Australian Government
Department of Agriculture, Fisheries and Forestry

Biosecurity Import Risk Analysis Guidelines

Managing biosecurity risks for imports into Australia

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Acknowledgement of Country

We acknowledge the continuous connection of First Nations Traditional Owners and Custodians to the lands, seas, and waters of Australia. We recognise their care for and cultivation of Country. We pay respect to Elders past and present, and recognise their knowledge and contribution to the productivity, innovation and sustainability of Australia's agriculture, fisheries, and forestry industries.

Foreword

Australia is committed to maintaining a world-leading biosecurity system which plays a critical role in protecting our unique environment, ecosystems, and agriculture. Our robust biosecurity measures not only protect the health of animals, plants and people but also strengthen our position as a global trading partner. Australia's proactive biosecurity approach reflects our responsibility to uphold international standards while supporting sustainable development and environmental protection.

In an increasingly dynamic and interconnected world, the importance of robust biosecurity measures cannot be overstated. As global trade and travel levels continue to increase, the likelihood of introducing diseases and pests to new environments rises significantly. The Biosecurity Import Risk Analysis (BIRA) process plays an important role in establishing these robust biosecurity measures.

These guidelines set out matters to be considered when conducting a Biosecurity Import Risk Analysis under the *Biosecurity Act 2015* (Biosecurity Act) and the *Biosecurity Regulation 2016* (Biosecurity Regulation). The guidelines are aligned with international standards and emphasise use of a science-based methodology to ensure that biosecurity measures are both efficient and effective, balancing the need to facilitate trade and safeguard Australia's strong plant, animal, and human health status.

The BIRA guidelines help ensure import risk analyses are consistent with international standards and support a robust biosecurity system that protects public health and the environment, and promotes economic growth now and in the future.

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Introduction

The department is tasked with safeguarding Australia's animal and plant health status from the impact of diseases and pests of biosecurity concern, through risk analysis, risk mitigation measures, inspection and certification, and the implementation of emergency response arrangements for Australian agricultural, food and fibre industries. This work is done in collaboration 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 goods import requests, where those goods have not been imported to Australia before, or have not been imported 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.

A BIRA is an assessment of the level of biosecurity risk associated with particular goods, or a particular class of goods, that may be imported, or are proposed to be imported, into an Australian territory. Where necessary, the assessment includes identification of conditions that must be met to manage the biosecurity risk to a level that achieves Australia's Appropriate Level of Protection (ALOP).

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 Australia's ALOP, 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 eligible for import into Australia.

1 Biosecurity risks and Australia's biosecurity framework

1.1 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, or the economy. As part of the BIRA, a risk assessment is undertaken.

BIRAs are risk assessments of goods conducted under the Biosecurity Act and in accordance with the World Trade Organization (WTO) Agreement on the Application of Sanitary and Phytosanitary Measures (SPS) and other international obligations. Under a BIRA, the level of biosecurity risk for a particular disease or pest is determined by combining the likelihood of the entry, establishment and spread with its potential consequences. It considers the whole risk pathway from the identification of diseases or pests to the harm or consequence within Australia.

These two components of likelihood and consequence are combined to give an estimate of the level of biosecurity risk for each disease or pest associated with an imported good and whether sanitary or phytosanitary measures are required to reduce risk to a level which achieves Australia's ALOP.

1.2 Biosecurity framework

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

1.2.1 Australia's federal biosecurity legislation

Australia's biosecurity system is supported by Commonwealth biosecurity laws including the Biosecurity Act and subordinate legislation made under the Biosecurity 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 Minister for Agriculture, Fisheries and Forestry who may direct the Director of Biosecurity to commence a BIRA.

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 (SAG) 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 a person may request the Inspector-General of Biosecurity to review a BIRA process
- makes provisions for the termination of a BIRA
- describes the role of the Director of Biosecurity in the BIRA process.

1.2.2 International agreements and standards

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 World Health Organization (WHO) 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 to protect human, animal and plant life or health.

The agreement requires governments to base their SPS measures on international standards, guidelines, and recommendations, including, for plant health, the International Standards for Phytosanitary Measures (ISPMs) adopted under the International Plant Protection Convention (IPPC), and, for animal health, the standards of the World Organisation for Animal Health (WOAH).

Australia bases its risk analysis methodologies and import risk management measures on the standards, guidelines and recommendations set by the IPPC and WOAH. 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.

2 Australia's biosecurity import risk analysis process

2.1 Decision to commence a BIRA

Under the Biosecurity Act, the decision to commence a BIRA is only exercised by the Minister for Agriculture, Fisheries and Forestry (by directing the Director of Biosecurity), or by the Director of Biosecurity, to ensure import settings remain consistent with Australia's biosecurity policy objectives and ALOP. This includes, but is not limited to:

- where new import pathways are proposed,
- where existing risk management measures are not established, or
- where previously assessed measures may no longer be sufficient because the likelihood or consequences of pest or disease entry, establishment or spread could differ materially from comparable goods or country/region combinations.

The department works to identify and, as much as possible, notify stakeholders directly related to the potential BIRA, including through publication of a Biosecurity Advice Notice, on the department's website and directly to stakeholders who have subscribed to receive email notifications.

The department also contacts relevant Commonwealth, state and territory government departments and agencies when necessary.

2.2 Decision to terminate a BIRA

The Director of Biosecurity may decide to terminate a BIRA before it is completed if they are satisfied that there is insufficient information or policy rationale to complete the BIRA; or it is not appropriate to complete the BIRA for any other reason.

2.3 How biosecurity risk is assessed

The department evaluates the likelihood of entry, establishment and spread of a disease or pest and the magnitude of potential consequences, using biological or other scientific evidence and economic evidence. The evaluation follows internationally agreed principles and standards relating to import risk analyses.

2.3.1 Within the department

BIRAs are conducted by departmental staff with appropriate technical expertise and experience in biosecurity risk assessment. These analyses are informed by scientific knowledge and draw on input from officers with tertiary qualifications across a broad range of relevant disciplines, including plant and animal health, environmental and biological sciences, veterinary science, microbiology, and quantitative and analytical fields. This supports assessments that are evidence-based and scientifically robust.

2.3.2 Use of external expertise

Where appropriate, the department draws on external expertise in addition to the SAG. This may include collaboration with state and territory biosecurity agencies, the Commonwealth Scientific and Industrial Research Organisation (CSIRO), the Centre of Excellence for Biosecurity Risk Analysis (CEBRA), universities, and industry. When required, the department may also convene formal meetings or workshops with scientific and technical experts to inform its assessments.

2.3.3 Methodology

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

Risk estimation is used by the department to combine the likelihood of a disease or pest entering, establishing, and spreading in Australia with the potential consequences should that occur, and to determine whether specific risk management measures are required to achieve Australia's ALOP.

The components of biosecurity risk, as previously outlined, 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.'

3 Matters to be taken into account in conducting a BIRA

3.1 BIRA Principles

A BIRA must first completely align with Commonwealth legislation, specifically the Biosecurity Act and Biosecurity Regulation. In addition, a BIRA must be conducted with regard to the following principles:

3.1.1 Alignment with international standards

Risk assessments and associated biosecurity measures are science-based, proportionate to the level of assessed risk, applied consistently, and no more trade restrictive than necessary to achieve the ALOP.

Where appropriate, internationally recognised standards, including those developed by the WOAH, IPPC and Codex Alimentarius Commission, and the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) are taken into account to support a credible and internationally defensible assessment.

3.1.2 Fit-for-purpose methodology

Each BIRA applies a sound and fit-for-purpose technical methodology that is appropriate to the commodity, pathway and risk context being assessed.

Where an alternative methodology is used, it is expected to emulate the essential features of the department's formal approach. This includes providing a structured, science-based assessment of the likelihood of pest or disease entry, establishment and spread, and the magnitude of potential consequences, consistent with Australia's international obligations and ALOP.

Regardless of the methodology selected, a BIRA must remain a systematic, evidence-based assessment, grounded in the best available biological, scientific, and relevant economic information. Where gaps or uncertainties are identified, the department may undertake further research or gather additional information to address them.

The methodology aims to recognise and respond to regional differences, including variation in pest and disease status, climate, host and vector distribution and management practices. The department may also collaborate with state and territory agencies where appropriate to inform the analysis, including the consideration of regional biosecurity conditions into the analysis.

3.1.3 Conclusions are drawn from an evidence-based assessment of scientific information

The scientific evidence is evaluated to determine whether the unrestricted risk exceeds the ALOP. Risk is considered in terms of both the likelihood of disease or pest entry, establishment, or spread, and the potential consequences. Conclusions are based on the best available science, consistent across comparable situations, and aligned with the Biosecurity Act, the Biosecurity Regulation, and Australia's obligations under the SPS Agreement.

3.1.4 Use of expert advice

BIRAs are informed by relevant scientific and technical expertise to support robust and transparent decision-making. Where further information, research, or specialised advice is considered necessary to complete the assessment, the Director of Biosecurity may seek input from an appropriate person.

The Director of Biosecurity may also consult the SAG to examine and provide comments on any aspects of the BIRA. The SAG is available for use only for a BIRA and only where necessary. For example, where the BIRA is of highly complex nature or where differing stakeholder views make it difficult to reach scientific based conclusions. The SAG's comments and any findings must be taken into account in preparing the provisional BIRA report.

3.1.5 Adheres to the ALOP

The ALOP articulates the level of biosecurity protection that Australia considers acceptable to safeguard human, animal, and plant health. It recognises that biosecurity risk cannot be reduced to zero and instead establishes an acceptable level of risk that reflects national policy objectives.

Within a BIRA, the ALOP operates as a fundamental policy benchmark against which identified biosecurity risks are evaluated and managed. Risk assessment processes estimate the likelihood and consequences of disease or pest entry, establishment, and spread, while risk management measures are selected and calibrated to reduce those risks to a level that achieves the ALOP.

3.1.6 Consultation and transparency

The BIRA process is designed to be transparent, evidence-based, and inclusive of expert and stakeholder input. Stakeholder engagement is built into the BIRA process through the publication of draft, provisional, and final reports, allowing for consultation at key stages.

Arrangements are made to engage relevant stakeholders, from risk identification through to the design of mitigation measures. Sufficient time is allowed for stakeholders and the public to consider and respond to provisional reports.

The BIRA process may be subject to independent review by the Inspector-General of Biosecurity to ensure integrity and adherence to the regulatory framework.

4 Consultation and communication

4.1 Communication with stakeholders

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 public.

Consultation throughout the BIRA process is both formal and informal and aims to obtain 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.

Interested stakeholders may register for inclusion on the department's communications database. The database enables stakeholders to indicate areas of interest and their preferred form of communication.

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

4.2 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 written submission process with set time frames.

5 Inspector-General of Biosecurity

The Inspector-General of Biosecurity is an independent statutory officer appointed by the Federal Minister for Agriculture, Fisheries and Forestry.

Any person may request in writing that the Inspector-General review a BIRA process where they believe the process did not accord with the process required by the Biosecurity Regulation, the departure from the process was significant, and the person's interests were, are or may be adversely affected by the failure to conduct the process in accordance with the Biosecurity Regulation. The Inspector-General must consider any request for review made in accordance with the Biosecurity Regulation.

Appendix A: 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 900 090**.

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

Animal Biosecurity
Email animalbiosecurity@aff.gov.au

Plant Biosecurity
Email plantstakeholders@aff.gov.au

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

Chief Veterinary Officer
Email OCVO@aff.gov.au

Chief Plant Protection Officer
Email ippc.contactpoint@aff.gov.au

The department's postal address is:

Department of Agriculture, Fisheries and Forestry
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 Act 2015	This Act is about managing diseases and pests that may cause harm to human, animal or plant health or the environment.
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.
World Organisation for Animal Health (WOAH)	The intergovernmental organisation responsible for improving animal health worldwide. WOAH 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.