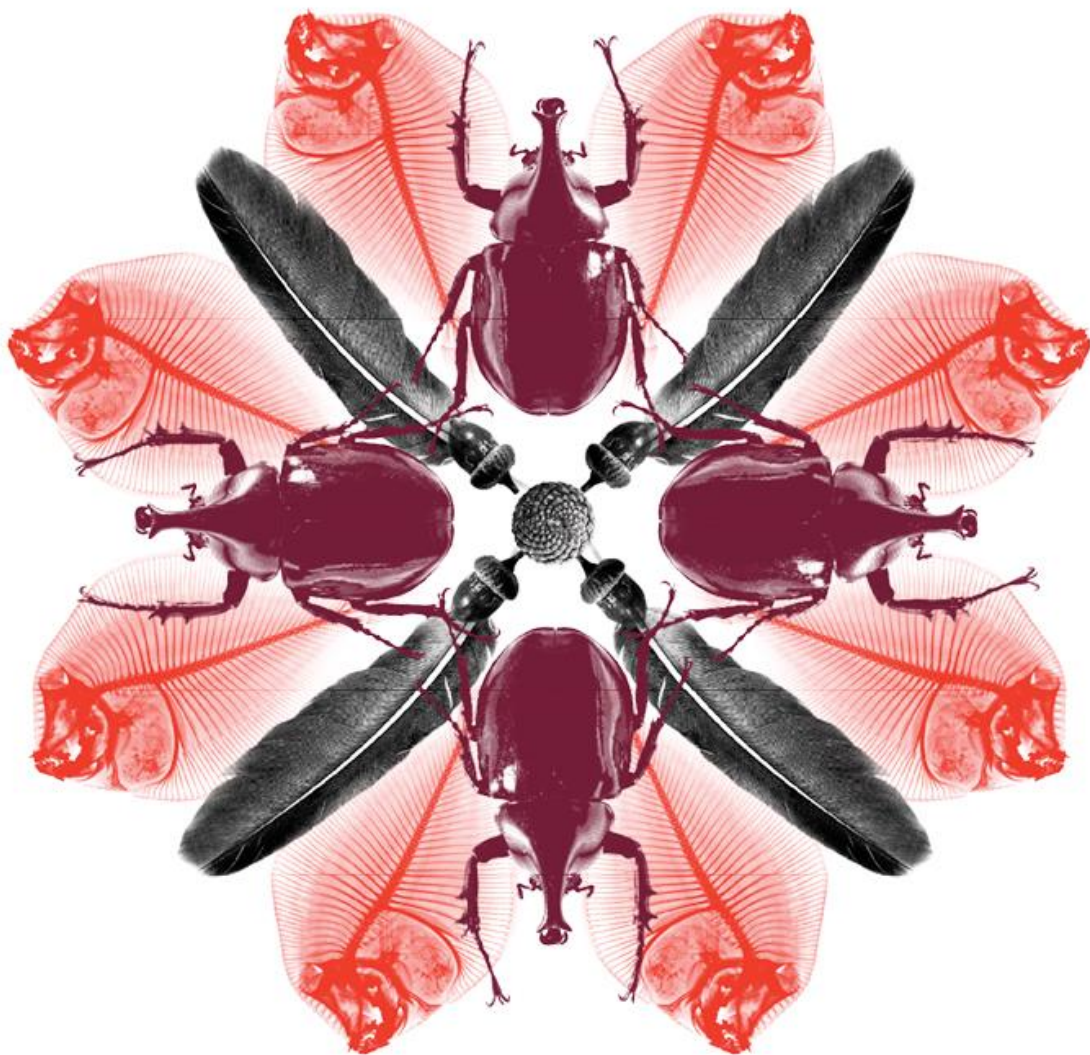




Australian Government
Department of Agriculture
and Water Resources

Biosecurity Import Risk Analysis Guidelines 2016

Managing biosecurity risks for
imports into Australia



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About these guidelines

The Biosecurity Import Risk Analysis Guidelines 2016 describe the process the Australian Government Department of Agriculture and Water Resources follows and matters to be taken into account when conducting a Biosecurity Import Risk Analysis (BIRA) under the *Biosecurity Act 2015* and the Biosecurity Regulation 2016.

These guidelines describe a structured approach for conducting BIRAs that is consistent with Australian Government policy, the Biosecurity Act and subordinate legislation, the obligations of the World Trade Organization (WTO) Agreement on the Application of Sanitary and Phytosanitary Measures (SPS agreement), and the standards developed by the World Organization for Animal Health (OIE) and the International Plant Protection Convention (IPPC).

These guidelines are a living document and minor amendments will be made from time to time as necessary. Any major review of the guidelines will involve stakeholder consultation.

1 Introduction

The department is tasked with safeguarding Australia's animal and plant health status from the impact of exotic diseases and pests, through risk analysis, risk mitigation measures, inspection and certification, and implementation of emergency response arrangements for Australian agricultural, food and fibre industries. This work is done in association with state and territory governments.

Australia's agriculture sector has a strong trade focus and relies on the biosecurity system to safeguard the nation's favourable human, animal and plant health status to protect both our domestic production and to maintain competitiveness and access to overseas markets.

The department undertakes a range of risk analyses in response to requests to import goods into Australia, where those goods have not been imported before, or have not been imported into Australia from a particular country or region. The department also undertakes reviews of existing trade.

Risk analyses consider the level of biosecurity risk that may be associated with the importation of a good, and identifies appropriate ways to manage these risks.

There are two main types of risk analyses used by the department:

- a BIRA which is conducted through a regulated process provided for in the Biosecurity Act and the Biosecurity Regulation
- a non-regulated risk analysis (such as scientific reviews of existing policy and import conditions, pest-specific assessments, weed risk assessments, biological control agent assessments or scientific advice).

In these guidelines, the term 'risk analysis' is a generic term referring to the technical or scientific process for assessing biosecurity risk and the development of risk mitigation measures. The term 'biosecurity import risk analysis' or 'BIRA', refers to the process that is regulated under legislation, and the term 'non-regulated risk analysis' refers to those risk analysis that follows a process that is not regulated under legislation.

BIRAs assist the department in considering the level of biosecurity risk that may be associated with the importation of goods into Australia. If the biosecurity risks do not achieve the appropriate level of protection (ALOP) for Australia, risk management measures are proposed to reduce the risks to an acceptable level. If the risks cannot be reduced to an acceptable level, the goods will not be imported into Australia, until suitable measures are identified.

More information about Australia's ALOP is on the [department's website](#).

2 Biosecurity risks and Australia's biosecurity framework

Biosecurity risks

The term 'biosecurity risk' is defined in the Biosecurity Act. It refers to the likelihood of a disease or pest entering, establishing or spreading in Australian territory, and the potential for the disease or pest causing harm to human, animal or plant health, the environment, economic or community activities. As part of the BIRA a risk assessment is undertaken.

The definition of risk assessment under the SPS agreement is:

The evaluation of the likelihood of entry, establishment or spread of a pest or disease within the territory of an importing WTO member according to the SPS measures which might be applied, and of the associated potential biological and economic consequences. (World Trade Organization, 1995)

BIRAs are risk assessments conducted under the Biosecurity Act and in accordance with the SPS agreement and other international obligations. Under a BIRA, risk is determined by combining the likelihood of the entry, establishment and spread of a disease or pest with the consequence. It takes into account the whole of the risk pathway from the identified hazard to the unwanted outcome or consequence.

These two components of likelihood and consequence are combined to give an estimate of the risks for each disease or pest associated with an imported good and whether those risks achieve Australia's ALOP; or if sanitary or phytosanitary measures are required.

BIRA framework

BIRAs, including identified risk management measures, are one part of Australia's biosecurity system. Australia's approach to managing the risk of exotic diseases and pests is a multi-layered system involving complementary measures applied along the biosecurity continuum—offshore, at the border and onshore. This section outlines Australia's biosecurity laws and policies and the international standards that apply to Australia's biosecurity risk framework.

Australia's biosecurity legislation

Australia's biosecurity system is supported by Commonwealth, state and territory biosecurity laws. At the Commonwealth level, this includes the Biosecurity Act and subordinate legislation made under the Act.

The Biosecurity Act provides for certain matters to be dealt with in more detail in subordinate legislation such as the Biosecurity Regulation and supporting administrative documents such as these guidelines.

It also outlines the role of the Agriculture Minister in directing the Director of Biosecurity to commence a BIRA. The Director of Biosecurity is the person who is, or is acting as, the Agriculture Secretary. Under the Biosecurity Act, the Director of Biosecurity can delegate their functions and powers to department employees.

The Biosecurity Regulation sets out and regulates the process for conducting a BIRA. It:

- identifies the steps that must be included in a BIRA
- specifies time frames for BIRAs
- specifies publication and consultation requirements

- specifies that at any stage in the BIRA process the Director of Biosecurity may request the scientific advisory group to examine and provide comment on any aspect of the BIRA
- specifies that a provisional BIRA report must be released to communicate the results of the BIRA
- specifies that an appeal on the process only used to conduct a BIRA can be made to the Inspector-General of Biosecurity
- makes provisions for the termination of a BIRA.

The Biosecurity Regulation also describes the role of the Director of Biosecurity in the BIRA process.

The Biosecurity Act and the Biosecurity Regulation are available on the [Federal Register of Legislation](#).

Administrative documents

The department also uses administrative documents, such as guidelines and policies, to administer and undertake biosecurity related services and activities. These documents set out the processes for conducting BIRAs and the matters that must be taken into account.

International agreements and standards

Australia has its own biosecurity laws and policies which take into account our international trade obligations when conducting risk analyses.

International agreements to which Australia is a party define the rights and obligations of countries in relation to implementing biosecurity arrangements. These agreements include the SPS agreement and the International Health Regulations.

All WTO members are signatories to the SPS agreement, under which they have both rights and obligations. The SPS agreement provides WTO members with the right to use sanitary (human and animal health) and phytosanitary (plant health) measures (SPS measures) to protect human, animal and plant life or health.

The agreement requires governments to base their SPS measures on international standards, guidelines and recommendations, such as those established for plant health by the IPPC and for animal health by the OIE.

Australia bases its risk analysis methodologies and import risk management measures on the standards, guidelines and recommendations set by the IPPC and OIE. However, when such standards do not achieve Australia's ALOP, or relevant standards do not exist, Australia exercises its right under the SPS agreement to apply appropriate measures, justified on scientific grounds and supported by risk analysis.

The International Health Regulations were established by the World Health Organization to prevent, protect against, control and respond to the international spread of disease in ways that are commensurate with and restricted to public health risks, and that avoid unnecessary interference with international traffic and trade. As a World Health Organization member state and a signatory to the regulations, Australia upholds the regulations' standards and values in protecting public health.

More information about Australia's international biosecurity obligations is on the [department's website](#).

3 Australia's biosecurity import risk analysis process

Before a BIRA begins

There are a number of ways a BIRA may begin:

- the Agriculture Minister directs the Director of Biosecurity to commence a BIRA in relation to a particular good or class of goods if they are satisfied that the BIRA should be commenced (Biosecurity Act), or
- the Director of Biosecurity decides to commence a BIRA in relation to a particular good or class of goods should the Director of Biosecurity believe the criteria for a BIRA has been met (Biosecurity Regulation).

An import proposal may be provided to the department by government authorities of an exporting country in the form of a market access request, or when people or organisations want to import goods (plants, animals and other goods). An import proposal is a generic term used to describe a proposal to bring plants, animals or other goods into Australia in circumstances where import conditions have not been established.

The department may consult with the party making the import proposal, where required, to confirm the scope of the request and to ensure that any required information has been provided to support their request. The department prioritises valid proposals, then considers the type of risk analysis that is required and whether the criteria for conducting a BIRA have been met.

The department will work to identify stakeholders directly related to the potential BIRA and notify them. It may not be possible for the department to identify and contact all stakeholders before publishing the notice advising that a BIRA is commencing. However, a Biosecurity Advice Notice will be sent to all stakeholders who have subscribed to receive notifications.

The department also contacts relevant Australian Government and state and territory departments and agencies when necessary.

More information about import proposals is on the [department's website](#).

Criteria for a BIRA

A BIRA will be undertaken when:

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

A risk analysis which does not meet the criteria for a BIRA is undertaken as a non-regulated risk analysis. Further information about the types of non-regulated risk analyses the department conducts is on the [department's website](#).

Summary of regulated BIRA steps

This section describes the steps to be undertaken in a BIRA.

- 1) The Director of Biosecurity must appoint a scientific advisory group.
- 2) The Director of Biosecurity must publish a notice on the department's website stating:
 - a) that a BIRA is commencing
 - b) the opportunities for consultation that will occur during the BIRA process.
- 3) The Director of Biosecurity must prepare an issues paper and publish it on the department's website. The issues paper will set out background information about the request, the commodity/goods and some of the main matters that will be considered during the analysis.
- 4) The Director of Biosecurity must:
 - a) Prepare a draft BIRA report
 - b) Publish on the department's website the draft report and an invitation to the public to provide submissions about the assessment of the level of biosecurity risk associated with the relevant goods or class of goods including proposed risk measures for the goods to achieve ALOP within a period specified in the invitation.

The consultation period must be at least 60 calendar days, including the day the invitation is published.

If the Director of Biosecurity considers that the public may not have a reasonable opportunity to consider the draft BIRA report, the period for public submissions may be extended only once for a period of up to 60 calendar days.

- 5) The Director of Biosecurity must prepare a provisional BIRA report and publish it on the department's website.
- 6) Within 30 calendar days of the provisional BIRA report's publication, a person may make a request to the Inspector-General of Biosecurity to review the process used to conduct the BIRA.
- 7) If a person requests a review of the process for conducting the BIRA, and the Inspector-General is satisfied that a review can proceed, the Inspector-General must tell the Director of Biosecurity, in writing, about the request. The Inspector-General must then conduct the review the process for conducting the BIRA.
- 8) If the Inspector-General conducts a reviews the process for conducting the BIRA, the Director of Biosecurity must consider any recommendations in their report and must publish a final BIRA review report.
- 9) If the Inspector-General is not requested to conduct a review the process for conducting a BIRA, the Director of Biosecurity must publish the provisional BIRA report as the final BIRA report as soon as practical to do so.

The final BIRA report must be published within 30 months from the day the notice announcing the BIRA was published, unless specific circumstances apply.

The Director of Biosecurity may publish a notice on the department's website to stop the counting of time for a BIRA if:

- the Director of Biosecurity is waiting for requested further information, research or expert advice, or
- the Director of Biosecurity is waiting for examination by the scientific advisory group of a requested part of the BIRA process.

If the Inspector-General reviews the process for conducting a BIRA, the time taken for the review does not count towards the 30-month time frame.

The 30-month time frame also may not be met if a biosecurity circumstance of national or international significance occurs.

How biosecurity risk is assessed

This section describes how the department assesses biosecurity risk in relation to the importation of goods. The department evaluates the likelihood of entry, establishment and spread of a disease or pest and the magnitude of potential consequences in a defined area, using biological or other scientific evidence and economic evidence. The evaluation follows internationally agreed principles and standards relating to import and pest risk analyses.

Within the department

BIRAs and other types of risk analyses are conducted by departmental staff with technical and scientific expertise relevant to the biosecurity risks being considered.

The department employs a range of scientific and technical staff with tertiary qualifications in relevant scientific fields such as aquatic animal health, botany, ecology, entomology, environmental science, food and nutrition science, geospatial analysis, microbiology, molecular biology, plant pathology, quantitative science, veterinary science and zoology.

Use of external expertise

When appropriate, the department uses external resources in addition to the scientific advisory group. (See chapter 7 for more information on the advisory group.) For example, the department may request advice or information from relevant technical or scientific experts from state and territory biosecurity agencies, CSIRO, the Centre of Excellence for Biosecurity Risk Analysis, universities and industry to access the technical expertise needed for a particular risk analysis.

Sometimes the department needs to validate complex or contentious science, or there may be uncertainty about critical aspects of science. In these cases the department may organise formal meetings or workshops with scientific and technical experts.

More information about the roles and responsibilities of parties involved in a BIRA is on the [department's website](#).

The risk estimation matrix

The department uses a formal methodology to assess biosecurity risk. The methodology is consistent with international guidelines and includes assessment tools, such as a risk estimation matrix.

Because plant and animal analyses are covered by two different international standards, detail on the specific methodology used to conduct a given BIRA are each contained in individual BIRA reports and are appropriate to the circumstances, as required by the SPS agreement.

A risk estimation matrix is used by the department to combine the likelihood of a disease or pest entering, establishing and spreading in Australia with the potential consequences (Table 1) should that occur, and to determine whether specific risk management measures are required to achieve Australia's ALOP. It takes into account the whole of the risk pathway from the identified hazard to the unwanted outcome or consequence.

The components of risk are combined to give an overall estimate of the unrestricted risks for each disease or pest associated with an imported good and whether those risks achieve Australia's ALOP. If the estimated risk does not achieve Australia's ALOP, the department considers whether sanitary or phytosanitary measures will be considered to mitigate the risk. Australia's ALOP is achieved if the estimated risk is at or below 'very low'.

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

An adapted form of Australia’s risk estimation matrix is used as a basis by Plant Health Australia and by affiliated industries in their industry biosecurity plans.

Examples of Import Risk Analyses showing the application of the risk estimation matrix are on the [department’s website](#).

Table 1 The risk estimation matrix

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

Source: Department of Agriculture and Water Resources

4 Matters to be taken into account in conducting a BIRA

Technical methodology used for a BIRA

As discussed in chapter 3, the department uses a formal methodology to assess biosecurity risk. Australia's risk assessment method has been used since 2001 and includes the risk estimation matrix (Table 1). A matrix-based approach is the supported approach for this type of risk assessment under international standards. These are consistent with OIE and IPPC risk management standards.

Each BIRA has a unique set of circumstances and requirements. While the overarching risk assessment methodology follows international principles, the specific methodology may vary between BIRAs so that it is appropriate to the circumstances. Each BIRA report will detail the technical methodology used to conduct the assessment.

The BIRA process evaluates the likelihood of the entry, establishment or spread of a disease or pest and the magnitude of potential consequences in a defined area, using biological or other scientific and economic evidence.

Assessment of the likelihood of entry, establishment and spread

The likelihood of entry is the likelihood that a biosecurity disease or pest will enter Australian territory as a result of importation of a good, be distributed in the imported area and subsequently be transferred to a host. Establishment is the perpetuation for the foreseeable future, of a disease or pest within an area after entry. Spread is the expansion of the geographical distribution of a disease or pest within an area.

Assessment of potential consequences

The objective of the consequence assessment is to provide a structured assessment of the consequences if a disease or pest were to enter, establish and spread in Australian territory. The assessment considers direct and indirect disease or pest effects and their economic and environmental consequences.

Direct disease or pest effects are considered in the context of the effects on plant, animal and/or human life/health and other aspects of the environment. Indirect disease or pest effects are considered in the context of the effects on eradication and control, domestic trade, international trade and the environment. Consequences are estimated over four geographical levels: local, district, regional and national.

Economic considerations

In keeping with the scope of the Biosecurity Act and Australia's obligations as a WTO member, economic considerations are taken into account only in relation to matters arising from potential negative direct and indirect impact of diseases and pests that could enter, establish or spread in Australian territory as a result of a good being imported.

BIRAs cannot take into account the potential economic impact of matters such as the effect on market competition caused by importing goods, or the net national benefit resulting from the importation as this would not be consistent with Australia's international trade obligations.

Regional differences

Differences in disease and pest status, geography, climate, and host and vector distribution across geographical regions are considered throughout a BIRA and are intrinsic parts of the risk analysis. This differentiation is commonly referred to as regional differences, and under the SPS agreement it is known as regional conditions. Under the Biosecurity Act, regional difference is referred to in the definition of biosecurity risk as the likelihood of a disease or pest entering or establishing itself in Australian territory, or part of Australian territory.

Regional differences may exist in both the exporting and importing countries. The SPS agreement requires WTO members to adapt their SPS measures to the regional conditions from which the product originated and to which the product is destined.

The BIRA process provides for consideration of regional differences so long as it is consistent with Australia's rights and obligations under the SPS agreement and relevant international standards such as those set by the OIE and IPPC.

The department recognises that certain areas of Australia have a different pest and disease status from other areas. Recognising different areas, subpopulations and management practices as having different disease or pest statuses or low disease or pest prevalence is consistent with the standards set by the OIE and the IPPC.

The department works with state and territory authorities to determine regional disease and pest status and any information provided that may assist in determining the level of risk. Early in the BIRA process the department provides a preliminary disease and pest list and categorisation to state and territory authorities for consideration and confirmation on whether identified diseases and pests are regional pests and under official control.

Plant pests that are present in Australia and not under official control as defined by the IPPC cannot be regulated in international trade (see Box 1). When an exporting country claims to have a low pest prevalence or a pest- and disease-free area in its territory, or part of its territory, it must provide sufficient supporting evidence to the department to substantiate the claim. Following consideration of the evidence, the department may decide to recognise the claim.

Examples of Import Risk Analyses showing the application of the consideration of regional differences are on the [department's website](#).

Box 1 Regional differences and 'official control'

The IPPC has the concept of regional differences embedded into its definition of 'quarantine pest'. Pests must first meet this definition before they can be considered for regulation in international trade.

If a pest is present in Australia and not under [official control](#), it does not meet the definition of a quarantine pest and cannot be considered for regulation in international trade.

In all BIRAs and non-regulated complex risk analyses conducted for plants and plant products, each pest is categorised to determine whether it is a regional pest for a part or parts of Australia. Regional considerations are then taken into account in the risk analysis and the development of import conditions, where these are justified.

5 Potential outcomes from a BIRA

Policy determination

A policy determination specifies whether trade may be permitted and if so, what conditions, if any, must be applied to the good to achieve Australia's ALOP.

A BIRA is not a decision to import.

In making a policy determination, the Director of Biosecurity considers:

- the final BIRA report and its recommendations
- any final IGB report if completed
- any other relevant information, including Australia's international rights and obligations.

Once the Director of Biosecurity makes a policy determination, the department notifies the proposer, registered stakeholders and the WTO secretariat. The policy determination, and information about what occurs after a policy determination, is available on the department's website.

A policy determination can be reviewed at any time if relevant new information is received, or a review can be initiated by the department for other reasons

Decision to terminate a BIRA

In most cases, when a BIRA is started it will be completed. However, there are situations when it is not appropriate, or necessary, to complete a BIRA. The Director of Biosecurity may decide to terminate a BIRA at any time if the Director of Biosecurity has requested information from a person, including an external expert, or has requested that the scientific advisory group examine and provide comment on an aspect of the BIRA, and either:

- has been given an adequate response to the request and is satisfied that there is insufficient reason to complete the BIRA, or
- is satisfied that there is insufficient information or reason to complete the BIRA.

The Director of Biosecurity will consider the requested information or comments received and decide, based on all other available information and evidence, and taking into account international trade obligations, whether terminating the BIRA is appropriate.

Including a provision that allows the Director of Biosecurity to terminate a BIRA before it is complete ensures that a BIRA is not continued where needs have changed. Some examples of this include:

- in circumstances where the Director of Biosecurity is reacting to changing priorities (such as where a country withdraws its request for market access), or
- where the policy rationale no longer exists for a BIRA process, or
- where new science or information has emerged.

In some of these cases, the BIRA may transition into a non-regulated risk analysis.

If the Director of Biosecurity terminates a BIRA, they must publish a notice on the department's website stating that the BIRA has been terminated and the reasons for the termination.

Provisional sanitary and phytosanitary measures

Under the SPS agreement, in cases where relevant scientific evidence is insufficient, WTO members may adopt provisional SPS measures on the basis of available relevant information. However, they are required to seek to obtain the additional information necessary for a more objective risk analysis within a reasonable period of time.

Where provisional SPS measures have been applied, the BIRA report will detail the information on which they are based and undertake to review the measure within a reasonable period of time.

6 Consultation and communication

Communication with stakeholders

Engagement with stakeholders is an important part of the BIRA process. Stakeholders include anyone with an interest in the specific BIRA underway and may include, but are not limited to, foreign governments, industry groups, state and territory governments, other federal agencies, research organisations, environmental organisations, farmers, importers, exporters and the general public.

Consultation throughout the BIRA process is both formal and informal and aims to seek stakeholder views on technical issues relevant to the risk analysis. Engagement with stakeholders occurs through conversations and meetings, as well as through website updates, publication of biosecurity advice notices and information sent directly to registered stakeholders.

The department maintains a database of registered stakeholders to facilitate engagement and communication with people and organisations with an interest in the department's work. The database enables stakeholders to indicate areas of interest and the way they prefer to receive information.

The department also welcomes stakeholder comments or submissions at any time on matters relevant to the BIRA or other import conditions.

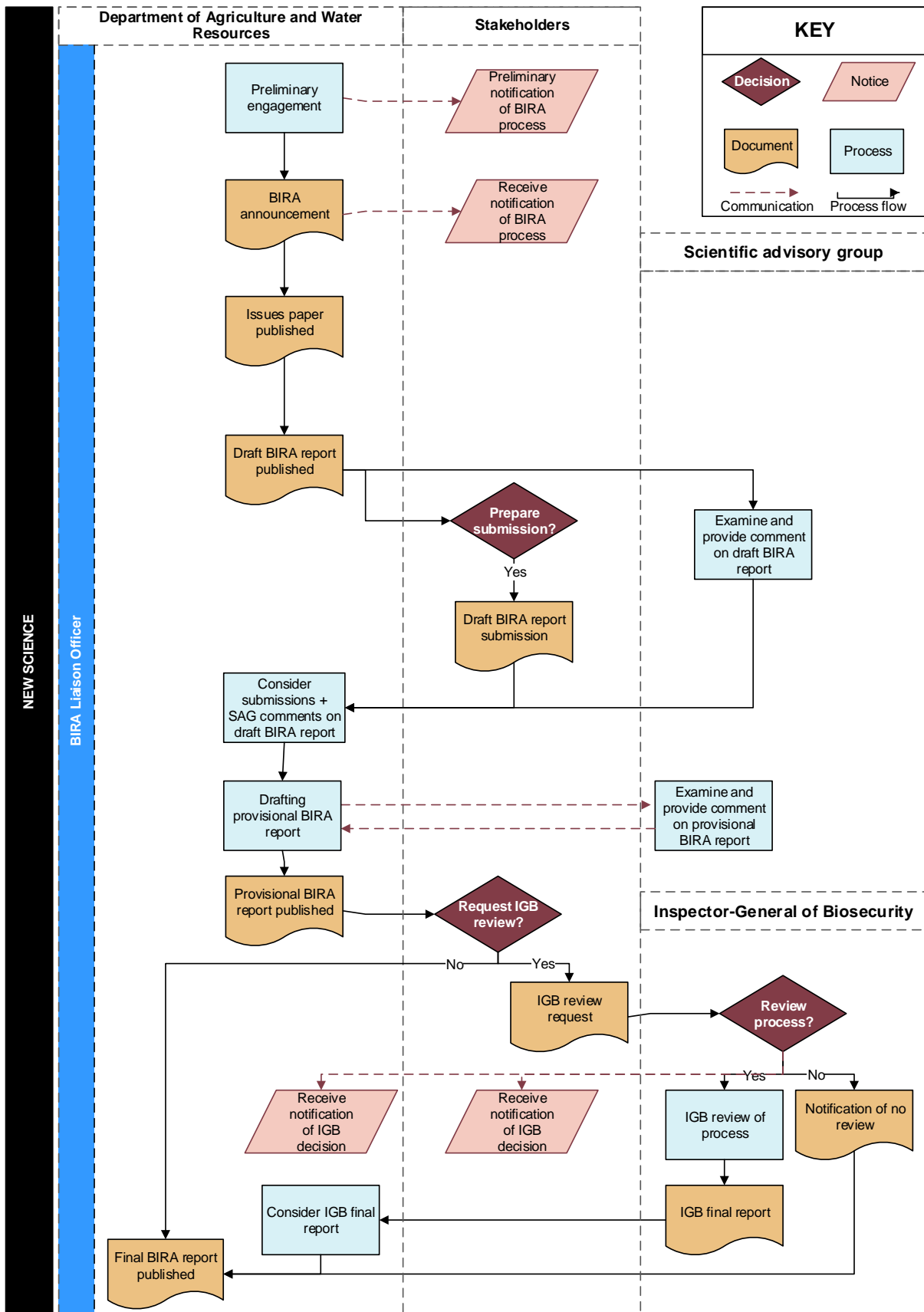
Opportunities for stakeholders to contribute to the BIRA process

The Biosecurity Regulation specifies the stages of the BIRA process at which stakeholder consultation is required. This is in the form of a formal submission process with set time frames.

In addition to this regulated process, the department welcomes comments, concerns, queries and scientific information from stakeholders at any time. Additional comments can be provided either through the [BIRA Liaison Officer](#) or to the relevant area (Plant Biosecurity or Animal Biosecurity) that is conducting the BIRA (see the appendix to these guidelines for contact details).

Figure 1 outlines BIRA process and the opportunities for consultation at various stages of the process.

Figure 1 The BIRA process



IGB = Inspector-General of Biosecurity.
 Source: Department of Agriculture and Water Resources

BIRA Liaison Officer

One BIRA Liaison Officer will be assigned to each BIRA. The role will be undertaken by a departmental officer.

Purpose

The BIRA Liaison Officer will be the first point of contact for BIRA inquiries when a BIRA is underway. The officer will act as a conduit between domestic stakeholders, the BIRA project team and other interested parties throughout the BIRA process. The officer will facilitate two-way information sharing between stakeholders and the BIRA project team.

The BIRA Liaison Officer will be responsible for sharing information, consulting with stakeholders and communicating the process and outcomes of the BIRA to stakeholders.

The BIRA Liaison Officer will be an optional contact for stakeholders as already established relationships and contacts can be used instead.

Tasks

The BIRA Liaison Officer's role will be to:

- facilitate greater understanding of BIRA processes and issues, including how, when and why BIRAs are conducted and their importance, through regular two-way communication and consultation with domestic stakeholders
- be the first point of contact for BIRA inquiries and act as a conduit between those conducting the BIRA and domestic stakeholders. This includes:
 - notifying identified stakeholders that a BIRA is going to be conducted
 - informing relevant stakeholders of the issues that will be considered in the BIRA
 - providing regular updates, including clarifying information, throughout the BIRA process
 - communicating the timing of a BIRA, including when submissions can be made
 - providing information from domestic stakeholders to the department
 - communicating the outcomes of the BIRA process
 - organising and coordinating face-to-face meetings and teleconferences as and when required
 - continuing to provide support after the completion of the BIRA, up until first import (if relevant).

NOTE: The role of the BIRA Liaison Officer may be revised after first being used following stakeholder feedback.
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7 Scientific advisory group

Under the BIRA Regulation, the Director of Biosecurity must appoint, in writing, external persons to be members of a scientific advisory group (the group). The group will be established at the commencement of a BIRA.

At any stage in the process of conducting a BIRA, the Director of Biosecurity may (either orally or in writing) request the group examine and provide comments on **any aspect** of the BIRA. The group must then complete an examination of the requested aspect, and give its comments and findings to the Director of Biosecurity, in the form requested by the Director of Biosecurity.

Any requested comments and findings given by the group must be considered by the Director of Biosecurity in preparing the final BIRA report.

Composition

To ensure consistency between BIRAs, the Director of Biosecurity will appoint three standing members to the group with relevant experience in risk analyses. This will include a chair, an economist, and a person experienced in risk analysis.

Outside of the standing members, the composition of the group will be decided depending on the BIRA to be conducted. Selections will be based on the scientific and technical expertise that is relevant to the good or class of goods being analysed in the BIRA. There will not be a pre-determined number of people who can be appointed to the group.

Suggestions for additional members will be sought from state and territory governments and other stakeholders prior to the commencement of any new BIRA.

Selected members will have a proven record of scientific or technical expertise relevant to the BIRA or will have made a significant contribution to the science or technical methods relevant to the BIRA. Overseas experts may be appointed as members of the group.

Conflicts of interest and confidentiality

The department recognises that depending on the particular BIRA being conducted that there may be limited scientific/technical expertise available to draw from. As such it is anticipated that conflicts of interest may arise from time to time. Any conflicts of interest must be declared by members of the group and documented.

All members of the group will be required to sign confidentiality agreements.

The Director of Biosecurity will make the final decision on the composition of the group.

It is also important to note that the group is not the final decision maker and can only make recommendations to the department.

Role

The group may be asked to examine or provide comment on any aspect of the BIRA. This includes examining or providing comment on issues that have arisen during the development of the BIRA.

The group will be asked to examine and provide comments on the draft and provisional BIRA reports. The group may be asked to consider whether:

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

NOTE: This approach is a trial and may be revised after the first BIRA, taking into account stakeholder feedback on the group.
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8 Inspector-General of Biosecurity

The Inspector-General of Biosecurity is a statutory position that reports directly to the Agriculture Minister.

Any person who believes there was a significant deviation from the process set out in the Biosecurity Regulation that has adversely affected, or might adversely affect, their interests may request in writing that the Inspector-General review the process used to conduct the BIRA.

Requests for review must be lodged within 30 calendar days of the publication of the provisional BIRA report.

The Inspector-General reviews the process only, not the scientific merits of the BIRA, the merits of the recommendations made, or the conclusions reached by the department. It is a non-judicial review.

The Inspector-General considers any requests for review and decides in each case whether the evidence warrants a review. If so, they will review the process used to conduct the BIRA. If, after considering the grounds of the review, the Inspector-General decides that a review is not appropriate, they will notify the person who requested the review and the Director of Biosecurity.

The Inspector-General has 45 calendar days to conduct a review and prepare a final report. The report will outline their findings, the evidence and other material which the findings were based on and any recommendation resulting from the review. The report will be provided to the Director of Biosecurity before being published on the department's website. The Inspector-General will write to the person who requested the review to tell them the report has been published.

Appendix: Biosecurity contact details

Australian stakeholders are encouraged to provide any information to the department regarding what may be a biosecurity risk by calling the department's hotline on **1800 798 636**.

Domestic stakeholders can also contact the department through the following contact points:

Animal Biosecurity

Email animal@agriculture.gov.au

Plant Biosecurity

Email plant@agriculture.gov.au

BIRA Liaison Officer

Email liaisonofficer@agriculture.gov.au

International stakeholders can contact the department through the following contact points:

Chief Veterinary Officer

Email OCVO@agriculture.gov.au

Chief Plant Protection Officer

Email ippc.contactpoint@agriculture.gov.au

The department's postal address is:

Department of Agriculture and Water Resources
GPO Box 858
Canberra ACT 2601
Australia

Glossary

appropriate level of protection (ALOP)	The level of protection that a country considers appropriate to protect human, animal or plant life or health within its territory.
Biosecurity Import Risk Analysis (BIRA)	A regulated scientific evaluation of the level of biosecurity risk associated with particular goods, or a class of goods, that may be imported into Australian territory. A BIRA can identify conditions that must be satisfied to manage the level of biosecurity risk to achieve Australia's ALOP.
Biosecurity Regulation 2016	A legislative instrument that sets out and regulates key steps of the BIRA process.
International Plant Protection Convention (IPPC)	An international plant health agreement established in 1951 that aims to protect cultivated and wild plants from harmful pests that may be introduced through international trade. WTO members are expected to base their phytosanitary measures on international standards developed by the IPPC.
International Standards for Phytosanitary Measures (ISPMs)	Standards adopted by the Commission on Phytosanitary Measures, the governing body of the IPPC. ISPMs are recognised as the basis for phytosanitary measures applied in trade by WTO members under the SPS agreement.
official control	As defined under the IPPC, the active enforcement of mandatory phytosanitary regulations, and the application of mandatory phytosanitary procedures with the objective of eradication or containment of quarantine pests, or management of regulated non-quarantine pests.
World Organization for Animal Health (OIE)	The intergovernmental organisation responsible for improving animal health worldwide. The OIE develops documents relating to rules that WTO members can use to protect themselves from the introduction of diseases and pathogens, without setting up unjustified sanitary barriers.
risk management	The process of identifying, selecting and implementing measures that can be applied to reduce and manage the level of biosecurity risk.
SPS agreement	The WTO Agreement on the Application of Sanitary and Phytosanitary Measures, which establishes rights and obligations of WTO members when applying measures to protect human, animal or plant health in international trade.
World Trade Organization (WTO)	A global international organisation dealing with the rules of trade between nations.