

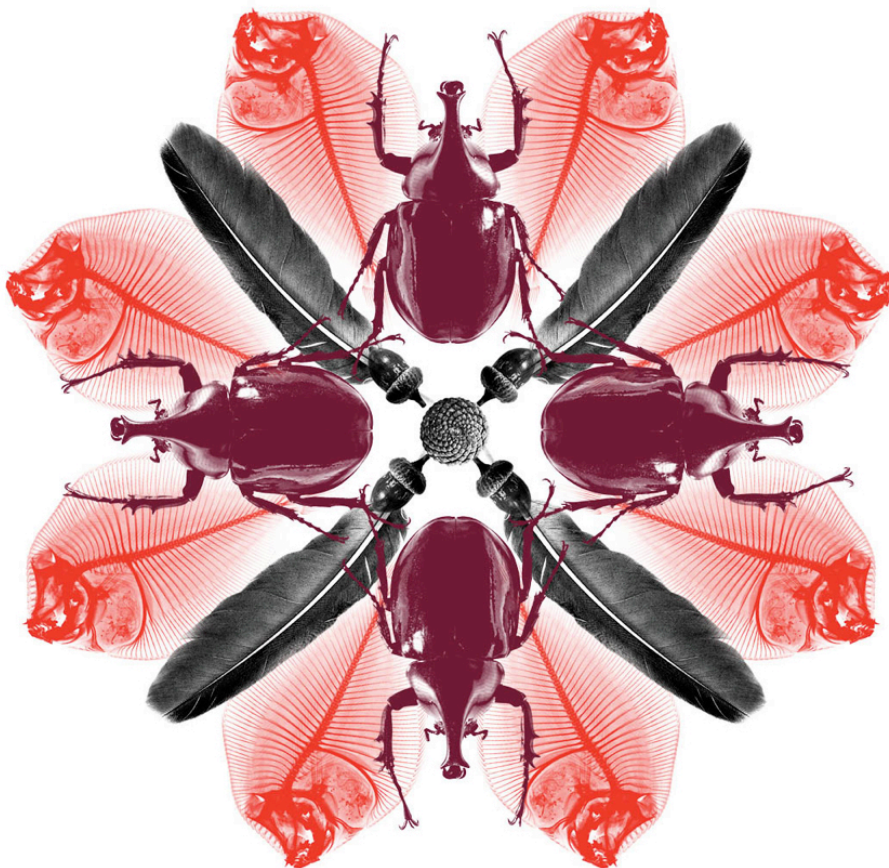


Australian Government
Department of Agriculture

Final Risk Analysis Report for the release of *Eueupithecia* sp.2 for the biological control of the weed *Parkinsonia aculeata*

Biosecurity

MARCH 2014



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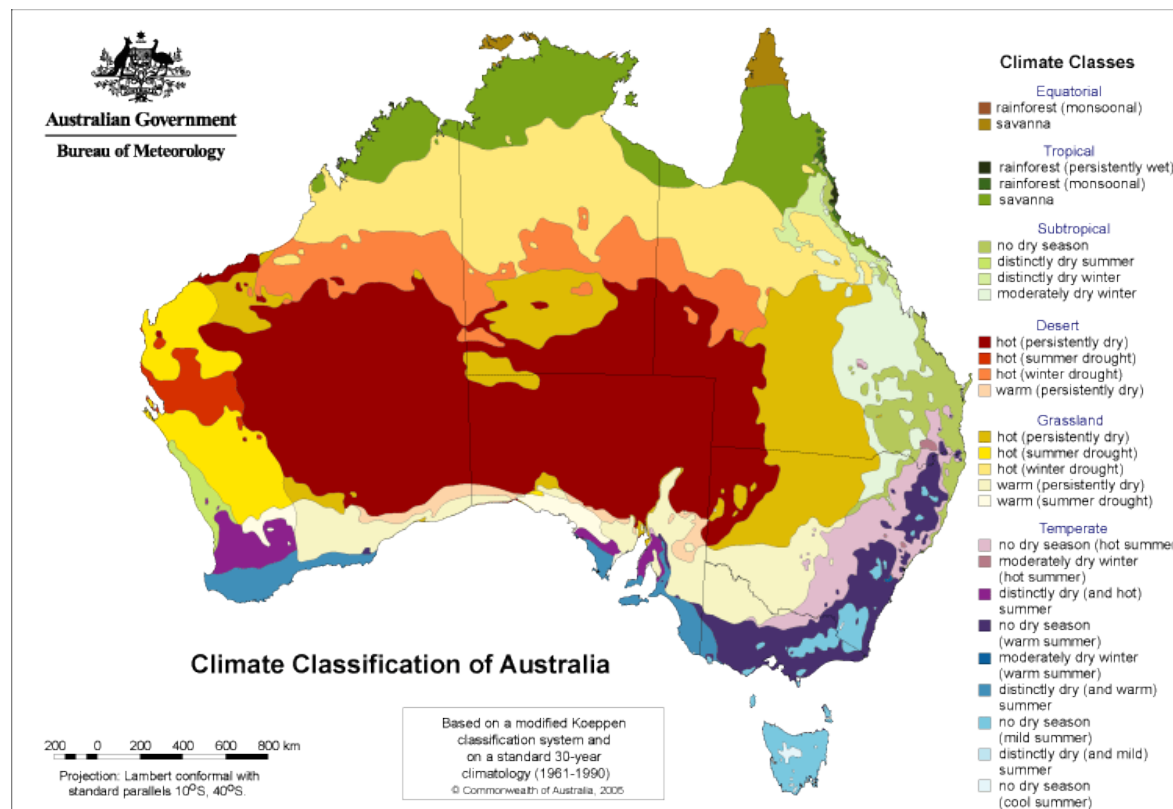
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Figure 1 Map of Australia



Figure 2 A guide to Australia's bio-climate zones



Acronyms and abbreviations

Term or abbreviation	Definition
ALOP	Appropriate level of protection
APPD	Australian Plant Pest Database (Plant Health Australia)
BCA	Biological Control Agent
CABI	CAB International, Wallingford, UK
CMI	Commonwealth Mycological Institute
FAO	Food and Agriculture Organization of the United Nations
IPC	International Phytosanitary Certificate
IPM	Integrated Pest Management
IPPC	International Plant Protection Convention
ISPM	International Standard for Phytosanitary Measures
NPPO	National Plant Protection Organization
NSW	New South Wales
NT	Northern Territory
Qld	Queensland
RA	Risk Analysis
Tas.	Tasmania
Vic.	Victoria
WA	Western Australia
WTO	World Trade Organisation

Summary

This final risk analysis finalises an application from CSIRO Ecosystem Sciences to release the geometrid moth *Eueupithecia* sp.2 for the biological control of the weed *Parkinsonia aculeata*. In accordance with the IRA handbook 2011, this risk analysis has been undertaken as a non-regulated analysis of existing policy.

The report recommends that the biological control agent should be released, subject to standard quarantine conditions associated with the import and release of biological control agents.

The report has determined that the probability of off-target effects and potential consequences that would be associated with the release of *Eueupithecia* sp.2 are negligible. The risk is estimated to be negligible, which meets Australia's appropriate level of protection (ALOP).

The report takes into account stakeholders' comments on the December 2013 draft risk analysis report. Comments were received from 3 stakeholders.

The Department of Environment also has an approval process for the import and release of biological control agents under the Environment Protection and Biodiversity Conservation (EPBC) Act 1999. There has been consultation with the Department of the Environment prior to the release of this report. The Department of the Environment has supported the findings of the report.

A preliminary draft of this report was distributed to state and territory departments of primary industry and the Commonwealth Scientific and Industrial Research Organisation (CSIRO) through the Plant Health Committee (PHC). Comments received via this consultation process were incorporated into the risk analysis report. All comments endorsed the preliminary draft and its recommendations.

Introduction

1.1 Australia's biosecurity policy framework

Australia's biosecurity policies aim to protect Australia against the risks that may arise from exotic pests¹ entering, establishing and spreading in Australia, thereby threatening Australia's unique flora and fauna, as well as those agricultural industries that are relatively free from serious pests.

Risk analysis is an important part of Australia's biosecurity policies. It enables the Australian Government to formally consider the risks that could be associated with proposals to release a new organism into Australia. If the risks are found to exceed Australia's appropriate level of protection (ALOP) then release will not be allowed.

Successive Australian Governments have maintained a conservative, but not a zero risk, approach to the management of biosecurity risks. This approach is expressed in terms of Australia's ALOP, which reflects community expectations through government policy and is currently described as providing a high level of protection aimed at reducing risk to a very low level, but not to zero.

Risk analyses for biological control agents are undertaken within the Department of Agriculture by technical and scientific experts with consultation with appropriate scientific specialists. Consultation with stakeholders also occurs. The Department of Agriculture provides recommendations for animal and plant quarantine policy to Australia's Director of Animal and Plant Quarantine (the Secretary of the Australian Government Department of Agriculture). The Director, or delegate, is responsible for determining whether or not release of a biological control agent can be permitted under the Quarantine Act 1908, and if so, under what conditions.

1.2 This risk analysis

1.2.1 Background

An application has been submitted by CSIRO Ecosystem Sciences to release a biological control agent (Attachment 1). The biological control agent, *Eueupithecia* sp.2 is a leaf defoliating caterpillar proposed for the biological control of the weed *Parkinsonia aculeata* (Leguminosae: Caesalpinioideae). The applicant has followed the steps outlined in the Biosecurity Guidelines for the Introduction of Exotic Biological Control Agents for the Control of Weeds and Plant Pests (daff.gov.au/ba/reviews/biological_control_agents/protocol_for_biological_control_agents).

1.2.2 Scope

This report assesses the risk associated with the release of a biological control agent into the Australian environment. The primary risk with a release of this nature is the possibility of unwanted off-target effects on other species already present in Australia. The Department of Agriculture assesses the risk under the Quarantine Act 1908. The Department of the Environment also has an approval process under the Environment Protection and Biodiversity Conservation Act 1999. This final risk analysis report may be used by the responsible Minister in making a determination to include the item on the List of specimens taken to be suitable for live import (live import list).

¹ A pest is any species, strain or biotype of plant, animal, or pathogenic agent injurious to plants or plant products (FAO 2012).

Plants that are considered weeds are sometimes considered to have value. For example, as ornamental species, traditional medicine, feed for stock etc. Consideration of the benefits and therefore any concerns about eradication of the target weed species are out of scope of this analysis.

The Department of Agriculture will not commence an assessment to release a biological control agent unless the target has been approved by an appropriate government body. *Parkinsonia aculeata* was approved as a target for biological control in Australia by The Australian Weeds Committee in 1983.

1.2.3 Contaminating pests

There are organisms that may arrive with imported biological control agents. These organisms may include parasitoids, mites or fungi. The Department of Agriculture considers these organisms to be contaminating pests that could pose sanitary and phytosanitary risks. Should this application to release be approved, these risks will be addressed by existing operational procedures that apply to the importation and final release of biological control agents. These procedures include detailed examination of imported material, confirmation of identity and breeding through one generation before release. For this reason, contaminating pests are not considered in this risk analysis.

1.2.4 Consultation

On 15 August 2013 a preliminary draft of this report was distributed to state and territory departments of primary industry and the Commonwealth Scientific and Industrial Research Organisation (CSIRO) through the Plant Health Committee (PHC) as well as the Department of the Environment. Comments received via this consultation process were incorporated into the draft risk analysis report. All comments endorsed the preliminary draft and its recommendations.

On 19 December 2013, Biosecurity Advice (BA) 2013/23 informed stakeholders of the release of a draft risk analysis report for the release of the moth *Eueupithecia* sp.2 for the biological control of the weed *Parkinsonia aculeata*. The draft report was also released at this time for a 30-day stakeholder consultation period that closed on 19 January 2014. Written submissions received from 3 stakeholders were considered. All comments endorsed the draft and its recommendations.

The Department of the Environment also has an approval process for the import and release of biological control agents under the *Environment Protection and Biodiversity Conservation (EPBC) Act 1999*. There has been consultation with the Department of the Environment prior to the release of this report and it has endorsed the findings of this report.

Method for analysis

Biological control agents (BCAs) intended for release are deliberately introduced, distributed, aided to establish and spread. Therefore it would be inappropriate to assess the probability of entry, establishment and spread using the processes described in ISPM 11 (FAO 2013). This BCA RA will focus only on off-target effects, as this is the only concern with regard to the release of biological control agents.

Australia's appropriate level of protection (ALOP)

The SPS Agreement defines the concept of an 'appropriate level of sanitary or phytosanitary protection (ALOP)' as the level of protection deemed appropriate by the WTO Member establishing a sanitary or phytosanitary measure to protect human, animal or plant life or health within its territory.

Like many other countries, Australia expresses its ALOP in qualitative terms. Australia's ALOP, which reflects community expectations through government policy, is currently expressed as providing a high level of sanitary or phytosanitary protection aimed at reducing risk to a very low level, but not to zero.

Assessment of off-target risks

This section sets out the assessment of off-target risks that could be associated with the release of the biological control agent. Where appropriate, the methods followed those used for pest risk analysis (PRA) by the Department of Agriculture in accordance with the *International Standards for Phytosanitary Measures* (ISPMs), including *ISPM 2: Framework for Pest Risk Analysis* (FAO 2007) and *ISPM 11: Pest Risk Analysis for Quarantine Pests* (FAO 2013). The methodology for a commodity-based PRA is provided in Appendix A.

The risk associated with release of a biological control agent is a combination of the probability of off-target effects and the potential magnitude of the consequences of any off-target impacts.

1.3 Stage 1: Initiation

Initiation commences when the applicant provides a submission proposing the release of the biological control agent.

The risk analysis area is defined as all of Australia given that once released there will be no control of spread of the agent other than environmental constraints related to the biology of the organism.

1.4 Stage 2: Risk assessment

This assessment evaluates the probability of off-target effects and the potential economic and environmental consequences of these effects.

Assessment of the probability of off-target effects

Given that the proposal is for deliberate release the probability of entry, establishment and spread is assumed to be certain and therefore the assessment relates to the host specificity of the proposed agent.

A qualitative likelihood is assigned to the estimate of probability of off-target effects. Six descriptors are used: high; moderate; low; very low; extremely low; and negligible. Definitions of each descriptor are given in Appendix A, Table 1.

Attachment 1 gives details provided by the proponent of the host specificity testing that was carried out.

1.4.1 Background to this application

Eueupithecia cisplatensis was approved by the Department of Agriculture for release as a biological control agent for *Parkinsonia aculeata* in 2012, and released in 2013. *Eueupithecia cisplatensis* and the moth species described in this application as "*Eueupithecia* sp.2" are currently the only known members of the genus *Eueupithecia*.

The moth proposed for release in this application has not been formally described. However, the applicant has provided a table of traits, based on the morphology of adult genitalia, that can be used to distinguish *Eueupithecia* sp.2 from *Eueupithecia cisplatensis* (Attachment 1). Voucher specimens will be deposited with the Department of Agriculture and the Australian National Insect Collection prior to release. A formal species description is anticipated to be published prior to release.

1.4.2 Preliminary surveys

In the field in Argentina, *Eueupithecia* sp.2 was only recovered from *Parkinsonia aculeata*. *Eueupithecia* sp.2 was not found on any other co-occurring legume species, including the congeneric *P. praecox*, at four sample sites. These preliminary findings were followed by more extensive host specificity testing.

1.4.3 Host specificity testing methodology

Compilation of the host test list followed an acceptable methodology; test plant species were selected based on relatedness to the target. The list of test plant species is very similar to the list used for the previously approved *Eueupithecia cisplatensis*. Host specificity testing was sufficiently extensive and included two types of no-choice tests:

- testing of larval development on cut plant material of 42 plant species in Argentina and Australia, and
- testing of larval development on 21 live plant species in Australia.

Negative results in no-choice feeding tests provide strong evidence that the test plant will not serve as a host, as it demonstrates an agent is incapable of surviving on the test plant. Choice tests may provide additional information in cases where no-choice tests indicate that potential non target effects may occur. Choice tests are typically conducted between the target and a selected test plant to determine the oviposition preferences of adult females or feeding preferences of larvae. However, in the case of *Eueupithecia* sp.2, no plant was identified as a potential host besides *P. aculeata*, therefore no-choice tests are sufficient in establishing confidence that the outcomes of the host testing indicate all possible off-target effects.

1.4.4 Results of host specificity testing

Of the plant species tested, feeding and the ability to complete a life cycle occurred on both cuttings and live plants of only the target species, *Parkinsonia aculeata*. Host testing on cut plant material was carried out in Argentina on 20 legume plant species and in Australia on 42 legume plant species. Host

testing on living plants was carried out in Australia on 21 species. All host testing was in the form of no-choice larval development tests. No feeding or damage was observed on any non-target plant species tested either as cuttings or as live plants. The applicant states in their report (Attachment 1) that “our larvae died rather than feed on all test plant species except *P. aculeata*”.

On the basis of the work presented in Attachment 1 it is concluded that the probability of off-target effects is: NEGLIGIBLE (the event would almost certainly not occur).

Assessment of potential consequences to off-target species

The potential consequences of the off-target effects of this biological control agent have been assessed using the same methodology (Appendix A) as used in the import risk analyses for pests that may be associated with imported produce.

Criterion	Estimate and rationale
Direct	
Plant life or health	Impact score: A – Indiscernible. Of all the plant species tested in Australia and Argentina, only <i>Parkinsonia aculeata</i> was able to support <i>Eueupithecia</i> sp.2 pupation and adult emergence. Therefore no off-target effects or consequences are anticipated. The target organism <i>Parkinsonia aculeata</i> is the only naturalised <i>Parkinsonia</i> species in Australia and there are no indigenous species of this group present in Australia.
Other aspects of the environment	Impact score: A There is no known evidence of any negative impact caused by <i>Eueupithecia</i> sp.2 within its native range.
Indirect	
Eradication, control etc.	Impact score: A <i>Eueupithecia</i> sp.2 is proposed for release for the biological control of the weed parkinsonia and testing has shown it to be very host specific. As it is host specific on parkinsonia, and does not affect other economic or environmental attributes, it would be extremely unlikely to meet criterion for eradication. Therefore, the need for eradication and or control is not anticipated.
Domestic trade	Impact score: A <i>Eueupithecia</i> sp.2 is host specific to the weed parkinsonia and is not a pest of primary industries. Therefore impacts on domestic trade would not be expected.
International trade	Impact score: A <i>Eueupithecia</i> sp.2 is host specific to the weed parkinsonia and is not a pest of primary industries. Therefore impacts on international trade would not be expected.
Environmental and non-commercial	Impact score: A As the only direct effects of <i>Eueupithecia</i> sp.2 are on the introduced species <i>Parkinsonia aculeata</i> , this species is not likely to have any negative indirect environmental or non-commercial effects. Reduction of the weed parkinsonia is unlikely to have any negative indirect effects on the environment.

Based on this assessment the potential consequences of off-target effects are: **NEGLIGIBLE**.

Estimating the off-target risk of release of the biological control agent

The estimate of probability of off-target effects of **negligible** are combined with the estimate of potential consequences of **negligible** to provide an estimate of risk of **NEGLIGIBLE**.

The estimate of risk is the result of combining the probability of off-target effects with the outcome of overall potential consequences. Probabilities and consequences are combined using the risk estimation matrix shown in Appendix A, Table 5.

A risk estimate of '**negligible**' achieves Australia's appropriate level of protection.

Recommendation on release

Given that the estimate of risk is negligible it is recommended that this biological control agent should be released subject to standard import and release conditions to ensure that the released material is free of other organisms.

Stakeholder responses to draft risk analysis report

Written submissions were received from 3 stakeholders. All stakeholders supported the release of *Eueupithecia* sp. 2 into the Australian environment;

AUSVEG (Dean Schrieke, AUSVEG Biosecurity and Special Projects Coordinator)

Department of Agriculture and Food, Western Australia (John van Schagen, Director of Plant Biosecurity)

Department of Parks and Wildlife, Western Australia (Ken Atkins, Manager, Species and Communities Branch)

Therefore the outcome of the risk analysis has not been altered from the draft recommendation to release *Eueupithecia* sp. 2.

Attachments

Attachment 1 - Application to release the defoliating caterpillar *Eueupithecia* sp.2 for biological control of the weed *Parkinsonia aculeata* – May 2013

Appendix A Method for pest risk analysis

This chapter sets out the method used for the pest risk analysis (PRA) in this report. The Department of Agriculture conducts PRAs in accordance with the International Standards for Phytosanitary Measures (ISPMs), including ISPM 2: Framework for pest risk analysis (FAO 2007) and ISPM 11: Pest risk analysis for quarantine pests (FAO 2013) that have been developed under the SPS Agreement (WTO 1995).

A PRA is 'the process of evaluating biological or other scientific and economic evidence to determine whether an organism is a pest, if a pest should be regulated and the strength of any phytosanitary measures to be taken against it' (FAO 2012). A pest is 'any species, strain or biotype of plant, animal, or pathogenic agent injurious to plants or plant products' (FAO 2012).

Quarantine risk consists of two major components: the probability of a pest entering, establishing and spreading in Australia from imports; and the consequences should this happen. These two components are combined to give an overall estimate of the risk.

Unrestricted risk is estimated taking into account the existing commercial production practices of the exporting country and that, on arrival in Australia, the Department of Agriculture will verify that the consignment received is as described on the commercial documents and its integrity has been maintained.

Restricted risk is estimated with phytosanitary measure(s) applied. A phytosanitary measure is 'any legislation, regulation or official procedure having the purpose to prevent the introduction and/or spread of quarantine pests, or to limit the economic impact of regulated non-quarantine pests' (FAO 2012).

A glossary of the terms used is provided at the back of this report.

PRAs are conducted in the following three consecutive stages: initiation, pest risk assessment and pest risk management.

1.5 Stage 1: Initiation

Initiation identifies the pest(s) and pathway(s) that are of quarantine concern and should be considered for risk analysis in relation to the identified PRA area.

For this PRA, the 'PRA area' is defined as Australia for pests that are absent, or of limited distribution and under official control. For areas with regional freedom from a pest, the 'PRA area' may be defined on the basis of a state or territory of Australia or may be defined as a region of Australia consisting of parts of a state or territory or several states or territories.

For pests that had been considered by the Department of Agriculture in other risk assessments and for which import policies already exist, a judgement was made on the likelihood of entry of pests on the commodity and whether existing policy is adequate to manage the risks associated with its import. Where appropriate, the previous policy has been adopted.

1.6 Stage 2: Pest risk assessment

A pest risk assessment (for quarantine pests) is: 'the evaluation of the probability of the introduction and spread of a pest and of the likelihood of associated potential economic consequences' (FAO 2012).

In this report, the pest risk assessments were divided into the following interrelated processes:

1.6.1 Pest categorisation

Pest categorisation identifies which pests with the potential to be on the commodity are pests of quarantine concern and require pest risk assessment.

The pests identified in Stage 1 were categorised using the following primary elements to identify the pests of quarantine concern for the commodity being assessed:

- identity of the pest
- presence or absence in the PRA area and the rest of Australia
- regulatory status
- potential for establishment and spread in the PRA area
- potential for economic consequences (including environmental consequences) in the PRA area.

The results of pest categorisation for the pests considered in this PRA are set out in the Appendixes. The pests of quarantine concern identified during pest categorisation were carried forward for pest risk assessment and are listed in the document.

1.6.2 Assessment of the probability of entry, establishment and spread

Details of how to assess the 'probability of entry', 'probability of establishment' and 'probability of spread' of a pest are given in ISPM 11 (FAO 2013). A summary of this process is given below, followed by a description of the qualitative methodology used in this report.

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 in the PRA area and subsequently be transferred to a host. It is based on pathway scenarios depicting necessary steps in the sourcing of the commodity for export, its processing, transport and storage, its use in Australia and the generation and disposal of waste. In particular, the ability of the pest to survive is considered for each of these various stages.

The probability of entry estimates for the quarantine pests for a commodity are based on the use of the existing commercial production, packaging and shipping practices of the exporting country. Details of the existing commercial production practices for the commodity are set out in Chapter 3. These practices are taken into consideration by the Department of Agriculture when estimating the probability of entry.

For the purpose of considering the probability of entry, the Department of Agriculture divides this step into two components:

- **Probability of importation:** the probability that a pest will arrive in Australia when a given commodity is imported.
- **Probability of distribution:** the probability that the pest will be distributed, as a result of the processing, sale or disposal of the commodity, in the PRA area and subsequently transfer to a susceptible part of a host.

Factors considered in the probability of importation include:

- distribution and incidence of the pest in the source area

- occurrence of the pest in a life-stage that would be associated with the commodity
- mode of trade (e.g. bulk, packed)
- volume and frequency of movement of the commodity along each pathway
- seasonal timing of imports
- pest management, cultural and commercial procedures applied at the place of origin
- speed of transport and conditions of storage compared with the duration of the lifecycle of the pest
- vulnerability of the life-stages of the pest during transport or storage
- incidence of the pest likely to be associated with a consignment
- commercial procedures (e.g. refrigeration) applied to consignments during transport and storage in the country of origin, and during transport to Australia.
- Factors considered in the probability of distribution include:
 - commercial procedures (e.g. refrigeration) applied to consignments during distribution in Australia
 - dispersal mechanisms of the pest, including vectors, to allow movement from the pathway to a host
 - whether the imported commodity is to be sent to a few or many destination points in the PRA area
 - proximity of entry, transit and destination points to hosts
 - time of year at which import takes place
 - intended use of the commodity (e.g. for planting, processing or consumption)
 - risks from by-products and waste.

Probability of establishment

Establishment is defined as the 'perpetuation for the foreseeable future, of a pest within an area after entry' (FAO 2012). In order to estimate the probability of establishment of a pest, reliable biological information (lifecycle, host range, epidemiology, survival, etc.) is obtained from the areas where the pest currently occurs. The situation in the PRA area can then be compared with that in the areas where it currently occurs and expert judgement used to assess the probability of establishment.

Factors considered in the probability of establishment in the PRA area include:

- availability of hosts, alternative hosts and vectors
- suitability of the environment
- reproductive strategy and potential for adaptation
- minimum population needed for establishment

- cultural practices and control measures.

Probability of spread

Spread is defined as ‘the expansion of the geographical distribution of a pest within an area’ (FAO 2012)(FAO 2013). The probability of spread considers the factors relevant to the movement of the pest, after establishment on a host plant or plants, to other susceptible host plants of the same or different species in other areas. In order to estimate the probability of spread of the pest, reliable biological information is obtained from areas where the pest currently occurs. The situation in the PRA area is then carefully compared with that in the areas where the pest currently occurs and expert judgement used to assess the probability of spread.

Factors considered in the probability of spread include:

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

Assigning qualitative likelihoods for the probability of entry, establishment and spread

In its qualitative PRAs, the Department of Agriculture uses the term ‘likelihood’ for the descriptors it uses for its estimates of probability of entry, establishment and spread. Qualitative likelihoods are assigned to each step of entry, establishment and spread. Six descriptors are used: high; moderate; low; very low; extremely low; and negligible (Table 1). Descriptive definitions for these descriptors are given in Table 1. The standardised likelihood descriptors provide guidance to the risk analyst and promote consistency between different risk analyses.

Table 1 – Nomenclature for qualitative likelihoods

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

The likelihood of entry is determined by combining the likelihood that the pest will be imported into the PRA area and the likelihood that the pest will be distributed within the PRA area, using a matrix of rules (Table 2). This matrix is then used to combine the likelihood of entry and the likelihood of establishment, and the likelihood of entry and establishment is then combined with the likelihood of spread to determine the overall likelihood of entry, establishment and spread.

For example, if the probability of importation is assigned a likelihood of 'low' and the probability of distribution is assigned a likelihood of 'moderate', then they are combined to give a likelihood of 'low' for the probability of entry. The likelihood for the probability of entry is then combined with the likelihood assigned to the probability of establishment (e.g. 'high') to give a likelihood for the probability of entry and establishment of 'low'. The likelihood for the probability of entry and establishment is then combined with the likelihood assigned to the probability of spread (e.g. 'very low') to give the overall likelihood for the probability of entry, establishment and spread of 'very low'. A working example is provided below;

P [importation] x P [distribution] = P [entry] e.g. low x moderate = low

P [entry] x P [establishment] = P [EE] e.g. low x high = low

P [EE] x [spread] = P [EES] e.g. low x very low = very low

Table 2 – Matrix of rules for combining qualitative likelihoods

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

Time and volume of trade

One factor affecting the likelihood of entry is the volume and duration of trade. If all other conditions remain the same, the overall likelihood of entry will increase as time passes and the overall volume of trade increases.

The Department of Agriculture normally considers the likelihood of entry on the basis of the estimated volume of one year's trade. This is a convenient value for the analysis that is relatively easy to estimate and allows for expert consideration of seasonal variations in pest presence, incidence and behaviour to be taken into account. The consideration of the likelihood of entry, establishment and spread and subsequent consequences takes into account events that might happen over a number of years even though only one year's volume of trade is being considered. This difference reflects biological and ecological facts, for example where a pest or disease may establish in the year of import but spread may take many years.

The use of a one year volume of trade has been taken into account when setting up the matrix that is used to estimate the risk and therefore any policy based on this report does not simply apply to one year of trade. Policy decisions that are based on the Department of Agriculture method that uses the estimated volume of one year's trade are consistent with Australia's policy on appropriate level of protection and meet the Australian Government's requirement for ongoing quarantine protection.

In assessing the volume of trade in this PRA, the Department of Agriculture assumed that a substantial volume of trade will occur.

1.6.3 Assessment of potential consequences

The objective of the consequence assessment is to provide a structured and transparent analysis of the likely consequences if the pests or disease agents were to enter, establish and spread in Australia. The assessment considers direct and indirect pest effects and their economic and environmental consequences. The requirements for assessing potential consequences are given in Article 5.3 of the SPS Agreement (WTO 1995), ISPM 5 (FAO 2012) and ISPM 11 (FAO 2013).

Direct pest effects are considered in the context of the effects on:

- plant life or health
- other aspects of the environment.

Indirect pest effects are considered in the context of the effects on:

- eradication, control, etc.
- domestic trade
- international trade
- environment.

For each of these six criteria, the consequences were estimated over four geographic levels, defined as:

Local: an aggregate of households or enterprises (a rural community, a town or a local government area).

District: a geographically or geopolitically associated collection of aggregates (generally a recognised section of a state or territory, such as 'Far North Queensland').

Regional: a geographically or geopolitically associated collection of districts in a geographic area (generally a state or territory, although there may be exceptions with larger states such as Western Australia).

National: Australia wide (Australian mainland states and territories and Tasmania).

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

Indiscernible: pest impact unlikely to be noticeable.

Minor significance: expected to lead to a minor increase in mortality/morbidity of hosts or a minor decrease in production but not expected to threaten the economic viability of production. Expected to decrease the value of non-commercial criteria but not threaten the criterion's intrinsic value. Effects would generally be reversible.

Significant: expected to threaten the economic viability of production through a moderate increase in mortality/morbidity of hosts, or a moderate decrease in production. Expected to significantly diminish or threaten the intrinsic value of non-commercial criteria. Effects may not be reversible.

Major significance: expected to threaten the economic viability through a large increase in mortality/morbidity of hosts, or a large decrease in production. Expected to severely or irreversibly damage the intrinsic 'value' of non-commercial criteria.

- The estimates of the magnitude of the potential consequences over the four geographic levels were translated into a qualitative impact score (A-G) using Table 3.
- For example, a consequence with a magnitude of 'significant' at the 'district' level will have a consequence impact score of D.

Table 3 – Decision rules for determining the consequence impact score based on the magnitude of consequences at four geographic scales

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

The overall consequence for each pest is achieved by combining the qualitative impact scores (A–G) for each direct and indirect consequence using a series of decision rules (Table 4). These rules are mutually exclusive, and are assessed in numerical order until one applies.

Table 4 – Decision rules for determining the overall consequence rating for each pest

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

1.6.4 Estimation of the unrestricted risk

Once the above assessments are completed, the unrestricted risk can be determined for each pest or groups of pests. This is determined by using a risk estimation matrix (Table 5) to combine the estimates of the probability of entry, establishment and spread and the overall consequences of pest establishment and spread. Therefore, risk is the product of likelihood and consequence.

When interpreting the risk estimation matrix, note the descriptors for each axis are similar (e.g. low, moderate, high) but the vertical axis refers to likelihood and the horizontal axis refers to consequences. Accordingly, a 'low' likelihood combined with 'high' consequences, is not the same as a 'high' likelihood combined with 'low' consequences – the matrix is not symmetrical. For example, the former combination would give an unrestricted risk rating of 'moderate', whereas, the latter would be rated as a 'low' unrestricted risk.

Table 5 – Risk estimation matrix

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

1.6.5 Australia's appropriate level of protection (ALOP)

The SPS Agreement defines the concept of an 'appropriate level of sanitary or phytosanitary protection (ALOP)' as the level of protection deemed appropriate by the WTO Member establishing a sanitary or phytosanitary measure to protect human, animal or plant life or health within its territory.

Like many other countries, Australia expresses its ALOP in qualitative terms. Australia's ALOP, which reflects community expectations through government policy, is currently expressed as providing a high level of sanitary or phytosanitary protection aimed at reducing risk to a very low level, but not to zero. The band of cells in Table 5 marked 'very low risk' represents Australia's ALOP.

1.7 Stage 3: Pest risk management

Pest risk management describes the process of identifying and implementing phytosanitary measures to manage risks to achieve Australia's ALOP, while ensuring that any negative effects on trade are minimised.

The conclusions from pest risk assessment are used to decide whether risk management is required and if so, the appropriate measures to be used. Where the unrestricted risk estimate exceeds Australia's ALOP, risk management measures are required to reduce this risk to a very low level. The guiding principle for risk management is to manage risk to achieve Australia's ALOP. The effectiveness of any proposed phytosanitary measures (or combination of measures) is evaluated, using the same approach as used to evaluate the unrestricted risk, to ensure it reduces the restricted risk for the relevant pest or pests to meet Australia's ALOP.

ISPM 11 (FAO 2013) provides details on the identification and selection of appropriate risk management options and notes that the choice of measures should be based on their effectiveness in reducing the probability of entry of the pest.

Examples given of measures commonly applied to traded commodities include:

- options for consignments – e.g., inspection or testing for freedom from pests, prohibition of parts of the host, a pre-entry or post-entry quarantine system, specified conditions on preparation of the consignment, specified treatment of the consignment, restrictions on end-use, distribution and periods of entry of the commodity
- options preventing or reducing infestation in the crop – e.g., treatment of the crop, restriction on the composition of a consignment so it is composed of plants belonging to resistant or less susceptible species, harvesting of plants at a certain age or specified time of the year, production in a certification scheme
- options ensuring that the area, place or site of production or crop is free from the pest – e.g., pest-free area, pest-free place of production or pest-free production site
- options for other types of pathways – e.g., consider natural spread, measures for human travellers and their baggage, cleaning or disinfestations of contaminated machinery
- options within the importing country – e.g., surveillance and eradication programs
- prohibition of commodities – if no satisfactory measure can be found.

Risk management measures are identified for each quarantine pest where the risk exceeds Australia's ALOP. These are presented in the pest risk management chapter of this report.

Appendix B Biosecurity framework

Australia's biosecurity policies

The objective of Australia's biosecurity policies and risk management measures is the prevention or control of the entry, establishment or spread of pests and diseases that could cause significant harm to people, animals, plants and other aspects of the environment.

Australia has diverse native flora and fauna and a large agricultural sector, and is relatively free from the more significant pests and diseases present in other countries. Therefore, successive Australian Governments have maintained a conservative, but not a zero-risk, approach to the management of biosecurity risks. This approach is consistent with the World Trade Organization's (WTO's) Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement).

The SPS Agreement defines the concept of an 'appropriate level of protection' (ALOP) as the level of protection deemed appropriate by a WTO Member establishing a sanitary or phytosanitary measure to protect human, animal or plant life or health within its territory. Among a number of obligations, a WTO Member should take into account the objective of minimising negative trade effects in setting its ALOP.

Like many other countries, Australia expresses its ALOP in qualitative terms. Australia's ALOP, which reflects community expectations through Australian Government policy, is currently expressed as providing a high level of sanitary and phytosanitary protection, aimed at reducing risk to a very low level, but not to zero.

Consistent with the SPS Agreement, in conducting risk analyses Australia takes 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 in the territory of Australia
- the costs of control or eradication of a pest or disease
- and the relative cost-effectiveness of alternative approaches to limiting risks.

Roles and responsibilities within Australia's quarantine system

Australia protects its human², animal and plant life or health through a comprehensive quarantine system that covers the quarantine continuum, from pre-border to border and post-border activities.

- **Pre-border**, Australia participates in international standard-setting bodies, undertakes risk analyses, develops offshore quarantine arrangements where appropriate, and engages with our neighbours to counter the spread of exotic pests and diseases.
- **At the border**, Australia screens vessels (including aircraft), people and goods entering the country to detect potential threats to Australian human, animal and plant health.

The Australian Government also undertakes targeted measures at the immediate post-border level within Australia. This includes national co-ordination of emergency responses to pest and disease

² The Australian Government Department of Health is responsible for human health aspects of quarantine.

incursions. The movement of goods of quarantine concern within Australia's border is the responsibility of relevant state and territory authorities, which undertake inter- and intra-state quarantine operations that reflect regional differences in pest and disease status, as a part of their wider plant and animal health responsibilities.

Roles and responsibilities within the Department

The Australian Government Department of Agriculture is responsible for the Australian Government's animal and plant biosecurity policy development and the establishment of risk management measures. The Secretary of the Department is appointed as the Director of Animal and Plant Quarantine under the Quarantine Act 1908 (the Act).

The Department takes the lead in biosecurity and quarantine policy development and the establishment and implementation of risk management measures across the biosecurity continuum, and:

- **Pre-border** conducts risk analyses, including IRAs, and develops recommendations for biosecurity policy as well as providing quarantine policy advice to the Director of Animal and Plant Quarantine
- **At the border** develops operational procedures, makes a range of quarantine decisions under the Act (including import permit decisions under delegation from the Director of Animal and Plant Quarantine) and delivers quarantine services
- **Post-border** coordinates pest and disease preparedness, emergency responses and liaison on inter- and intra-state quarantine arrangements for the Australian Government, in conjunction with Australia's state and territory governments.

Roles and responsibilities of other government agencies

State and territory governments play a vital role in the quarantine continuum. The Department works in partnership with state and territory governments to address regional differences in pest and disease status and risk within Australia, and develops appropriate sanitary and phytosanitary measures to account for those differences. Australia's partnership approach to quarantine is supported by a formal Memorandum of Understanding that provides for consultation between the Australian Government and the state and territory governments.

Depending on the nature of the good being imported or proposed for importation, the Department of Agriculture may consult other Australian Government authorities or agencies in developing its recommendations and providing advice.

As well as a Director of Animal and Plant Quarantine, the Act provides for a Director of Human Quarantine. The Australian Government Department of Health is responsible for human health aspects of quarantine and Australia's Chief Medical Officer within that Department holds the position of Director of Human Quarantine. The Department of Agriculture may, where appropriate, consult with that Department on relevant matters that may have implications for human health.

The Act also requires the Director of Animal and Plant Quarantine, before making certain decisions, to request advice from the Environment Minister and to take the advice into account when making those decisions. The Australian Government Department of the Environment is responsible under the Environment Protection and Biodiversity Conservation Act 1999 for assessing the environmental

impact associated with proposals to import live species. Anyone proposing to import such material should contact the Department of the Environment directly for further information.

When undertaking risk analyses, the Department of Agriculture consults with the Department of the Environment about environmental issues and may use or refer to Environment's assessment.

Australian quarantine legislation

The Australian quarantine system is supported by Commonwealth, state and territory quarantine laws. Under the Australian Constitution, the Commonwealth Government does not have exclusive power to make laws in relation to quarantine, and as a result, Commonwealth and state quarantine laws can co-exist.

Commonwealth quarantine laws are contained in the *Quarantine Act 1908* and subordinate legislation including the Quarantine Regulations 2000, the Quarantine Proclamation 1998, the Quarantine (Cocos Islands) Proclamation 2004 and the Quarantine (Christmas Island) Proclamation 2004.

The quarantine proclamations identify goods which cannot be imported into Australia, the Cocos Islands and or Christmas Island unless the Director of Animal and Plant Quarantine or delegate grants an import permit or unless they comply with other conditions specified in the proclamations. Section 70 of the Quarantine Proclamation 1998, section 34 of the Quarantine (Cocos Islands) Proclamation 2004 and section 34 of the Quarantine (Christmas Island) Proclamation 2004 specify the things a Director of Animal and Plant Quarantine must take into account when deciding whether to grant a permit.

In particular, a Director of Animal and Plant Quarantine (or delegate):

- must consider the level of quarantine risk if the permit were granted, and
- must consider whether, if the permit were granted, the imposition of conditions would be necessary to limit the level of quarantine risk to one that is acceptably low, and
- for a permit to import a seed of a plant that was produced by genetic manipulation – must take into account any risk assessment prepared, and any decision made, in relation to the seed under the Gene Technology Act, and
- may take into account anything else that he or she knows is relevant.

The level of quarantine risk is defined in section 5D of the *Quarantine Act 1908*. The definition is as follows:

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

1. the probability of:
2. a disease or pest being introduced, established or spread in Australia, the Cocos Islands or Christmas Island; and
3. the disease or pest causing harm to human beings, animals, plants, other aspects of the environment, or economic activities; and
4. the probable extent of the harm.

The Quarantine Regulations 2000 were amended in 2007 to regulate key steps of the import risk analysis process. The Regulations:

- define both a standard and an expanded IRA;
- identify certain steps, which must be included in each type of IRA;
- specify time limits for certain steps and overall timeframes for the completion of IRAs (up to 24 months for a standard IRA and up to 30 months for an expanded IRA);
- specify publication requirements;
- make provision for termination of an IRA; and
- allow for a partially completed risk analysis to be completed as an IRA under the Regulations.

The Regulations are available at www.comlaw.gov.au

International agreements and standards

The process set out in the *Import Risk Analysis Handbook 2011* is consistent with Australia's international obligations under the SPS Agreement. It also takes into account relevant international standards on risk assessment developed under the International Plant Protection Convention (IPPC) and by the World Organisation for Animal Health (OIE).

Australia bases its national risk management measures on international standards where they exist and when they achieve Australia's ALOP. Otherwise, Australia exercises its right under the SPS Agreement to apply science-based sanitary and phytosanitary measures that are not more trade restrictive than required to achieve Australia's ALOP.

Notification obligations

Under the transparency provisions of the SPS Agreement, WTO Members are required, among other things, to notify other members of proposed sanitary or phytosanitary regulations, or changes to existing regulations, that are not substantially the same as the content of an international standard and that may have a significant effect on trade of other WTO Members.

Risk analysis

Within Australia's quarantine framework, the Australian Government uses risk analyses to assist it in considering the level of quarantine risk that may be associated with the importation or proposed importation of animals, plants or other goods.

In conducting a risk analysis, the Department of Agriculture:

- identifies the pests and diseases of quarantine concern that may be carried by the good
- assesses the likelihood that an identified pest or disease or pest would enter, establish or spread
- assesses the probable extent of the harm that would result.

If the assessed level of quarantine risk exceeds Australia's ALOP, the Department of Agriculture will consider whether there are any risk management measures that will reduce quarantine risk to

achieve the ALOP. If there are no risk management measures that reduce the risk to that level, trade will not be allowed.

Risk analyses may be carried out by the Department of Agriculture's specialists, but may also involve relevant experts from state and territory agencies, the Commonwealth Scientific and Industrial Research Organisation (CSIRO), universities and industry to access the technical expertise needed for a particular analysis.

Risk analyses are conducted across a spectrum of scientific complexity and available scientific information. An IRA is a type of risk analysis with key steps regulated under the Quarantine Regulations 2000. the Department of Agriculture's assessment of risk may also take the form of a non-regulated analysis of existing policy or technical advice. Further information on the types of risk analysis is provided in the *Import Risk Analysis Handbook 2011*.

Glossary

Term or abbreviation	Definition
Additional declaration	A statement that is required by an importing country to be entered on a phytosanitary certificate and which provides specific additional information on a consignment in relation to regulated pests (FAO 2012).
Appropriate level of protection (ALOP)	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 (WTO 1995).
Area	An officially defined country, part of a country or all or parts of several countries (FAO 2012).
Area of low pest prevalence	An area, whether all of a country, part of a country, or all parts of several countries, as identified by the competent authorities, in which a specific pest occurs at low levels and which is subject to effective surveillance, control or eradication measures (FAO 2012).
Biological Control Agent (BCA)	A natural enemy, antagonist or competitor, or other organism, used for pest control (FAO 2012).
Consignment	A quantity of plants, plant products and/or other articles being moved from one country to another and covered, when required, by a single phytosanitary certificate (a consignment may be composed of one or more commodities or lots) (FAO 2012).
Control (of a pest)	Suppression, containment or eradication of a pest population (FAO 2012).
Endangered area	An area where ecological factors favour the establishment of a pest whose presence in the area will result in economically important loss (FAO 2012).
Entry (of a pest)	Movement of a pest into an area where it is not yet present, or present but not widely distributed and being officially controlled (FAO 2012).
Establishment (of a pest)	Perpetuation, for the foreseeable future, of a pest within an area after entry (FAO 2012).
Fresh	Living; not dried, deep-frozen or otherwise conserved (FAO 2012).
Host range	Species capable, under natural conditions, of sustaining a specific pest or other organism (FAO 2012).
Import permit	Official document authorising importation of a commodity in accordance with specified phytosanitary import requirements (FAO 2012).
Import risk analysis	An administrative process through which quarantine policy is developed or analysed, incorporating risk assessment, risk management and risk communication.
Infestation (of a commodity)	Presence in a commodity of a living pest of the plant or plant product concerned. Infestation includes infection (FAO 2012).
Inspection	Official visual examination of plants, plant products or other regulated articles to determine if pests are present and/or to determine compliance with phytosanitary regulations (FAO 2012).
Intended use	Declared purpose for which plants, plant products, or other regulated articles are imported, produced, or used (FAO 2012).
Interception (of a pest)	The detection of a pest during inspection or testing of an imported consignment (FAO 2012).
International Standard for Phytosanitary Measures (ISPM)	An international standard adopted by the Conference of the Food and Agriculture Organization, the Interim Commission on phytosanitary measures or the Commission on phytosanitary measures, established under the IPPC (FAO 2012).
Introduction (of a pest)	The entry of a pest resulting in its establishment (FAO 2012).
Lot	A number of units of a single commodity, identifiable by its homogeneity of composition, origin etc., forming part of a consignment (FAO 2012).
National Plant Protection Organization (NPPO)	Official service established by a government to discharge the functions specified by the IPPC (FAO 2012).
Official control	The active enforcement of mandatory phytosanitary regulations and the application of mandatory phytosanitary procedures with the objective of eradication or containment of quarantine pests or for the management of regulated non-quarantine pests (FAO 2012).
Pathway	Any means that allows the entry or spread of a pest (FAO 2012).

Term or abbreviation	Definition
Pest	Any species, strain or biotype of plant, animal, or pathogenic agent injurious to plants or plant products (FAO 2012).
Pest categorisation	The process for determining whether a pest has or has not the characteristics of a quarantine pest or those of a regulated non-quarantine pest (FAO 2012).
Pest free area (PFA)	An area in which a specific pest does not occur as demonstrated by scientific evidence and in which, where appropriate, this condition is being officially maintained (FAO 2012).
Pest free place of production	Place of production in which a specific pest does not occur as demonstrated by scientific evidence and in which, where appropriate, this condition is being officially maintained for a defined period (FAO 2012).
Pest free production site	A defined portion of a place of production in which a specific pest does not occur as demonstrated by scientific evidence and in which, where appropriate, this condition is being officially maintained for a defined period and that is managed as a separate unit in the same way as a pest free place of production (FAO 2012).
Pest risk analysis (PRA)	The process of evaluating biological or other scientific and economic evidence to determine whether an organism is a pest, whether it should be regulated, and the strength of any phytosanitary measures to be taken against it (FAO 2012).
Pest risk assessment (for quarantine pests)	Evaluation of the probability of the introduction and spread of a pest and of the associated potential economic consequences (FAO 2012).
Pest risk management (for quarantine pests)	Evaluation and selection of options to reduce the risk of introduction and spread of a pest (FAO 2012).
Phytosanitary certificate	Certificate patterned after the model certificates of the IPPC (FAO 2012).
Phytosanitary measure	Any legislation, regulation or official procedure having the purpose to prevent the introduction and/or spread of quarantine pests, or to limit the economic impact of regulated non-quarantine pests (FAO 2012).
Phytosanitary regulation	Official rule to prevent the introduction and/or spread of quarantine pests, or to limit the economic impact of regulated non-quarantine pests, including establishment of procedures for phytosanitary certification (FAO 2012).
Polyphagous	Feeding on a relatively large number of hosts from different plant family and/or genera.
PRA area	Area in relation to which a pest risk analysis is conducted (FAO 2012).
Quarantine pest	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 (FAO 2012).
Regulated article	Any plant, plant product, storage place, packing, conveyance, container, soil and any other organism, object or material capable of harbouring or spreading pests, deemed to require phytosanitary measures, particularly where international transportation is involved (WTO 1995).
Restricted risk	Risk estimate with phytosanitary measure(s) applied.
Spread (of a pest)	Expansion of the geographical distribution of a pest within an area (FAO 2012).
SPS Agreement	WTO Agreement on the Application of Sanitary and Phytosanitary Measures.
Stakeholders	Government agencies, individuals, community or industry groups or organizations, whether in Australia or overseas, including the proponent/applicant for a specific proposal, who have an interest in the policy issues.
Systems approach(es)	The integration of different risk management measures, at least two of which act independently, and which cumulatively achieve the appropriate level of protection against regulated pests.
Unrestricted risk	Unrestricted risk estimates apply in the absence of risk mitigation measures.

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