



Australian Government

Department of Agriculture, Fisheries and Forestry

Biosecurity Australia

Import Risk Analysis

HANDBOOK

2011



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Department of Agriculture, Fisheries and Forestry

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Updates to the Handbook

This version of the IRA Handbook has been updated to reflect interim arrangements (see BAA 2009/14) for the coordination and delivery of biosecurity services in Australia. Note that the import risk analysis process has not changed.

Additional copies of the Handbook

The *Import Risk Analysis Handbook 2011* is available in printed and electronic form. Electronic copies (in PDF format) are available on the Biosecurity Australia website www.biosecurityaustralia.gov.au.

If you experience problems accessing the file on the website or wish to obtain a hard copy, please contact:

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Contents

1. Introduction.....	5
2. Biosecurity framework	6
3. Managing import proposals.....	10
4. The import risk analysis process	12
5. Steps in an import risk analysis	15
6. Determination by the Director of Animal and Plant Quarantine	19
7. Steps that follow the IRA process	20
Annex 1 Import risk analysis flowchart	21
Annex 2 SPS Agreement	22
Annex 3 Australia's Appropriate Level of Protection.....	33
Annex 4 Import Market Access Advisory Group.....	34
Annex 5 Eminent Scientists Group	36
Annex 6 Import Risk Analysis Appeals Panel.....	37
Annex 7 Requirements for import proposals	39
Annex 8 Stakeholder register	41
Annex 9 Public file	42
Annex 10 Contact information.....	43
Annex 11 Acronyms and definitions.....	44

1. Introduction

The *Import Risk Analysis Handbook 2011* describes the process Australia follows in assessing proposals to import animals, plants and/or other goods. It provides information about the risk analysis process for import proposals, with particular emphasis on those analyses with regulated steps under the Quarantine Regulations 2000.

The Handbook takes account of reforms to the import risk analysis process announced by the Australian Government in October 2006.

Risk analysis plays an important part in Australia's biosecurity protection. It assists the Australian Government in considering the level of quarantine risk that may be associated with the importation or proposed importation of animals, plants or other goods into Australia. If the risks are found to exceed the level of quarantine risk that is acceptable to Australia, risk management measures are proposed to reduce them to that level. If the quarantine risks cannot be reduced to an acceptable level, trade will not be allowed.

Import risk analyses (IRAs) are risk analyses with key steps that are conducted under regulation. They are conducted by Biosecurity Australia, part of the Biosecurity Services Group, within the Department of Agriculture, Fisheries and Forestry, using technical and scientific experts in the relevant fields and involving consultation with stakeholders.

Biosecurity Australia provides recommendations for animal and plant quarantine policy to Australia's Director of Animal and Plant Quarantine. The Director, or delegate, is responsible for determining whether or not an importation can be permitted under the *Quarantine Act 1908*, and if so, under what conditions. The Australian Quarantine and Inspection Service (AQIS), also part of the Biosecurity Services Group, is responsible for implementing appropriate risk management measures.

2. Biosecurity framework

2.1 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) (see Annex 2).

Annex A of 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. Our 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. Further detail on Australia's ALOP is at Annex 3.

Consistent with the SPS Agreement (Article 5, paragraph 3), 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
- the relative cost-effectiveness of alternative approaches to limiting risks.

2.2 Roles and responsibilities within Australia's quarantine system

Australia protects its human¹, 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 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.

¹ The Australian Government Department of Health and Ageing is responsible for human health aspects of quarantine. Further information is at 2.2.2.

2.2.1 Roles and responsibilities within the Department

The Australian Government Department of Agriculture, Fisheries and Forestry 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 Biosecurity Services Group within 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, through Biosecurity Australia, 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, through the Australian Quarantine and Inspection Service, 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.

2.2.2 Roles and responsibilities of other government agencies

State and territory governments play a vital role in the quarantine continuum. The Biosecurity Services Group, through Biosecurity Australia, 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, Biosecurity Australia 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 and Ageing 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. Biosecurity Australia 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 Sustainability, Environment, Water, Population and Communities (SEWPAC) 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 SEWPAC directly for further information.

When undertaking risk analyses, Biosecurity Australia consults with SEWPAC about environmental issues and may use or refer to SEWPAC's assessment.

2.3 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 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:

- (a) the probability of:
 - (i) a disease or pest being introduced, established or spread in Australia, the Cocos Islands or Christmas Island; 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.

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
- 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.

2.4 International agreements and standards

The process set out in this Handbook 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.

2.4.1 Notification obligations

Under the transparency provisions of the SPS Agreement (Article 7 and Annex B), 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.

2.5 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, Biosecurity Australia:

- 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, and
- assesses the probable extent of the harm that would result.

If the assessed level of quarantine risk exceeds Australia's ALOP, Biosecurity Australia 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 Biosecurity Australia'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. Biosecurity Australia's assessment of risk may also take the form of a non-regulated analysis of existing policy or technical advice to AQIS. Further information on the types of risk analysis is provided in section 3.3.

3. Managing import proposals

3.1 The import proposal

An 'import proposal' is a generic term used to describe a proposal to bring into Australia plants, animals or other goods not imported previously, or not imported previously from the country or region concerned. An import proposal is usually provided to Biosecurity Australia by exporting country authorities, agencies or individual exporters requesting market access.

An import permit application received by AQIS for a good which has not been imported previously, or not imported previously from the country or region concerned, may be referred to Biosecurity Australia and lead to an import proposal.

3.2 Requirements for import proposals

Regardless of the origin of an import proposal, it must be in writing.

While there is no standard form for import proposals, a proposal should provide relevant scientific and other information to the extent that it is available. This information may be provided by the person or agency proposing the import (the proposer), the national Competent Authority of the exporting country, or may be available to Biosecurity Australia through scientific literature or other sources. The required information may include, but is not limited to, distribution records of pests associated with particular plants, or information on the incidence of animal diseases or treatments used on the goods.

A proposal will not be considered valid until relevant information is available to Biosecurity Australia. More information is at Annex 7. Biosecurity Australia will examine the completeness of the documentation and inform the proposer of any deficiencies.

3.3 Determining the need for, and type of, risk analysis

After receiving an import proposal, Biosecurity Australia will consider whether a new risk analysis is required and, if so, whether there is sufficient information to proceed. If the required information is not available, special surveys and monitoring may be needed. Without all relevant information, it may not be possible for a risk analysis to be considered for Biosecurity Australia's work program.

A risk analysis may also be undertaken when the risk profile of existing trade in a good, or of a pest or disease has changed or may change. Such a risk analysis is usually initiated within the Department.

Where a risk analysis is required, the Chief Executive of Biosecurity Australia will determine if it should be conducted as an import risk analysis with key steps regulated under the Quarantine Regulations 2000. The criteria for conducting an IRA are outlined in section 4.1. A risk analysis which does not meet the criteria for an IRA will be undertaken as a non-regulated analysis of existing policy.

3.4 Assigning priority to import proposals

The Import Market Access Advisory Group (IMAAG) is a high-level group within the Department. It is responsible for assigning priority to import proposals and monitoring progress of risk analyses undertaken by Biosecurity Australia.

The IMAAG's advice to Biosecurity Australia on the priority of import proposals will be publicly available on the Department's website.

The IMAAG's terms of reference are at Annex 4.

3.5 Biosecurity Australia's work program

Biosecurity Australia's Chief Executive determines the unit's work program. In doing so, the Chief Executive takes into account the priorities assigned to import proposals by the IMAAG, Biosecurity Australia's available expertise and the resources necessary to conduct any risk analysis. Biosecurity Australia's work program is published on its website.

4. The import risk analysis process

4.1 Criteria for an IRA

Biosecurity Australia's Chief Executive determines if a risk analysis will be conducted as an import risk analysis. An IRA will be undertaken when:

- relevant risk management measures have not been established or
- relevant risk management measures for a similar good and pest/disease combination do exist, but the likelihood and/or consequences of entry, establishment or spread of pests or diseases could differ significantly from those previously assessed.

A risk analysis which does not meet these criteria will be undertaken as a non-regulated analysis of existing policy.

The Chief Executive decides whether an IRA will follow the standard or expanded process.

4.2 Standard or expanded IRAs

The Quarantine Regulations 2000 provide for standard and expanded IRAs and outline the steps and maximum timeframes that apply for each type of IRA (see section 4.4).

The Chief Executive may decide the expanded process will be followed where:

- the IRA involves significant differences in scientific opinion or
- significant harm to people, animals, plants or the environment may result from an importation.

The standard IRA process will be followed in all other circumstances.

4.3 Regulated steps in an IRA

Under the Regulations, an IRA commences when the Chief Executive of Biosecurity Australia makes an announcement to that effect. For the purposes of the Regulations, an IRA ends when a provisional final IRA report is issued. The report is 'provisional' because stakeholders can request a review of the provisional report by an appeals panel. This review process is not included in the Regulations.

The steps covered by the Regulations are identified at section 5. The Regulations provide for overall maximum timeframes and timeframes for certain steps. In certain circumstances, the Regulations allow for certain periods of time be disregarded and also for the termination of an IRA.

4.4 Calculating time for completing IRAs

Maximum timeframes for completing an IRA are specified in the Regulations. A standard IRA must be completed within 24 months and an expanded IRA within 30 months. Because these are maximum timeframes, some IRAs may be completed in a shorter timeframe. There are also timeframes in the Regulations for some specific steps. The regulated timeframe for an IRA ends when a provisional final IRA report is issued.

Additionally, under the Regulations, certain periods of time may be disregarded in circumstances where delays are not attributable to Biosecurity Australia (also known as a ‘stop the clock’ mechanism). The Chief Executive may choose to stop the clock in the following circumstances:

- where the Chief Executive believes that further information is essential to complete an IRA and that a proposer or another person can provide the information
- where the Chief Executive believes that it is essential to undertake research, or to seek substantial expert advice, to complete an IRA or
- where a significant national or international quarantine circumstance exists that limits Biosecurity Australia’s ability to complete an IRA within the time required under the Regulations.

If the Chief Executive stops the clock, Biosecurity Australia will issue a notice to this effect on its website. The notice will state the reason for stopping the clock and when the IRA will restart.

4.5 Termination of an IRA

Work on an IRA may be terminated at any time:

- if a proposer notifies Biosecurity Australia in writing that they no longer wish to proceed with an import proposal
- if, despite requesting further information from a proposer or another person, or requesting further research or advice, the Chief Executive determines that insufficient information is available to complete the IRA satisfactorily or
- where the IRA has been initiated from within the Department (that is, there is no proposer), at the Chief Executive’s discretion.

When an IRA is terminated, Biosecurity Australia will publish a notice to this effect on its website.

4.6 Communication with stakeholders

Engagement with stakeholders is an important part of the IRA process. Biosecurity Australia will consult with stakeholders early in, and throughout, the IRA process. Consultation will be both formal and informal and will aim to seek stakeholder views on all issues relevant to the IRA. Relevant consultative steps are included in the IRA process as described at section 5.

Information on Biosecurity Australia’s work program and on the status of IRAs is available on Biosecurity Australia’s website, www.biosecurityaustralia.gov.au.

Biosecurity Australia maintains a database of registered stakeholders to facilitate engagement and communication with people and organisations with an interest in Biosecurity Australia’s work.

The database enables stakeholders to indicate areas of interest and the way they prefer to receive information. More information concerning the stakeholder database and the process for interested persons to register is at Annex 8.

4.6.1 Confidential submissions

Subject to the *Freedom of Information Act 1982* and the *Privacy Act 1988*, all submissions received will be publicly available and may be listed or referred to in documents and publications.

Biosecurity Australia cannot guarantee the confidentiality of material provided to it in the IRA process. Biosecurity Australia's approach to confidentiality is detailed at Annex 9.

The contents of a submission will not be treated as confidential unless they are marked 'confidential' and they are capable of being classified as such in accordance with the *Freedom of Information Act 1982*.

4.6.2 Public file

Biosecurity Australia maintains a public file of non-confidential submissions and other documentation relating to each IRA. These files are available at Biosecurity Australia's office in Canberra and on Biosecurity Australia's website.

Further details of the material to be placed on each public file and how it may be accessed are provided at Annex 9.

5. Steps in an import risk analysis

This section describes the steps to be undertaken in standard and expanded import risk analyses. A flowchart outlining the steps in the IRA process is at Annex 1.

5.1 Consultation on scope and approach

Biosecurity Australia will consult, whenever necessary, with the proposer, industry and other stakeholders on the scope and approach of an IRA before the Chief Executive announces the commencement of the regulated steps of the IRA. Consultation will extend to state and territory governments, when necessary, and include discussion of regional differences in pest and disease status and risk. Biosecurity Australia will also consult with the Australian Government Department of Sustainability, Environment, Water, Population and Communities and the Australian Government Department of Health and Ageing when necessary.

5.2 Announcement of IRA (step 1)

Applies to: Standard IRA Expanded IRA

An IRA will commence when the Chief Executive of Biosecurity Australia makes an announcement to that effect. A Biosecurity Australia Advice (BAA) will be issued on the Biosecurity Australia website to announce that an IRA has commenced and whether the IRA will be undertaken as a standard or an expanded IRA. The BAA will also provide information on the scope and approach of the IRA. If the risk analysis is to be conducted as an expanded IRA, the BAA will state whether an issues paper will be produced.

This announcement triggers the start of the regulated timeframe for an IRA.

5.3 Issues paper—preparation (step 2)

Applies to: Standard IRA Expanded IRA

An issues paper may be prepared as part of the expanded process if the Chief Executive of Biosecurity Australia considers that significant issues need to be explored and raised formally with stakeholders. Where most of this information is already available, the Chief Executive may decide that an issues paper is not required.

Biosecurity Australia will advise stakeholders when an issues paper is placed on its website.

The issues paper may:

- summarise background and administrative matters pertaining to the IRA
- list the pests and diseases that Biosecurity Australia believes may be associated with the import or proposed import
- categorise pests and diseases according to whether they need to be considered in the subsequent risk assessment and
- outline additional tasks identified at this stage.

5.4 Consultation on issues paper (step 3)

Applies to: Standard IRA Expanded IRA

If an issues paper is published, Biosecurity Australia will invite comment on the paper.

The Chief Executive of Biosecurity Australia will advise stakeholders of the deadline for submissions. Under the Quarantine Regulations 2000, stakeholders will have up to 60 days to submit written comments.

Biosecurity Australia may meet with stakeholders to discuss matters raised in their submissions.

Submissions received will be placed on the public file, unless they are marked 'confidential' and are capable of being classified as such in accordance with the *Freedom of Information Act 1982*. Biosecurity Australia's approach to confidentiality is explained further at Annex 9.

5.5 Risk analysis and report preparation (step 4)

Applies to: Standard IRA Expanded IRA

Biosecurity Australia will conduct its risk analysis with whatever input is needed from specialists, taking into account information gained from consultation with stakeholders, and prepare a draft IRA report.

The draft IRA report will:

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

Relevant state and territory government agencies will be consulted on regional pest and disease status and risk.

5.6 Consultation on draft IRA report (step 5)

Applies to: Standard IRA Expanded IRA

Biosecurity Australia will issue a draft IRA report to present the results of the risk analysis, taking into account all relevant input received. Biosecurity Australia will announce that a draft IRA report has been placed on its website and invite comment on the draft IRA report.

Biosecurity Australia will also place the draft IRA report on the public file.

The Chief Executive of Biosecurity Australia will inform stakeholders of the deadline for submissions. Under the Regulations, stakeholders will have up to 60 days to submit written comments on a draft IRA report.

Biosecurity Australia may meet with stakeholders to discuss the draft IRA report.

If the Chief Executive of Biosecurity Australia considers stakeholders may not have reasonable opportunity to comment on the draft IRA report within the normal consultation period, the Regulations provide for a single extension to the timeframe of up to 60 days.

Submissions received will be placed on the public file, unless they are marked 'confidential' and are capable of being classified as such in accordance with the *Freedom of Information Act 1982*. Biosecurity Australia's approach to confidentiality is explained further at Annex 9.

The Department will notify the WTO Secretariat of the draft IRA report. The notification will include the date by which comments should be provided.

5.7 Revising the draft IRA report (step 6)

Applies to: Standard IRA Expanded IRA

Biosecurity Australia will consider submissions received on a draft IRA report and may consult informally with stakeholders. Biosecurity Australia may revise the draft IRA report as appropriate.

5.8 Review by the Eminent Scientists Group (step 7)

Applies to: Standard IRA Expanded IRA

The Eminent Scientists Group (ESG) is a high level review group that is tasked with providing external, independent, scientific and economic scrutiny of expanded IRAs.

The role of the ESG is to review the draft IRA report, as revised by Biosecurity Australia after consideration of stakeholder comments, prior to its publication. The ESG's review will take account of any relevant new information brought to its attention, and assess conflicting scientific views, to ensure that:

- all submissions received from stakeholders in response to the draft IRA report have been properly considered
- all relevant matters relating to the likely economic consequences of a pest or disease incursion have been properly considered and
- the conclusions of the revised draft IRA report are scientifically reasonable, based on the material presented.

As part of this review, the Chairman of the ESG may co-opt additional expertise or seek advice to assist the ESG in meeting its terms of reference. The ESG may consult with Biosecurity Australia and with stakeholders during its review.

The ESG will prepare a report to the Director of Animal and Plant Quarantine on its findings and recommend any action to overcome any identified deficiencies. The Regulations set out a maximum timeframe of 60 days for the ESG to provide its report to the Director of Animal and Plant Quarantine.

The ESG's report will be provided to the Chief Executive of Biosecurity Australia and will subsequently be publicly released.

The ESG's terms of reference are at Annex 5.

5.9 Preparation and publication of provisional final IRA report (step 8)

Applies to: Standard IRA Expanded IRA

Biosecurity Australia will prepare a provisional final IRA report, taking into account stakeholder comments and, in the case of expanded IRAs, any recommendations made by the ESG.

In considering the recommendations in the provisional final IRA report, the Chief Executive of Biosecurity Australia must be satisfied that, in his or her opinion, the IRA has been conducted in accordance with the Regulations and the process described in this Handbook, and that the recommendations:

- are reasonable, in the light of the evidence
- meet the Government's objectives for biosecurity
- are consistent with Australian legislation
- accord with Australia's international rights and obligations.

Before the provisional final IRA report is published, Biosecurity Australia will consult with state and territory governments on the proposed outcomes of the IRA. This consultation will include, for example, issues of regional pest status and risk, and aspects of joint responsibility arising from the IRA's recommendations.

Biosecurity Australia will announce that a provisional final IRA report has been placed on the Biosecurity Australia website. Biosecurity Australia will also distribute the provisional final IRA report to the proposer and registered stakeholders together with the ESG report and any response by Biosecurity Australia to the ESG's report. These documents will also be placed on the public file.

The regulated timeframe for an IRA ends when a provisional final IRA report is issued.

5.10 Appeal on the provisional final IRA report

Stakeholders who believe there was a significant deviation from the IRA process set out in this Handbook that adversely affected their interests may appeal to the Import Risk Analysis Appeals Panel (IRAAP). Appeals must be lodged within 30 days of the publication of the provisional final IRA report.

The appeals process, which is independent of Biosecurity Australia, is a non-judicial review that is not regulated under the Regulations.

The IRAAP Chairman will consider any appeals received and decide in each case whether the statement of reasons provides evidence warranting consideration by an IRAAP. If so, he or she will convene a panel to consider the appeal(s). The IRAAP will consider the appeal(s) and report its findings to the appellant(s) and the Director of Animal and Plant Quarantine within 45 days of the closing date for appeals.

Further details of the appeal process may be found at Annex 6.

5.11 The final IRA report

At the conclusion of the appeal process and after any issues arising from the IRAAP process have been addressed, the Chief Executive of Biosecurity Australia will provide the final IRA report and a recommendation for a policy determination to the Director of Animal and Plant Quarantine.

6. Determination by the Director of Animal and Plant Quarantine

The making of a determination is an administrative process undertaken by the Director of Animal and Plant Quarantine. The determination provides a policy framework for decisions on whether or not to grant an import permit and any conditions that may be attached to a permit. In making the determination, the Director of Animal and Plant Quarantine will consider:

- the final IRA report and its recommendations
- the outcome of any appeals
- the ESG report
- Biosecurity Australia's response to the ESG report
- any other relevant information, including Australia's international rights and obligations.

A policy determination represents the completion of the IRA process. The Director of Animal and Plant Quarantine notifies AQIS and Biosecurity Australia of the policy determination. In turn, Biosecurity Australia notifies the proposer and registered stakeholders, and the Department notifies the WTO Secretariat, of the determination. The determination will also be placed on the public file and on the Biosecurity Australia website.

7. Steps that follow the IRA process

7.1 Implementation of risk management measures

The risk management measures recommended in risk analysis, including import risk analyses, often become conditions imposed on import permits granted by the Director of Animal and Plant Quarantine, or delegate, to limit the level of quarantine risk to an acceptably low level. In some cases the recommended measures require arrangements that extend beyond the scope of conditions on an import permit. For example, an IRA might identify risk management measures that require preparatory work to be undertaken by the Competent Authority of the exporting country before trade can commence.

Where necessary, AQIS will work with the Competent Authority of the exporting country, in consultation with Biosecurity Australia, to ensure that the Competent Authority develops an operational work plan and implements the risk management measures recommended in an IRA.

7.2 Decision to issue an import permit

The Director of Animal and Plant Quarantine may delegate the power to grant import permits under the quarantine proclamations to a quarantine officer or another officer appointed under the *Quarantine Act 1908*.

When a completed valid application for an import permit has been received, along with any required fees, the Director of Animal and Plant Quarantine or delegate:

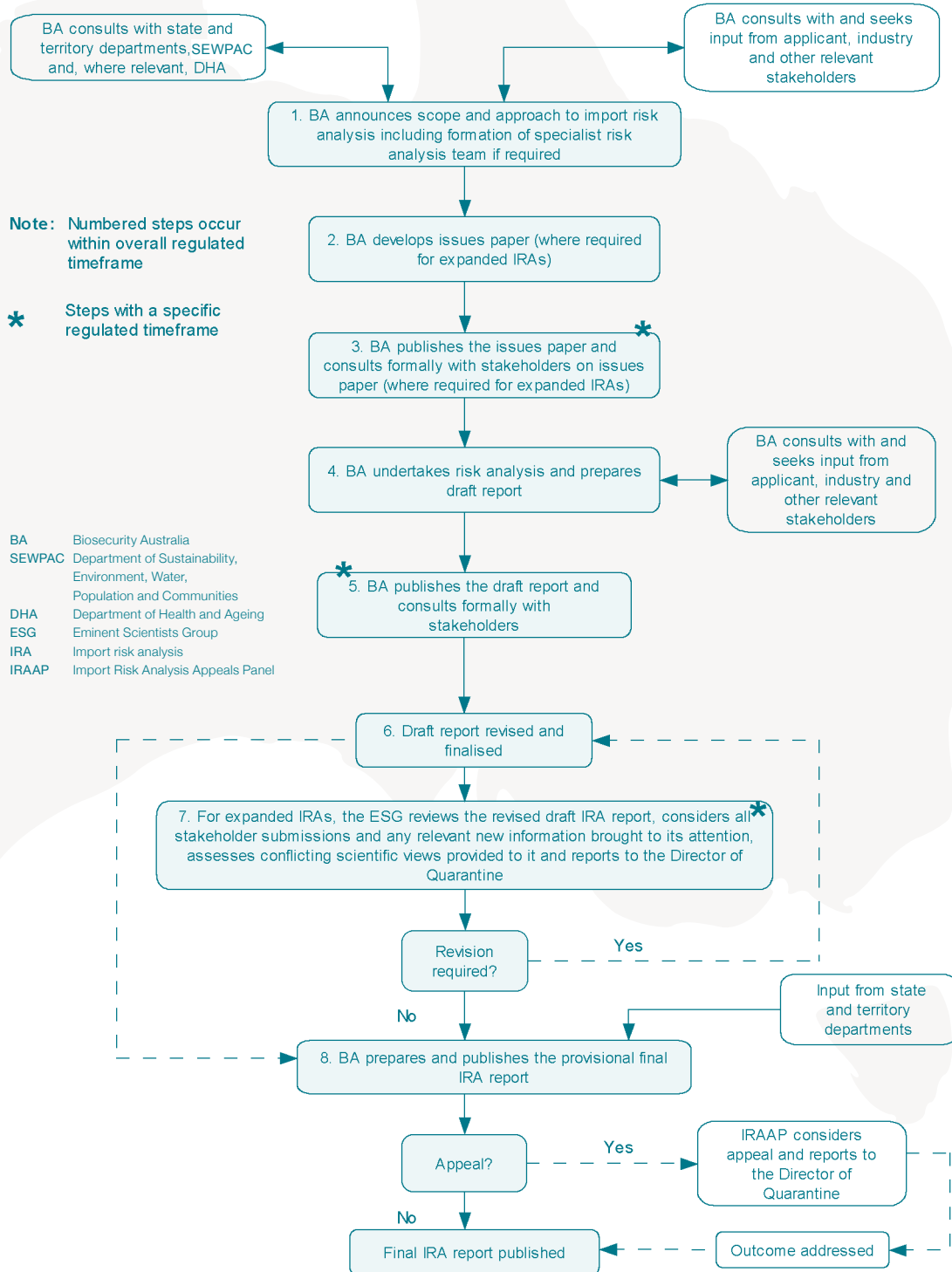
- must consider the level of quarantine risk if the permit were granted and
- must consider whether, if the permit were granted, the imposition of conditions would be necessary to limit the level of quarantine risk to one that is acceptably low and
- for a permit to import a seed of a plant that was 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.

In considering the level of quarantine risk and whether conditions should be imposed to limit the quarantine risk to an acceptably low level, the Director of Animal and Plant Quarantine, or delegate, may take into account any relevant information, including an IRA.

If the Director of Animal and Plant Quarantine, or delegate, is satisfied that an import permit can be granted, he or she provides the applicant with a copy of the permit. Any conditions that apply to the permit are recorded on the permit.

If the Director of Animal and Plant Quarantine, or delegate, decides that the imposition of conditions would not limit the quarantine risk to an acceptably low level, he or she must refuse to grant the import permit. The Director of Animal and Plant Quarantine, or delegate, advises the applicant in writing of the reasons for refusing to grant the import permit.

Annex 1 Import risk analysis flowchart



Annex 2 SPS Agreement

Agreement on the Application of Sanitary and Phytosanitary Measures

Members,

Reaffirming that no Member should be prevented from adopting or enforcing measures necessary to protect human, animal or plant life or health, subject to the requirement that these measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between Members where the same conditions prevail or a disguised restriction on international trade;

Desiring to improve the human health, animal health and phytosanitary situation in all Members;

Noting that sanitary and phytosanitary measures are often applied on the basis of bilateral agreements or protocols;

Desiring the establishment of a multilateral framework of rules and disciplines to guide the development, adoption and enforcement of sanitary and phytosanitary measures in order to minimize their negative effects on trade;

Recognizing the important contribution that international standards, guidelines and recommendations can make in this regard;

Desiring to further the use of harmonized sanitary and phytosanitary measures between Members, on the basis of international standards, guidelines and recommendations developed by the relevant international organizations, including the Codex Alimentarius Commission, the International Office of Epizootics, and the relevant international and regional organizations operating within the framework of the International Plant Protection Convention, without requiring Members to change their appropriate level of protection of human, animal or plant life or health;

Recognizing that developing country Members may encounter special difficulties in complying with the sanitary or phytosanitary measures of importing Members, and as a consequence in access to markets, and also in the formulation and application of sanitary or phytosanitary measures in their own territories, and desiring to assist them in their endeavours in this regard;

Desiring therefore to elaborate rules for the application of the provisions of GATT 1994 which relate to the use of sanitary or phytosanitary measures, in particular the provisions of Article XX(b)¹;

Hereby agree as follows:

¹ In this Agreement, reference to Article XX(b) includes also the chapeau of that Article.

Article 1 General Provisions

1. This Agreement applies to all sanitary and phytosanitary measures which may, directly or indirectly, affect international trade. Such measures shall be developed and applied in accordance with the provisions of this Agreement.
2. For the purposes of this Agreement, the definitions provided in Annex A shall apply.
3. The annexes are an integral part of this Agreement.
4. Nothing in this Agreement shall affect the rights of Members under the Agreement on Technical Barriers to Trade with respect to measures not within the scope of this Agreement.

Article 2 Basic Rights and Obligations

1. Members have the right to take sanitary and phytosanitary measures necessary for the protection of human, animal or plant life or health, provided that such measures are not inconsistent with the provisions of this Agreement.
2. Members shall ensure that any sanitary or phytosanitary measure is applied only to the extent necessary to protect human, animal or plant life or health, is based on scientific principles and is not maintained without sufficient scientific evidence, except as provided for in paragraph 7 of Article 5.
3. Members shall ensure that their sanitary and phytosanitary measures do not arbitrarily or unjustifiably discriminate between Members where identical or similar conditions prevail, including between their own territory and that of other Members. Sanitary and phytosanitary measures shall not be applied in a manner which would constitute a disguised restriction on international trade.
4. Sanitary or phytosanitary measures which conform to the relevant provisions of this Agreement shall be presumed to be in accordance with the obligations of the Members under the provisions of GATT 1994 which relate to the use of sanitary or phytosanitary measures, in particular the provisions of Article XX(b).

Article 3 Harmonization

1. To harmonize sanitary and phytosanitary measures on as wide a basis as possible, Members shall base their sanitary or phytosanitary measures on international standards, guidelines or recommendations, where they exist, except as otherwise provided for in this Agreement, and in particular in paragraph 3.
2. Sanitary or phytosanitary measures which conform to international standards, guidelines or recommendations shall be deemed to be necessary to protect human, animal or plant life or health, and presumed to be consistent with the relevant provisions of this Agreement and of GATT 1994.
3. Members may introduce or maintain sanitary or phytosanitary measures which result in a higher level of sanitary or phytosanitary protection than would be achieved by measures based on the relevant international standards, guidelines or recommendations, if there is a scientific justification, or as a consequence of the level of sanitary or phytosanitary protection a Member determines to be appropriate in accordance with the relevant provisions of paragraphs 1 through 8 of Article 5.² Notwithstanding the above, all measures which result in a level of sanitary or phytosanitary protection different from that which would be achieved by measures based on international standards, guidelines or recommendations shall not be inconsistent with any other provision of this Agreement.

² For the purposes of paragraph 3 of Article 3, there is a scientific justification if, on the basis of an examination and evaluation of available scientific information in conformity with the relevant provisions of this Agreement, a Member determines that the relevant international standards, guidelines or recommendations are not sufficient to achieve its appropriate level of sanitary or phytosanitary protection.

4. Members shall play a full part, within the limits of their resources, in the relevant international organizations and their subsidiary bodies, in particular the Codex Alimentarius Commission, the International Office of Epizootics, and the international and regional organizations operating within the framework of the International Plant Protection Convention, to promote within these organizations the development and periodic review of standards, guidelines and recommendations with respect to all aspects of sanitary and phytosanitary measures.
5. The Committee on Sanitary and Phytosanitary Measures provided for in paragraphs 1 and 4 of Article 12 (referred to in this Agreement as the “Committee”) shall develop a procedure to monitor the process of international harmonization and coordinate efforts in this regard with the relevant international organizations.

Article 4 Equivalence

1. 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. For this purpose, reasonable access shall be given, upon request, to the importing Member for inspection, testing and other relevant procedures.
2. Members shall, upon request, enter into consultations with the aim of achieving bilateral and multilateral agreements on recognition of the equivalence of specified sanitary or phytosanitary measures.

Article 5 Assessment of Risk and Determination of the Appropriate Level of Sanitary or Phytosanitary Protection

1. Members shall ensure that their sanitary or phytosanitary measures are based on an assessment, as appropriate to the circumstances, of the risks to human, animal or plant life or health, taking into account risk assessment techniques developed by the relevant international organizations.
2. 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 and environmental conditions; and quarantine or other treatment.
3. In assessing the risk to animal or plant life or health and determining the measure to be applied for achieving the appropriate level of sanitary or phytosanitary protection from such risk, Members shall take into account as relevant economic factors: the potential damage in terms of loss of production or sales in the event of the entry, establishment or spread of a pest or disease; the costs of control or eradication in the territory of the importing Member; and the relative cost-effectiveness of alternative approaches to limiting risks.
4. Members should, when determining the appropriate level of sanitary or phytosanitary protection, take into account the objective of minimizing negative trade effects.
5. 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 shall cooperate in the Committee, in accordance with paragraphs 1, 2 and 3 of Article 12, to develop guidelines to further the practical implementation of this provision. In developing the guidelines, the Committee shall take into account all relevant factors, including the exceptional character of human health risks to which people voluntarily expose themselves.

6. Without prejudice to paragraph 2 of Article 3, when establishing or maintaining sanitary or phytosanitary measures to achieve the appropriate level of sanitary or phytosanitary protection, Members shall ensure that such measures are not more trade-restrictive than required to achieve their appropriate level of sanitary or phytosanitary protection, taking into account technical and economic feasibility.³
7. 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.
8. When a Member has reason to believe that a specific sanitary or phytosanitary measure introduced or maintained by another Member is constraining, or has the potential to constrain, its exports and the measure is not based on the relevant international standards, guidelines or recommendations, or such standards, guidelines or recommendations do not exist, an explanation of the reasons for such sanitary or phytosanitary measure may be requested and shall be provided by the Member maintaining the measure.

Article 6 Adaptation to Regional Conditions, Including Pest- or Disease-Free Areas and Areas of Low Pest or Disease Prevalence

1. Members shall ensure that their sanitary or phytosanitary measures are adapted to the sanitary or phytosanitary characteristics of the area – whether all of a country, part of a country, or all or parts of several countries – from which the product originated and to which the product is destined. In assessing the sanitary or phytosanitary characteristics of a region, Members shall take into account, inter alia, the level of prevalence of specific diseases or pests, the existence of eradication or control programmes, and appropriate criteria or guidelines which may be developed by the relevant international organizations.
2. Members shall, in particular, recognize the concepts of pest- or disease-free areas and areas of low pest or disease prevalence. Determination of such areas shall be based on factors such as geography, ecosystems, epidemiological surveillance, and the effectiveness of sanitary or phytosanitary controls.
3. Exporting Members claiming that areas within their territories are pest- or disease-free areas or areas of low pest or disease prevalence shall provide the necessary evidence thereof in order to objectively demonstrate to the importing Member that such areas are, and are likely to remain, pest- or disease-free areas or areas of low pest or disease prevalence, respectively. For this purpose, reasonable access shall be given, upon request, to the importing Member for inspection, testing and other relevant procedures.

Article 7 Transparency

Members shall notify changes in their sanitary or phytosanitary measures and shall provide information on their sanitary or phytosanitary measures in accordance with the provisions of Annex B.

Article 8 Control, Inspection and Approval Procedures

Members shall observe the provisions of Annex C in the operation of control, inspection and approval procedures, including national systems for approving the use of additives or for establishing tolerances for contaminants in foods, beverages or feedstuffs, and otherwise ensure that their procedures are not inconsistent with the provisions of this Agreement.

³ For purposes of paragraph 6 of Article 5, a measure is not more trade-restrictive than required unless there is another measure, reasonably available taking into account technical and economic feasibility, that achieves the appropriate level of sanitary or phytosanitary protection and is significantly less restrictive to trade.

Article 9 Technical Assistance

1. Members agree to facilitate the provision of technical assistance to other Members, especially developing country Members, either bilaterally or through the appropriate international organizations. Such assistance may be, inter alia, in the areas of processing technologies, research and infrastructure, including in the establishment of national regulatory bodies, and may take the form of advice, credits, donations and grants, including for the purpose of seeking technical expertise, training and equipment to allow such countries to adjust to, and comply with, sanitary or phytosanitary measures necessary to achieve the appropriate level of sanitary or phytosanitary protection in their export markets.
2. Where substantial investments are required in order for an exporting developing country Member to fulfil the sanitary or phytosanitary requirements of an importing Member, the latter shall consider providing such technical assistance as will permit the developing country Member to maintain and expand its market access opportunities for the product involved.

Article 10 Special and Differential Treatment

1. In the preparation and application of sanitary or phytosanitary measures, Members shall take account of the special needs of developing country Members, and in particular of the least-developed country Members.
2. Where the appropriate level of sanitary or phytosanitary protection allows scope for the phased introduction of new sanitary or phytosanitary measures, longer time-frames for compliance should be accorded on products of interest to developing country Members so as to maintain opportunities for their exports.
3. With a view to ensuring that developing country Members are able to comply with the provisions of this Agreement, the Committee is enabled to grant to such countries, upon request, specified, time-limited exceptions in whole or in part from obligations under this Agreement, taking into account their financial, trade and development needs.
4. Members should encourage and facilitate the active participation of developing country Members in the relevant international organizations.

Article 11 Consultations and Dispute Settlement

1. The provisions of Articles XXII and XXIII of GATT 1994 as elaborated and applied by the Dispute Settlement Understanding shall apply to consultations and the settlement of disputes under this Agreement, except as otherwise specifically provided herein.
2. In a dispute under this Agreement involving scientific or technical issues, a panel should seek advice from experts chosen by the panel in consultation with the parties to the dispute. To this end, the panel may, when it deems it appropriate, establish an advisory technical experts group, or consult the relevant international organizations, at the request of either party to the dispute or on its own initiative.
3. Nothing in this Agreement shall impair the rights of Members under other international agreements, including the right to resort to the good offices or dispute settlement mechanisms of other international organizations or established under any international agreement.

Article 12 Administration

1. A Committee on Sanitary and Phytosanitary Measures is hereby established to provide a regular forum for consultations. It shall carry out the functions necessary to implement the provisions of this Agreement and the furtherance of its objectives, in particular with respect to harmonization. The Committee shall reach its decisions by consensus.

2. The Committee shall encourage and facilitate ad hoc consultations or negotiations among Members on specific sanitary or phytosanitary issues. The Committee shall encourage the use of international standards, guidelines or recommendations by all Members and, in this regard, shall sponsor technical consultation and study with the objective of increasing coordination and integration between international and national systems and approaches for approving the use of food additives or for establishing tolerances for contaminants in foods, beverages or feedstuffs.
3. The Committee shall maintain close contact with the relevant international organizations in the field of sanitary and phytosanitary protection, especially with the Codex Alimentarius Commission, the International Office of Epizootics, and the Secretariat of the International Plant Protection Convention, with the objective of securing the best available scientific and technical advice for the administration of this Agreement and in order to ensure that unnecessary duplication of effort is avoided.
4. The Committee shall develop a procedure to monitor the process of international harmonization and the use of international standards, guidelines or recommendations. For this purpose, the Committee should, in conjunction with the relevant international organizations, establish a list of international standards, guidelines or recommendations relating to sanitary or phytosanitary measures which the Committee determines to have a major trade impact. The list should include an indication by Members of those international standards, guidelines or recommendations which they apply as conditions for import or on the basis of which imported products conforming to these standards can enjoy access to their markets. For those cases in which a Member does not apply an international standard, guideline or recommendation as a condition for import, the Member should provide an indication of the reason therefore, and, in particular, whether it considers that the standard is not stringent enough to provide the appropriate level of sanitary or phytosanitary protection. If a Member revises its position, following its indication of the use of a standard, guideline or recommendation as a condition for import, it should provide an explanation for its change and so inform the Secretariat as well as the relevant international organizations, unless such notification and explanation is given according to the procedures of Annex B.
5. In order to avoid unnecessary duplication, the Committee may decide, as appropriate, to use the information generated by the procedures, particularly for notification, which are in operation in the relevant international organizations.
6. The Committee may, on the basis of an initiative from one of the Members, through appropriate channels invite the relevant international organizations or their subsidiary bodies to examine specific matters with respect to a particular standard, guideline or recommendation, including the basis of explanations for non-use given according to paragraph 4.
7. The Committee shall review the operation and implementation of this Agreement three years after the date of entry into force of the WTO Agreement, and thereafter as the need arises. Where appropriate, the Committee may submit to the Council for Trade in Goods proposals to amend the text of this Agreement having regard, inter alia, to the experience gained in its implementation.

Article 13 Implementation

Members are fully responsible under this Agreement for the observance of all obligations set forth herein. Members shall formulate and implement positive measures and mechanisms in support of the observance of the provisions of this Agreement by other than central government bodies. Members shall take such reasonable measures as may be available to them to ensure that non-governmental entities within their territories, as well as regional bodies in which relevant entities within their territories are members, comply with the relevant provisions of this Agreement.

In addition, Members shall not take measures which have the effect of, directly or indirectly, requiring or encouraging such regional or non-governmental entities, or local governmental bodies, to act in a manner inconsistent with the provisions of this Agreement. Members shall ensure that they rely on the services of non-governmental entities for implementing sanitary or phytosanitary measures only if these entities comply with the provisions of this Agreement.

Article 14 Final Provisions

The least-developed country Members may delay application of the provisions of this Agreement for a period of five years following the date of entry into force of the WTO Agreement with respect to their sanitary or phytosanitary measures affecting importation or imported products. Other developing country Members may delay application of the provisions of this Agreement, other than paragraph 8 of Article 5 and Article 7, for two years following the date of entry into force of the WTO Agreement with respect to their existing sanitary or phytosanitary measures affecting importation or imported products, where such application is prevented by a lack of technical expertise, technical infrastructure or resources.

Annex A Definitions⁴

1. *Sanitary or phytosanitary measure* – Any measure applied:
 - (a) 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;
 - (b) 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;
 - (c) 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; or
 - (d) to prevent or limit other damage within the territory of the Member from the entry, establishment or spread of pests.

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

2. *Harmonization* - The establishment, recognition and application of common sanitary and phytosanitary measures by different Members.
3. *International standards, guidelines and recommendations*
 - (a) for food safety, the standards, guidelines and recommendations established by the Codex Alimentarius Commission relating to food additives, veterinary drug and pesticide residues, contaminants, methods of analysis and sampling, and codes and guidelines of hygienic practice;
 - (b) for animal health and zoonoses, the standards, guidelines and recommendations developed under the auspices of the International Office of Epizootics;

⁴ For the purpose of these definitions, “animal” includes fish and wild fauna; “plant” includes forests and wild flora; “pests” include weeds; and “contaminants” include pesticide and veterinary drug residues and extraneous matter.

- (c) for plant health, the international standards, guidelines and recommendations developed under the auspices of the Secretariat of the International Plant Protection Convention in cooperation with regional organizations operating within the framework of the International Plant Protection Convention; and
 - (d) for matters not covered by the above organizations, appropriate standards, guidelines and recommendations promulgated by other relevant international organizations open for membership to all Members, as identified by the Committee.
4. *Risk assessment* - 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; or the evaluation of the potential for adverse effects on human or animal health arising from the presence of additives, contaminants, toxins or disease-causing organisms in food, beverages or feedstuffs.
 5. *Appropriate level of sanitary or phytosanitary protection* - The level of protection deemed appropriate by the Member establishing a sanitary or phytosanitary measure to protect human, animal or plant life or health within its territory.

NOTE: Many Members otherwise refer to this concept as the “acceptable level of risk”.

6. *Pest- or disease-free area* - An area, whether all of a country, part of a country, or all or parts of several countries, as identified by the competent authorities, in which a specific pest or disease does not occur.

NOTE: A pest- or disease-free area may surround, be surrounded by, or be adjacent to an area - whether within part of a country or in a geographic region which includes parts of or all of several countries -in which a specific pest or disease is known to occur but is subject to regional control measures such as the establishment of protection, surveillance and buffer zones which will confine or eradicate the pest or disease in question.

7. *Area of low pest or disease prevalence* - An area, whether all of a country, part of a country, or all or parts of several countries, as identified by the competent authorities, in which a specific pest or disease occurs at low levels and which is subject to effective surveillance, control or eradication measures.

Annex B Transparency of sanitary and phytosanitary regulations

Publication of regulations

1. Members shall ensure that all sanitary and phytosanitary regulations⁵ which have been adopted are published promptly in such a manner as to enable interested Members to become acquainted with them.
2. Except in urgent circumstances, Members shall allow a reasonable interval between the publication of a sanitary or phytosanitary regulation and its entry into force in order to allow time for producers in exporting Members, and particularly in developing country Members, to adapt their products and methods of production to the requirements of the importing Member.

Enquiry points

3. Each Member shall ensure that one enquiry point exists which is responsible for the provision of answers to all reasonable questions from interested Members as well as for the provision of relevant documents regarding:

⁵ Sanitary and phytosanitary measures such as laws, decrees or ordinances which are applicable generally.

- (a) any sanitary or phytosanitary regulations adopted or proposed within its territory;
 - (b) any control and inspection procedures, production and quarantine treatment, pesticide tolerance and food additive approval procedures, which are operated within its territory;
 - (c) risk assessment procedures, factors taken into consideration, as well as the determination of the appropriate level of sanitary or phytosanitary protection;
 - (d) the membership and participation of the Member, or of relevant bodies within its territory, in international and regional sanitary and phytosanitary organizations and systems, as well as in bilateral and multilateral agreements and arrangements within the scope of this Agreement, and the texts of such agreements and arrangements.
4. Members shall ensure that where copies of documents are requested by interested Members, they are supplied at the same price (if any), apart from the cost of delivery, as to the nationals⁶ of the Member concerned.

Notification procedures

5. Whenever an international standard, guideline or recommendation does not exist or the content of a proposed sanitary or phytosanitary regulation is not substantially the same as the content of an international standard, guideline or recommendation, and if the regulation may have a significant effect on trade of other Members, Members shall:
- (a) publish a notice at an early stage in such a manner as to enable interested Members to become acquainted with the proposal to introduce a particular regulation;
 - (b) notify other Members, through the Secretariat, of the products to be covered by the regulation together with a brief indication of the objective and rationale of the proposed regulation. Such notifications shall take place at an early stage, when amendments can still be introduced and comments taken into account;
 - (c) provide upon request to other Members copies of the proposed regulation and, whenever possible, identify the parts which in substance deviate from international standards, guidelines or recommendations;
 - (d) without discrimination, allow reasonable time for other Members to make comments in writing, discuss these comments upon request, and take the comments and the results of the discussions into account.
6. However, where urgent problems of health protection arise or threaten to arise for a Member, that Member may omit such of the steps enumerated in paragraph 5 of this Annex as it finds necessary, provided that the Member:
- (a) immediately notifies other Members, through the Secretariat, of the particular regulation and the products covered, with a brief indication of the objective and the rationale of the regulation, including the nature of the urgent problem(s);
 - (b) provides, upon request, copies of the regulation to other Members;
 - (c) allows other Members to make comments in writing, discusses these comments upon request, and takes the comments and the results of the discussions into account.
7. Notifications to the Secretariat shall be in English, French or Spanish.
8. Developed country Members shall, if requested by other Members, provide copies of the documents or, in case of voluminous documents, summaries of the documents covered by a specific notification in English, French or Spanish.
9. The Secretariat shall promptly circulate copies of the notification to all Members and interested international organizations and draw the attention of developing country Members to any notifications relating to products of particular interest to them.

⁶ When "nationals" are referred to in this Agreement, the term shall be deemed, in the case of a separate customs territory Member of the WTO, to mean persons, natural or legal, who are domiciled or who have a real and effective industrial or commercial establishment in that customs territory.

10. Members shall designate a single central government authority as responsible for the implementation, on the national level, of the provisions concerning notification procedures according to paragraphs 5, 6, 7 and 8 of this Annex.

General reservations

11. Nothing in this Agreement shall be construed as requiring:
- (a) the provision of particulars or copies of drafts or the publication of texts other than in the language of the Member except as stated in paragraph 8 of this Annex; or
 - (b) Members to disclose confidential information which would impede enforcement of sanitary or phytosanitary legislation or which would prejudice the legitimate commercial interests of particular enterprises.

Annex C Control, inspection and approval procedures⁷

1. Members shall ensure, with respect to any procedure to check and ensure the fulfilment of sanitary or phytosanitary measures, that:
- (a) such procedures are undertaken and completed without undue delay and in no less favourable manner for imported products than for like domestic products;
 - (b) the standard processing period of each procedure is published or that the anticipated processing period is communicated to the applicant upon request; when receiving an application, the competent body promptly examines the completeness of the documentation and informs the applicant in a precise and complete manner of all deficiencies; the competent body transmits as soon as possible the results of the procedure in a precise and complete manner to the applicant so that corrective action may be taken if necessary; even when the application has deficiencies, the competent body proceeds as far as practicable with the procedure if the applicant so requests; and that upon request, the applicant is informed of the stage of the procedure, with any delay being explained;
 - (c) information requirements are limited to what is necessary for appropriate control, inspection and approval procedures, including for approval of the use of additives or for the establishment of tolerances for contaminants in food, beverages or feedstuffs;
 - (d) the confidentiality of information about imported products arising from or supplied in connection with control, inspection and approval is respected in a way no less favourable than for domestic products and in such a manner that legitimate commercial interests are protected;
 - (e) any requirements for control, inspection and approval of individual specimens of a product are limited to what is reasonable and necessary;
 - (f) any fees imposed for the procedures on imported products are equitable in relation to any fees charged on like domestic products or products originating in any other Member and should be no higher than the actual cost of the service;
 - (g) the same criteria should be used in the siting of facilities used in the procedures and the selection of samples of imported products as for domestic products so as to minimize the inconvenience to applicants, importers, exporters or their agents;
 - (h) whenever specifications of a product are changed subsequent to its control and inspection in light of the applicable regulations, the procedure for the modified product is limited to what is necessary to determine whether adequate confidence exists that the product still meets the regulations concerned; and
 - (i) a procedure exists to review complaints concerning the operation of such procedures and to take corrective action when a complaint is justified.

⁷ Control, inspection and approval procedures include, inter alia, procedures for sampling, testing and certification.

Where an importing Member operates a system for the approval of the use of food additives or for the establishment of tolerances for contaminants in food, beverages or feedstuffs which prohibits or restricts access to its domestic markets for products based on the absence of an approval, the importing Member shall consider the use of a relevant international standard as the basis for access until a final determination is made.

2. Where a sanitary or phytosanitary measure specifies control at the level of production, the Member in whose territory the production takes place shall provide the necessary assistance to facilitate such control and the work of the controlling authorities.
3. Nothing in this Agreement shall prevent Members from carrying out reasonable inspection within their own territories.

Annex 3 Australia's Appropriate Level of Protection

As a nation that exports approximately two-thirds of its agricultural produce, Australia benefits from the World Trade Organization's (WTO's) system of rules-based trade. We must adhere to a science-based process for assessing quarantine import risks, and other WTO Members are required to do the same.

The WTO's Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) defines the concept of an 'appropriate level of sanitary and phytosanitary 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 WTO Members, Australia expresses its ALOP in qualitative terms. The Australian Government, with the agreement of all state and territory governments, has expressed Australia's ALOP as providing a high level of sanitary and phytosanitary protection aimed at reducing risk to a very low level, but not to zero.

The Australian Government's policy reflects community expectations and provides for a high standard of quarantine that manages risks to a very low level. It recognises that a zero risk stance is impractical as it would mean no tourists, no international travel and no imports.

Annex 4 Import Market Access Advisory Group

Terms of Reference

The Import Market Access Advisory Group (IMAAG):

1. assigns (and, when warranted, re-assigns) priorities to import proposals
2. advises Biosecurity Australia of the priorities assigned to import proposals and
3. monitors progress of Biosecurity Australia's work program.

The Chief Executive of Biosecurity Australia determines the order in which analyses are conducted, taking account of the priority assigned by the IMAAG and the available resources and expertise. Biosecurity Australia will publish a work program for undertaking IRAs.

Prioritising import proposals

The IMAAG assigns a priority to import proposals to be undertaken as IRAs and, when warranted, re-assesses an established priority when the analysis has not commenced. In assigning the priority, the IMAAG considers the following:

1. National interest considerations including:
 - alignment with Government priorities and international obligations
 - new and/or re-emerging risks
 - domestic stakeholder/industry demand for a good.
2. Exporting country(ies) considerations including:
 - exporting country's priority relative to that country's other access requests
 - time elapsed since a valid import proposal was submitted.
3. Practical considerations including:
 - requests or potential for other requests to import similar commodities or commodities with similar risks
 - extent of available pertinent technical information.

Advising Biosecurity Australia of priorities assigned to import proposals

The IMAAG advises the Chief Executive of Biosecurity Australia of the priorities assigned to import proposals within 15 days of its deliberations.

Monitoring the progress of Biosecurity Australia's work program

The IMAAG monitors the progress of Biosecurity Australia's work program. Biosecurity Australia will also periodically update the IMAAG on other significant work underway.

Consultation

The IMAAG may consult relevant parties when assigning priorities. These parties might include other areas within the Department of Agriculture, Fisheries and Forestry, state and territory governments, other relevant domestic and international government agencies and relevant industry bodies.

Membership

Membership of the IMAAG is based on particular roles within the Department. If position titles change, those undertaking the equivalent roles will be members of the IMAAG.

Chairman:	Deputy Secretary, Department of Agriculture, Fisheries and Forestry
Members:	Deputy Secretary, Biosecurity Services Group Chief Executive, Biosecurity Australia, Biosecurity Services Group Executive Manager, Animal Division, Biosecurity Services Group Executive Manager, Plant Division, Biosecurity Services Group Executive Manager, Trade and Market Access Division

Members may nominate a proxy to attend, subject to approval by the Chairman.

Other Australian Government officials may be invited to attend meetings as advisers and observers and may contribute to discussion.

Meeting arrangements

The IMAAG will meet every three months or as soon as possible after receiving advice that a priority allocation is required for an import proposal.

Secretariat

Secretariat services to the IMAAG will be provided by an area of the Department separate to Biosecurity Australia.

Public communication

The IMAAG's terms of reference, membership and advice to Biosecurity Australia will be published on the Department's website.

Biosecurity Australia publishes its work program on its website.

Annex 5 Eminent Scientists Group

The Eminent Scientists Group (ESG) is a high level review group tasked with providing external, independent, scientific and economic scrutiny of significant import risk analyses.

The key purpose of the ESG is to review the drafts of IRA reports, as revised by Biosecurity Australia after consideration of stakeholder comments, that have been through the expanded IRA process, prior to their release. In particular, the ESG has the following functions:

1. Review the revised draft IRA report prepared by Biosecurity Australia. This will take account of any relevant new information brought to the ESG's attention, including assessing conflicting scientific views provided to it, to ensure that:
 - (a) all technical submissions received from stakeholders in response to the draft IRA report have been properly considered and
 - (b) the conclusions of the revised draft IRA report are scientifically reasonable based on the material presented.
2. Review the revised draft IRA report prepared by Biosecurity Australia to ensure that all relevant matters relating to the likely economic consequences of a pest or disease incursion have been properly considered.
3. Within 60 days of being presented with the revised draft IRA report, prepare a report to the Director of Animal and Plant Quarantine on its findings and recommend any action considered necessary to overcome any identified deficiencies. The ESG will provide a copy of the report to the Chief Executive, Biosecurity Australia.

Members of the ESG will be selected by the Director of Animal and Plant Quarantine in consultation with the Chief Scientist and chief executive officers of state and territory departments responsible for primary industries. Each member selected will have a proven record of scientific leadership, have made significant contribution to science and be well respected in the broad scientific community. The Director of Animal and Plant Quarantine will select one member of the ESG as Chairman.

The Chairman of the ESG will appoint no less than two members of the ESG to undertake the review of each draft final IRA report referred to the ESG and will nominate one of those members to lead the review in circumstances where the ESG Chairman is unable to undertake this role for particular reviews.

The Chairman of the ESG may co-opt additional expertise or seek advice, for example, in statistics or economics, to assist the ESG in meeting its terms of reference.

Annex 6 Import Risk Analysis Appeals Panel

Lodging an appeal

Stakeholders have 30 days from the publication of the provisional final import risk analysis report to lodge an appeal. Appeals must be in writing and be addressed to the Import Risk Analysis Appeals Panel (IRAAP) secretariat as follows:

Secretariat
Import Risk Analysis Appeals Panel
Corporate Policy Division
Department of Agriculture, Fisheries and Forestry
GPO Box 858
CANBERRA ACT 2601

Email: IRAAP@daff.gov.au

Ground for appeal

Appeals to the IRAAP must outline a claim or claims based on the following ground:

- there was a significant deviation from the regulated IRA process that adversely affected the interests of a stakeholder.

Each claim must be supported by a statement of reasons.

The IRAAP does not consider matters relating to:

- the scientific merits of the IRA
- the merits of the recommendations made or the conclusions reached by Biosecurity Australia or the Eminent Scientists Group.

Membership

An IRAAP is not a single ongoing panel. It is convened, as appropriate, for the purpose of considering appeals relating to a particular provisional final IRA report.

An IRAAP will be chaired by the Chairman of the Biosecurity Advisory Council (BAC).

An IRAAP comprises three members:

- Chairman of BAC
- one other member of BAC
- a senior officer from the Department of Agriculture, Fisheries and Forestry.

The IRAAP Chairman nominates the BAC member of an IRAAP. The Secretary of the Department nominates the senior departmental member of an IRAAP.

Membership of an IRAAP is subject to conflict of interest considerations. Each potential member of an IRAAP declares any potential conflict of interest or any possible perception of bias that could prevent them from participating in a particular appeal. If this declaration raises concerns about whether the Chairman or member should participate in the appeal, the Chairman, in consultation with the Secretary of the Department, nominates an alternative member.

Operating procedures

When a provisional final IRA report is issued by Biosecurity Australia, the IRAAP secretariat will inform the Chairman of BAC, confirm his or her availability to chair an IRAAP should one be required, seek information on any potential conflict of interest and provide advice on the IRAAP process.

If one or more appeals are received by the closing date, the IRAAP Chairman will consider the appeals received and in each case decide whether the statement of reasons provides evidence warranting consideration by an IRAAP.

The secretariat will advise the appellant(s) and the Chief Executive of Biosecurity Australia of the Chairman's decision on whether the appeal(s) warrant consideration by an IRAAP. Biosecurity Australia will inform registered stakeholders of the Chairman's decision.

The IRAAP will consider the appeal(s) and deliver a finding or series of findings in relation to each appeal. The IRAAP's findings will fall into one or more of the following categories:

- outside the ground for appeal
- allowed
- disallowed.

The IRAAP will not consider verbal submissions from appellants unless they are determined by the IRAAP to be necessary to supplement an appellant's written submission.

An appeal outcome requires majority support.

The IRAAP will report its findings to the appellant(s) and the Director of Animal and Plant Quarantine within 45 days of the closing date for appeals.

If an appeal is allowed, the IRAAP may offer advice to the Chief Executive of Biosecurity Australia on ways of overcoming any identified deficiencies.

Role of the IRAAP secretariat

The IRAAP secretariat administers the appeal process. The secretariat is based within the Department. In addition to administrative tasks, the secretariat may undertake research or provide advice at the request of the IRAAP Chairman or members.

Annex 7 Requirements for import proposals

Import proposals must be in writing. While there is no standard form for import proposals, a proposal should provide relevant scientific and other information to the extent available. A proposal will not be considered valid until relevant information is available to Biosecurity Australia.

After receiving an import proposal, Biosecurity Australia will examine the completeness of the documentation and inform the proposer of any deficiencies.

The scientific information may be provided by the person or body proposing the import (the proposer), the Competent Authority of the exporting country, or may already be available to Biosecurity Australia through scientific literature or other sources.

The required information may include, but is not limited to, distribution records of pests associated with particular plants, or information on the incidence of animal diseases or treatments the goods have undergone. The following information about the proposed import must be provided:

- scientific name (including order, suborder, genus, species, sub-species and variety, where applicable)
- common name(s)
- country(ies), zone(s), state(s), region(s), province(s), district(s) of origin, where applicable.

In some cases, applicants may be required to supply additional information concerning the good to be imported, such as that listed below, before an import proposal can be considered valid. Additional information that may be required includes production and processing methods.

Proposals to import plants or plant goods may also require more specific information, including:

- pest and disease information
- plant pest(s) of interest
- scientific names of plant pests, including authors
- classification of plant pests (order, family etc)
- export destinations/existing protocols
- production area in country of origin
- cultivation methods
- pest management and general surveillance programs
- sourcing goods from pest free zones and/or other existing relevant phytosanitary measures
- harvesting methods and post-harvesting activities
- internal legislative restrictions (pest free areas) or other domestic legislation
- synonyms commonly used
- hosts (including variety if relevant)
- plant parts attacked
- symptoms/damage
- distribution (within country)
- prevalence (common, occasional or rare).

Biosecurity Australia will determine when there is sufficient information to proceed with a risk analysis. If the required information is not available, special surveys and monitoring may be needed. Without all relevant information, it will not be possible for a risk analysis to be considered for Biosecurity Australia's active work program.



Annex 8 Stakeholder register

Biosecurity Australia maintains a database, known as the stakeholder register, to facilitate engagement and communication with people and organisations that have an interest in Biosecurity Australia's work. A stakeholder can be a farmer or producer, an industry group or organisation, a government agency, individual person, or community, whether in Australia or overseas, that has an interest in the subject matter of an import risk analysis, including the applicant/proponent for a proposal.

Interested parties wishing to be informed or consulted on a proposal or application, or generally, should complete and return a stakeholder registration form to Biosecurity Australia. More than one person within an organisation may register as a stakeholder by lodging a separate registration for each person.

Stakeholders will be informed when an issue in which they have registered interest is being actively considered.

The registration form is available via www.biosecurityaustralia.gov.au.

Completed registration forms should be sent to:

Stakeholder Register Administrator
Biosecurity Australia
GPO Box 858
CANBERRA ACT 2601

Email: stakeholder@biosecurity.gov.au

Annex 9 Public file

Biosecurity Australia maintains public files for IRAs at Biosecurity Australia's office in Canberra. The files contain printed copies of non-confidential submissions and other documentation relating to IRAs.

Biosecurity Australia's website, www.biosecurityaustralia.gov.au is the main access point for public file information. Electronic images of documents that are placed on the public file are available via the website. This improved access was implemented with effect from 1 July 2006.

Printed copies of public files will continue to be maintained and be accessible at the Canberra office, by appointment. Documents prior to 1 July 2006 have not been placed on the website retrospectively.

The public files, including the website copies, for IRAs may contain non-confidential material such as:

- background to the import proposal
- scope of the IRA
- documents circulated publicly by Biosecurity Australia during the IRA process
- formal membership of any specialist IRA team
- technical submissions, where relevant
- stakeholder comments and submissions where stakeholders have not maintained a claim of confidentiality
- approved summaries of IRA team meetings
- policy determinations.

The public file will not contain material that is restricted by legislation, such as copyright material, or material considered exempt under the provisions of the *Freedom of Information Act 1982* or information protected under the *Privacy Act 1988*.

Some formal submissions from stakeholders in relation to IRAs are marked 'confidential'. However, if a submission is used in Biosecurity Australia's decision-making process, Biosecurity Australia cannot guarantee its confidentiality. Under the *Freedom of Information Act 1982* and the *Privacy Act 1988*, submissions or parts of them may well be released to a third party. Similarly, information held by the Australian Government can be legally requested by bodies such as the Parliament, the Australian National Audit Office and the Australian Courts.

Annex 10 Contact information

Biosecurity Australia

Chief Executive

Biosecurity Australia
GPO Box 858
CANBERRA ACT 2601
AUSTRALIA

Telephone: +61 2 6272 3933
Email: ba@biosecurity.gov.au

Animal Biosecurity import risk analyses

Biosecurity Australia
GPO Box 858
CANBERRA ACT 2601
AUSTRALIA

Telephone: +61 2 6272 3933
Email: animal@biosecurity.gov.au

Plant Biosecurity import risk analyses

Plant Biosecurity
Biosecurity Australia
GPO Box 858
CANBERRA ACT 2601
AUSTRALIA

Telephone: +61 2 6272 3933
Email: plant@biosecurity.gov.au

Department of Agriculture, Fisheries and Forestry

GPO Box 858
CANBERRA ACT 2601
AUSTRALIA

Telephone: +61 2 6272 3933

Import Risk Analysis Appeals Panel

IRAAP Secretariat
GPO Box 858
CANBERRA ACT 2601

Email: IRAAP@daff.gov.au

Annex 11 Acronyms and definitions

appropriate level of protection (ALOP)	the level of protection deemed appropriate by a country establishing a sanitary or phytosanitary measure to protect human, animal or plant life or health within its territory (according to Annex A of the SPS Agreement) – also known as the acceptable level of risk
AQIS	Australian Quarantine and Inspection Service
biosecurity	the prevention of the entry, establishment or spread of unwanted pests and infectious disease agents to protect human, animal or plant health or life, and the environment
Biosecurity Advisory Council (BAC)	a ministerially appointed council that advises the Minister for Agriculture, Fisheries and Forestry on matters across the biosecurity continuum including the performance of agencies delivering biosecurity services
Biosecurity Australia (BA)	the unit, within the Biosecurity Services Group, responsible for recommendations for the development of Australia's biosecurity policy
Biosecurity Australia Advice (BAA)	formal advice issued to registered stakeholders and posted on Biosecurity Australia's website
biosecurity continuum	the spectrum of Australia's biosecurity activities pre-border, at the border and post-border, involving risk assessment, monitoring and surveillance and response
Biosecurity Services Group (BSG)	the group responsible for the delivery of biosecurity policy and quarantine services within the Department of Agriculture, Fisheries and Forestry
Chief Executive	means the Chief Executive of Biosecurity Australia
Competent Authority	official service or authority, established by the government of an exporting state, having the responsibility and competence for ensuring or supervising the implementation of animal or plant health standards
Director of Animal and Plant Quarantine	a statutory position under the <i>Quarantine Act 1908</i> , undertaken by the Secretary of the Australian Government Department of Agriculture, Fisheries and Forestry
ESG	Eminent Scientists Group
good	article of trade, also 'goods' – the term 'goods' is used in the Quarantine Regulations 2000 to refer to plants, animals or other items that are the subject of an IRA.
Handbook	<i>Import Risk Analysis Handbook 2011</i>

IMAAG	Import Market Access Advisory Group
import proposal	a proposal – usually a market access request – to bring into Australia plants, animals or other goods not imported previously, or not imported previously from the country or region concerned
import risk analysis (IRA)	a type of risk analysis with key steps regulated under the Quarantine Regulations 2000
IPPC	International Plant Protection Convention
IRAAP	Import Risk Analysis Appeals Panel
market access request	a request from an exporting country authority, agency or individual exporter to export a good to Australia – the most common origin of an import proposal
non-regulated analysis	a risk analysis conducted as a non-regulated analysis of relevant existing policy
OIE	World Organisation for Animal Health
proposer	person or body proposing the importation of plants, animals or their products into Australia
risk analysis	assessment of the level of quarantine risk associated with the importation, or proposed importation of animals, plants or goods and, if necessary, identification of risk management options to limit the level of quarantine risk to achieve Australia's appropriate level of protection
Secretary	the chief executive of the Australian Government Department of Agriculture, Fisheries and Forestry declared to be the Director of Animal and Plant Quarantine by subsection 9AA(1) of <i>the Quarantine Act 1908</i>
SPS Agreement	WTO Agreement on the Application of Sanitary and Phytosanitary Measures
stakeholders	individuals, industry groups or community organisations, government agencies, whether in Australia or overseas, that have an interest in the subject matter of an IRA, including the proposer of a specific import proposal
WHO	World Health Organization of the United Nations
WTO	World Trade Organization

Import risk analysis flowchart

