevant acts and agreements, and in the standards prepared by the relevant international organisations.

In particular:

- the *Quarantine Act* requires decision-makers to take into account the likelihood of harm being caused (to humans, animals, plants, other aspects of the environment, or economic activities) and the probable extent of the harm (Section 5D)
- the *SPS Agreement* states that:

  Members shall take into account as relevant economic factors; the potential damage in terms of loss of production or sales in the event of 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
- OIE and IPPC expand the 'relevant economic factors' described in the *SPS Agreement* to differentiate between the 'direct' and 'indirect' effects of a disease, and to provide examples of factors that will typically be relevant to an import risk analysis.

In each case, consequence assessments do not extend to considering the benefits or otherwise of trade in a given commodity, nor to the impact of import competition on industries or consumers in the importing country.

In these *Guidelines*, the criteria described by OIE and IPPC have been combined, to give an approach to consequence assessment that can be applied to animals and plants and their products.

This approach is outlined below.

Direct consequences

Direct harm to:

- animal or plant life, health or welfare (whether native or introduced species), including animal and plant production losses
- human life, health or welfare
- any other aspects of the environment not covered above (e.g. the physical environment or other life forms — microorganisms, etc.).

Indirect consequences

Indirect consequences are the costs resulting from natural or human processes associated with the incursion of a pest or disease:

- new or modified eradication, control, surveillance/monitoring and compensation strategies/programs
- domestic trade or industry effects, including changes in consumer demand and effects on other industries supplying inputs to, or utilising outputs from, directly affected industries
- international trade effects, including loss of markets, meeting new technical requirements to enter/maintain markets and changes in international consumer demand
- indirect effects on the environment (see below), including biodiversity, endangered species, the integrity of ecosystems, reduced tourism, reduced rural and regional economic viability and loss of social amenity, and any 'side effects' of control measures.

A range of factors may be relevant to the consideration of harm to the environment, including those arising from the impact of the disease agent itself or from any treatments or procedures used to control it. The extent of harm should be evaluated taking into account the circumstances of the particular hazard using the schema that follows. Factors that should be considered include:

- all on-site and off-site impacts
- the geographical scope and magnitude of the impact
- the frequency and duration of the action causing the harm
- the total impact which can be attributed to that action over the entire geographic area affected, and over time (i.e. cumulative impact)
- any synergistic effect of hazards on impact
- reversibility of the impact
- the sensitivity of the receiving environment (recognised environmental features of high sensitivity)
- the degree of confidence with which the impacts of the action are known and understood.

The direct and indirect criteria described above collectively cover the *economic*, *environmental* and *social* effects of a disease. Given this, the criteria are also intended to be mutually exclusive — that is, an effect should not be assessed more than once. In particular, the direct effects of a disease on a native or wild species should be assessed under the criterion describing the '*animal or plant life, health or welfare*', whereas the indirect or 'flow-on' effects on the environment should be assessed under the last indirect criterion.

Assessing the consequences of a pest on the PRA area

The likely consequences of a pest on each of the direct and indirect criteria (see above) may be estimated using a purely economic scale, or using some form of non-economic (qualitative or semi-quantitative) scale. Some effects, such as change in commercial production, are relatively easy to measure. Others, such as change in social amenity or in biodiversity, are more difficult.

The direct and indirect consequences of a pest, or its direct and indirect 'impacts', are estimated at each of four levels — local, district, regional and national. In this context, 'local', 'district', 'regional' and 'national' effects have been described:[51]

Local: an aggregate of households or enterprises — e.g. 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, such as the 'North West Slopes and Plains' or 'Far North Queensland'

Region: a geographically or geopolitically associated collection of districts — generally a state, although there may be exceptions with larger states such as Western Australia

National: Australia-wide

At each level, the quantum of impact is described as 'unlikely to be discernible', of 'minor significance', 'significant' or 'highly significant':

- an '*unlikely to be discernible*' impact is not usually distinguishable from normal day-to-day variation in the criterion

[51] When assessing the local, district, regional and national consequences, the frame of reference should be the impact of the disease on the community as a whole. This will often differ markedly from the effect of the disease on the local, district, regional or national population of directly affected parties.

- an impact of '*minor significance*' is not expected to threaten economic viability, but would lead to a minor increase in mortality/morbidity or a minor decrease in production. For non-commercial factors, the impact is not expected to threaten the intrinsic 'value' of the criterion — though the value of the criterion would be considered as 'disturbed'. Effects would generally be reversible
- a '*significant*' impact would threaten economic viability through a moderate increase in mortality/morbidity, or a moderate decrease in production. For non-commercial factors, the intrinsic 'value' of the criterion would be considered as significantly diminished or threatened. Effects may not be reversible
- a '*highly significant*' impact would threaten economic viability through a large increase in mortality/morbidity, or a large decrease in production. For non-commercial factors, the intrinsic 'value' of the criterion would be considered as severely or irreversibly damaged.

When considering the extent of consequences of a pest it will be important to determine the likely persistence of its effects. In general, where an effect is prolonged, as may be the case if it persists for several production cycles, or if regeneration of an ecosystem would take several generations, the consequences are considered to be greater. If the effect is not prolonged, then consequences are likely to be less serious. In either case, it may be necessary to place the disease into the next higher or lower level for that consequence criterion.

The consequences of the introduction and spread of a pest are considered *for each consequence criterion* at the local, district, regional and national level. These four values are translated to a range (denoted A–F) using the schema outlined in Table 23.

Table 23 The assessment of local, district, regional and national consequences

Impact score	Local	District	Regional	National
F	-	-	-	Highly significant
E	-	-	Highly significant	Significant
D	-	Highly significant	Significant	Minor
C	Highly significant	Significant	Minor	Unlikely to be discernible
B	Significant	Minor	Unlikely to be discernible	Unlikely to be discernible
A	Minor	Unlikely to be discernible	Unlikely to be discernible	Unlikely to be discernible

Level

After obtaining a measure of the consequences of a pest on each direct and indirect criterion, these need to be combined to estimate the overall consequences when a pest is transferred to *each identified category of suitable host*.

Intuitively, the consequences of a pest on individual criteria should be summed, because these outcomes will be additive. However, because the system is qualitative, true summation is not possible, and the following rules should be used to provide an approximate solution. These rules are mutually exclusive, and should be addressed in the order that they appear in the list. For

example, *if the first set of conditions does not apply, the second set should be considered. If the second set does not apply, the third set should be considered ...*, and so forth until one of the rules applies:

1. Where the consequences of a pest with respect to any direct or indirect criterion is 'F', the overall consequences are considered to be 'extreme'.
2. Where the consequences of a pest with respect to more than one criterion is 'E', the overall consequences are considered to be 'extreme'.
3. Where the consequences of a pest with respect to a single criterion is 'E' and the consequences of a pest with respect to each remaining criterion is 'D', the overall consequences are considered to be 'extreme'.
4. Where the consequences of a pest with respect to a single criterion is 'E' and the consequences of a pest with respect to remaining criteria is not unanimously 'D', the overall consequences are considered to be 'high'.
5. Where the consequences of a pest with respect to all criteria is 'D', the overall consequences are considered to be 'high'.
6. Where the consequences of a pest with respect to one or more criteria is 'D', the overall consequences are considered to be 'moderate'.
7. Where the consequences of a pest with respect to all criteria is 'C', the overall consequences are considered to be 'moderate'.
8. Where the consequences of a pest with respect to one or more criteria is considered 'C', the overall consequences are considered to be 'low'.
9. Where the consequences of a pest with respect to all criteria is 'B', the overall consequences are considered to be 'low'.
10. Where the consequences of a pest with respect to one or more criteria is considered 'B', the overall consequences are considered to be 'very low'.
11. Where the consequences of a pest with respect to all criteria is 'A', the overall consequences are considered to be 'negligible'.

Conclusions: risk assessment

This phase of the assessment requires the integration of likelihood evaluation and the evaluation of consequences, with the objective of deriving a measure of the 'likely consequences' associated with each quarantine pest. The procedure used to integrate the various components of the risk assessment will depend upon several factors. These include:

- whether each component was obtained using a qualitative, semi-quantitative or quantitative approach
- whether one or more than one category of suitable host was identified
- the manner in which the volume of trade during a specified period [52] is to be included in the assessment.

Although it is generally accepted that the volume of trade may have a marked effect on various likelihoods calculated or derived during a risk assessment, this aspect of import risk analysis remains relatively experimental. In the situation where all likelihoods have been estimated or

[52] Biosecurity Australia has designated 1 year as to be the standard period for which the effect of trade volume is estimated

calculated semi-quantitatively or quantitatively, the effect of trade volume can be assessed relatively easily. One approach to this will be to construct a separate module to determine the number of 'units' of a commodity that are likely to enter the importing country during a year, and to modify estimates obtained for the probability of importation and distribution accordingly. An alternative approach will be to carry out assessments in which the likelihoods assigned to particular steps in pathways are based on trade volume.

When the assessments of the probabilities of importation, distribution, establishment and spread have been carried out qualitatively, a practical approach will be needed. The adjustment of qualitative descriptors to accommodate the consideration of trade volume is not a technically ideal proposition. Given this, it is also imperative that the effect of trade volume be investigated and documented, because this may have a significant bearing on the importing country's decision to vary risk management measures, depending on the annual volume of imports.

One solution for qualitative assessments may be to state at the start of the risk assessment that *all* likelihoods have been assigned or derived under the implicit assumption that they refer to the volume of commodity likely to be imported in a given period. However, because estimates assigned on this basis will be more difficult to defend, the approach is likely to be problematic. A more preferable solution for situations that require consideration of the effect of trade volume would be to provide a quantitative or semi-quantitative assessment, either as an embellishment of the qualitative assessment or in place of it.

Incorporation of an assessment of the effect of trade volume is explained in further detail with reference to the two broad forms of distribution scenario:

- distribution scenarios for which a single category of suitable host was identified
- distribution scenarios for which more than a single a single category of suitable host was identified.

Risk estimation with a single category of suitable host

It was shown in the previous discussions that, where a single category of suitable host has been identified, risk assessment would yield the following (qualitative, semi-quantitative or quantitative) results:

- the probability of entry
- the probability of establishment
- the probability of spread
- an assessment of likely consequences.

In addition, it was explained that, where possible, trade volume should also be investigated, and should be included in the process of risk estimation.

Trade volume can be included in the assessment of the probability of importation, distribution, establishment and spread, or examined at the completion of an assessment. The latter is considered more transparent. If trade volume is to be included at the completion of an assessment, it will be necessary to obtain the estimate of the probability of importation, distribution, establishment and spread using a suitable 'basic unit'. For example, if the commodity were a live plant, then the individual plant would be a suitable basic unit. Alternatively, it may be more sensible to consider batches of commodities, such as a consignment of grain or a shipping container of fruit. As a rule, commodities for human consumption will generally be more complex to 'model', because they are invariably broken up or repackaged during the process of importation and/or distribution.

After the most appropriate basic unit has been determined, the likelihoods of importation, distribution, establishment and spread should be combined to give an overall probability of entry, establishment and spread. Where both of the components have been estimated semi-quantitatively or quantitatively, this will be a mathematical procedure and can be incorporated in the spreadsheet model.[53] Where one or other components has been evaluated qualitatively, then it will be necessary to combine them by using the approaches described in the discussion of qualitative and semi-quantitative likelihood evaluation (see Probability of Importation).

The likelihood of entry, establishment and spread, once obtained, may be modified by considering trade volume. The appropriate result of this procedure will be a likelihood phrased as '*the probability that a given pest will be introduced at least once as a result of importing a given commodity for 1 year*'. Algebraically, this probability can be expressed as:

$$PEES_{annual} = 1 - (1 - PEES)^{VT}$$

where,

$PEES_{annual}$	is the annual probability of entry, establishment and spread — that is, the likelihood that a given pest will be introduced as a result of importing the commodity for 1 year
PEES	is the probability of entry, establishment and spread, expressed in terms of the chosen 'basic unit'
VT	is the volume of trade, expressed as the number of basic units imported during 1 year.

After an estimate for the probability of entry, establishment and spread has been obtained and expressed in units that reflect the likely trade volume, this can be combined with the assessment of consequences to derive a risk estimate. Where all components of the risk assessment are quantitative, this will simply be a mathematical procedure. In the more common situation where there are one or more qualitative elements, then a set of 'decision rules' will be required.

The risk estimation matrix shown in Table 24 provides one means by which decision rules can be intuitively displayed. The cells in this matrix represent risk, or 'expected loss' — that is, the combination of a measure of consequences and a measure of likelihood. Accordingly, risk will always be expressed in the same 'units' as consequences, and must be less than or equal to the original estimate of consequences.

[53] The mechanics of the model may be such that this step is more complex than simple 'multiplication'.

To illustrate by example:

If when tossing a coin, the likelihood of a head is 0.5 and the loss associated with it is $10, then the likely consequences will be expressed in dollars, and cannot be more than $10. In fact, the likely consequences are given by, $10 x 0.5 = $5.

A 2 x 2 risk estimation matrix could be drawn up for coin tossing. The purpose of the risk estimation matrix is thus to illustrate what is generally an intuitive relationship between 'likelihood' and 'consequences', and to formalise the rules that determine the result when specific values of each are combined.

If trade volume has been considered, the cells in the risk estimation matrix represent the 'risk associated with the importation of a given commodity for 1 year'. Interpretation of this result according to Australia's ALOP, or tolerance for loss, is discussed in the following section (see *Risk Management*).

Table 24 Risk estimation matrix

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

Consequences of entry, establishment and spread

Risk estimation with more than a single category of suitable host

It was shown in earlier discussions that where more than one category of suitable host has been identified, the risk assessment would yield the following qualitative, semi-quantitative or quantitative results:

- the probability of importation
- the partial probability of distribution for *each category of suitable host*

- the partial probability of establishment for *each category of suitable host*
- the partial probability of spread for *each category of suitable host*
- an assessment of consequences for *each category of suitable host*.

As was the case for the more simple distribution scenarios, it may be necessary to add an assessment of trade volume to this list and to include it in the process of risk estimation. The role of the 'basic unit' in which a commodity is imported will be identical to that described above. Indeed, the only difference between risk estimation for single versus multiple categories of suitable host will be the manner in which the partial probabilities of distribution are combined.

In the scenario diagram in Figure 23, there are essentially two distinct branches emanating from the two categories of suitable host and persisting through the assessment of consequences. This is sensible, because the consequences of a pest will most probably be different for each of the categories. Accepting this, risk estimation with multiple distribution scenarios will be carried out in two stages:

- an evaluation of the 'partial risk' associated with the transfer of a pest to each category of suitable host
- the combination of the partial risk for each category of suitable host to give an estimate of the 'overall risk' associated with the given commodity

The 'partial risk' associated with the transfer of a pest to each category of suitable host will be evaluated in essentially the same manner as described in the previous section, the only difference being the replacement of the single 'probability of distribution', 'probability of establishment' and 'probability of spread', with the partial probabilities obtained for each identified category of suitable host. Given this, the probability of importation and each partial probability of distribution, establishment and spread can be combined as described above, and the result modified to incorporate an estimate of the annual volume of trade. This probability can then be combined with the assessment of consequences to give the 'partial risk' associated with the transfer of a pest to a given category of suitable host. The process can be undertaken using the risk estimation matrix (Table 24).

After a partial risk estimate has been obtained for each category of suitable host, these can be combined to give an 'overall' estimate of risk. Where the estimates are purely quantitative, this will be achieved mathematically. In the more common situation where at least one component is qualitative or semi-quantitative, and the qualitative or semi-quantitative terminology described throughout this document has been adopted, partial risks can be combined by applying the eleven decision rules shown below. These rules are mutually exclusive, and should be addressed in the order that they appear in the list. For example, *if the first set of conditions does not apply, the second set should be considered. If the second set does not apply, the third set should be considered*... and so forth until one of the rules applies.

1. Where any one partial risk is 'extreme', the overall risk is also considered 'extreme'.
2. Where more than one partial risk is 'high', the overall risk is considered 'extreme'.
3. Where any one partial risk 'high' and each remaining partial risk is 'moderate', the overall risk is considered 'extreme'.
4. Where a single partial risk is 'high' and the remaining partial risks are not unanimously 'high', the overall risk is considered 'high'.
5. Where all partial risks are 'moderate', the overall risk is considered 'high'.
6. Where one or more partial risks are 'moderate', the overall risk is considered 'moderate'.
7. Where all partial risks are 'low', the overall risk is considered 'moderate'.

8. Where one or more partial risks are considered ‘low’, the overall risk is considered ‘low’.
9. Where all partial risks are very ‘low’, the overall risk is considered ‘low’.
10. Where one or more partial risks are ‘very low’, the overall risk is considered ‘very low’.
11. Where all partial risks are ‘negligible’, the overall risk is considered ‘negligible’.

When trade volume has been considered, the result of the procedure will be an estimate of the risk associated with importing a given commodity for 1 year. Interpretation of this result according to Australia’s ALOP, or tolerance for loss, is discussed in the following section.

STAGE 3: RISK MANAGEMENT

Risk management describes the process of identifying and implementing measures to manipulate risks and so achieve the importing country’s ALOP, or tolerance for loss, while ensuring that any negative effects on trade are minimised. As described previously in this document (see, Appropriate Level of Protection), ALOP is considered a societal value judgement that reflects the maximal risk (or expected loss) from a pest incursion that Australia considers ‘acceptable’.

According to the *SPS Agreement*, Members should base risk management on a *consistent* level of acceptable risk. That is, a Member Country should exercise a single ALOP. This requirement means that the outcome of measures imposed on one commodity should not be more ‘risk averse’ or ‘risk seeking’ than the outcome of measures imposed on other commodities, whether from the same exporting country or different exporting countries.

To implement risk management appropriately, it is necessary to recognise the difference between ‘unrestricted’ and ‘restricted’ risk estimates. Unrestricted risk estimates are those derived in the complete absence of any risk management, or using only internationally accepted baseline risk management strategies. In contrast, restricted or mitigated risk estimates are those derived when ‘risk management’ is applied.

The result of the ‘risk assessment’ for a given commodity (as described in the preceding section) will be a list of ‘unrestricted risk estimates’ corresponding to the list of identified quarantine pests. These unrestricted risk estimates should each be compared with Australia’s ALOP, which is shown in the risk estimation matrix (Table 24) as the band of cells associated with a ‘very low’ risk.

An unrestricted risk that is either ‘negligible’ or ‘very low’ meets Australia’s ALOP and should be considered ‘acceptable’ — in this situation, risk management is not justified. Where an unrestricted risk is ‘low’, ‘moderate’, ‘high’ or ‘extreme’, however, risk management measures would need to be identified and applied and, for each of these, the restricted risk should be calculated. This process is termed ‘option evaluation’.

Where the restricted risk derived using a particular risk management measure (or combination of measures)[54] is ‘very low’, that measure(s) should be considered acceptable. Where the restricted risk derived using a particular risk management measure (or combination of measures) is ‘negligible’, the measure(s) *may* be considered unnecessarily trade-restrictive, and a reassessment of the measures imposed is justified (taking into account the availability and feasibility of

[54] In some situations, identified risk management measures will not reduce the risk to an acceptable level when applied individually. Here it will be necessary to investigate the efficacy of the feasible combinations of identified measures, or risk management ‘strategies’. This process is considered an extension of ‘option evaluation’, and should be carried out in the same manner as is used to evaluate individual measures.

alternative measures). Where possible, risk management measures that are overly protective should either be rejected, or manipulated to be less trade-restrictive. The exception to this is the situation where production systems or other factors mean that 'overly trade-restrictive' risk management measures are more easily accommodated by the exporting country than less restrictive alternatives. The range of alternative risk management measures may in some situations be limited. Where this is the case, it may be necessary to specify measures that result in a level of risk lower than Australia's ALOP, and to justify this with a transparent statement describing the limitation.

It is possible that some quarantine treatments will cause harm to the environment. Quarantine treatments should not be authorised unless any potential harm to the environment has been assessed. This includes harm from residues. Relevant considerations could include local legal requirements, manufacturer's advice on usage and national or international standards. Decision-makers should be satisfied that appropriate precautions to protect the environment would be used when the treatment is conducted.

The iterative process of risk management leads to a set of acceptable measures or strategies for each identified hazard for which the unrestricted risk is considered higher than Australia's ALOP. These measures or strategies will reduce risk to a level that is considered acceptable. Where measures or strategies that reduce the risk associated with a particular hazard to an acceptable level cannot be identified, permission to import the relevant commodity will be denied.

IPPC (see IPPC ISPM) makes the following specific suggestions regarding the evaluation of options for pest risk management.

Identification and selection of appropriate risk management options

Appropriate measures should be chosen based on their effectiveness in reducing the probability of introduction of the pest. The choice should be based on the following considerations, which include several of the *Principles of Plant Quarantine as Related to International Trade* (ISPM No. 1):

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

The major risk of introduction of plant pests is with imported consignments of plants and plant products, but (especially for a PRA performed on a particular pest) it is necessary to consider the

risk of introduction with other types of pathways (e.g. packing materials, conveyances, travellers and their luggage, and the natural spread of a pest).

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

These include measures:

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

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

Options for consignments

Measures may include any combinations of the following:

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

Options preventing or reducing infestation in the crop

Measures may include:

- treatment of the crop, field, or place of production
- restriction of the composition of a consignment so that it is composed of plants belonging to resistant or less susceptible species
- growing plants under specially protected conditions (glasshouse, isolation)
- harvesting of plants at a certain age or a specified time of year

- production in a certification scheme. An officially monitored plant production scheme usually involves several carefully controlled generations, beginning with nuclear stock plants of high health status. It may be specified that the plants be derived from plants within a limited number of generations.

Options ensuring that the area, place or site of production or crop is free from the pest

Measures may include:

- pest-free area: requirements for pest-free area status are described in ISPM 4 (Requirements for the Establishment of Pest-Free Areas)
- pest-free place of production or pest-free production site — requirements are described in Requirements for the ISPM 10 (Establishment of Pest-Free Places of Production and Pest-Free Production Sites)
- inspection of crop to confirm pest freedom.

Generic import risk analyses[55] are those in which the likelihood of entry is not based on a consideration of risk factors in any individual exporting country. This is an intuitively attractive approach, because the import risk analysis will not have to be repeated for each prospective exporter. This will save time and will, theoretically, encourage greater consistency in the approach taken with particular exporting countries. The difficulty is, however, that to assess the 'acceptability' of an unrestricted risk, and thus validate any subsequent requirement for risk management, it will be necessary to estimate the unrestricted likelihood of pest or disease entry. By definition, this must be influenced by country-specific risk factors.

Approaches to circumvent this difficulty include the following:

- It may be useful to define an import risk analysis as 'generic', and yet carry out essentially independent risk analyses for each identified country, or for groups of countries. This would not require the background and Biosecurity Australia policy statements to be reiterated. Likewise, the outline of import risk analysis method and, particularly, the description of scenarios for likelihood and consequence assessments, would be identical for each country. Finally, the technical information upon which the evaluation of likelihoods is based, and the assessments of disease consequences, are generic, and would not need to be repeated. The approach would, however, require that risk assessments be carried out for each country that has made an access request. Further risk assessments could be added as new countries are identified. According to this approach, the 'generic import risk analysis' would be coordinated by a single Risk Analysis Panel (RAP) or team of Biosecurity Australia risk analysts, and would be carried out within the prescribed timeframe for a routine or non-routine import risk analysis.
- Countries may be grouped according to 'country factors', such as disease or pest prevalence, or the adequacy of disease or pest surveillance. This will enable country factors to be considered when estimating the probability of entry. Likewise risk estimation, and any ensuing decisions to implement risk management, will be based on a complete evaluation of unrestricted risk (see above). If this approach is to be adopted, it will be necessary to provide documentation that supports the grouping of countries according to particular country factors. Moreover, it will be necessary to explain why the specified factors are considered the critical factors in evaluating the probability of entry for the given commodity. The principal difficulty with this approach is that countries will need to be grouped when assessing each identified pathogenic agent. Where the number of pathogenic agents is large, this process may become an administrative challenge.
- It may be possible to demonstrate that country factors are not important in the determination of a release assessment for a given commodity (i.e. that the 'biological factors' or 'commodity factors' are those that are critical), or that the likelihoods assigned to country factors are truly 'generic'. The first case is more likely to be relevant to commodities produced according to a defined series of generic processing steps, where these may reduce the probability of entry to a given level regardless of country factors. The defined processing steps may be integral to the commodity, dictated by industry standards or, where the commodity is a foodstuff for human use, dictated by Australian standards. The second case may also be relevant to processed

[55] Generic import risk analyses are also, in some instances, termed 'global import risk analyses' — the term 'generic' has been adopted exclusively in this document.

commodities, but makes more specific reference to the fact that factors inherent to the epidemiology of a pest or disease may dictate country-specific likelihoods such as the prevalence of that pest or disease. In this situation, it may be more sensible to accept conservative estimates for these likelihoods, and assume that these estimates will be the same for all exporting countries.

A more complex modification of the first and second approaches (see above) might be to undertake the risk assessment in two phases. Initially, the release assessment would ignore country factors, and thus consider only those issues such as pathogen survivability in the commodity, that will be equivalent for all countries. Where the risk estimate derived from this abbreviated approach is less than Australia's ALOP, it will not be necessary to consider the hazard further (or to implement risk management). Those hazards for which the abbreviated risk is greater than Australia's ALOP should be summarised and, for each, a second country-specific assessment undertaken in reference to each of the countries for which access requests have been received. This second assessment will yield a series of true unrestricted risks, which may then be interpreted against Australia's ALOP. Those that exceed the maximum accepted level will require risk management.

INTERNET ADDRESSES FOR INTERNATIONAL AGREEMENTS AND STANDARDS

Agreement on the Application of Sanitary and Phytosanitary Measures

Available at: http://www.wto.org/english/docs_e/legal_e/15-sps.wpf

Section 1.4 of the OIE International Animal Health Code

Available at: http://www.oie.int/Norms/MCode/A_00007.htm

Section 1.4 of the OIE International Aquatic Animal Health Code

Available at: http://www.oie.int/norms/FCode/A_00007.htm

IPPC ISPM2 (Guidelines for Pest Risk Analysis)

Available at: http://www.fao.org/ag/agp/agpp/pq/default.htm

IPPC ISPM (Pest Risk Analysis for Quarantine Pests)

Available at: http://www.fao.org/ag/AGP/AGPP/PQ/En/IPPCe.htm