Australian Government
Department of Agriculture, Fisheries and Forestry





Regulating together

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What is DAFF's role?

DAFF manages biosecurity risks associated with the movement of goods, people and conveyances into Australia.

Identify pests, diseases and contaminants associated with imported goods.
Assess the likelihood and consequences of entry, establishment or spread.
Determine whether biosecurity risks are acceptable.
Apply conditions and other controls where risk management is required.
Verify compliance with applicable biosecurity requirements.

Protecting Australia from biosecurity risks associated with imported goods.

Why two regulators?

OGTR

- Risks of adverse outcomes to human health and safety and the environment from genetic modifications
- Risks arising from proposed dealings
- Controls needed for those dealings

DAFF

- Risks of pests, diseases or contaminants associated with imported goods
- Likelihood of entry, establishment or spread
- Biosecurity controls needed to manage risk

Same goods. Different risk questions. Complementary regulation.

Biosecurity Risk

Biosecurity risks means:

(a) the likelihood of a disease or pest:

(i) entering Australian territory or a part of Australian territory; or

(ii) establishing itself or spreading in Australian territory or a part of Australian territory; and

(b) the potential for any of the following:

(i) the disease or pest to cause harm to human, animal or plant health;

(ii) the disease or pest to cause harm to the environment;

(iii) economic consequences associated with the entry, establishment or spread of the disease or pest.

Biosecurity Act 2015
Chapter 1 Part 2, section 9-Definitions

DAFF's biosecurity risk lens

Key Questions:

- Could the goods contain a pest, disease or contaminant?
- Is the hazard associated with the source country or source material?
- Is the hazard present in Australia?
- Could the hazard pose a biosecurity risk to Australia?
- Are there economic or trade consequences

DAFF's focus is not on the genetic modification, but on whether the products pose a biosecurity risk

Biosecurity Act 2015
Chapter 1 Part 2, section 9-Definitions

Biosecurity Risk Assessment

Hazard identification	Likelihood entry	Likelihood establishment spread	Consequences	Risk	Risk management measures
What are the hazards?	Could they enter Australia?	Could they persist or spread?	What would be the impact?	Is the risk level acceptable	How can the risk level made be acceptable

ALOP

The ***Appropriate Level of Protection*** for Australia is a high level of sanitary and phytosanitary protection aimed at reducing biosecurity risks to a very low level, but not to zero.

Biosecurity Act 2015
Chapter 1 Part 1, section 5-ALOP

DAFF's risk management toolbox



Import conditions



Risk-based measures
Commodity-specific
Hazard-specific

May include:

- Country requirements
- Certification
- Treatments | Processing | Testing
- Containment
- End-use restrictions

Import permits

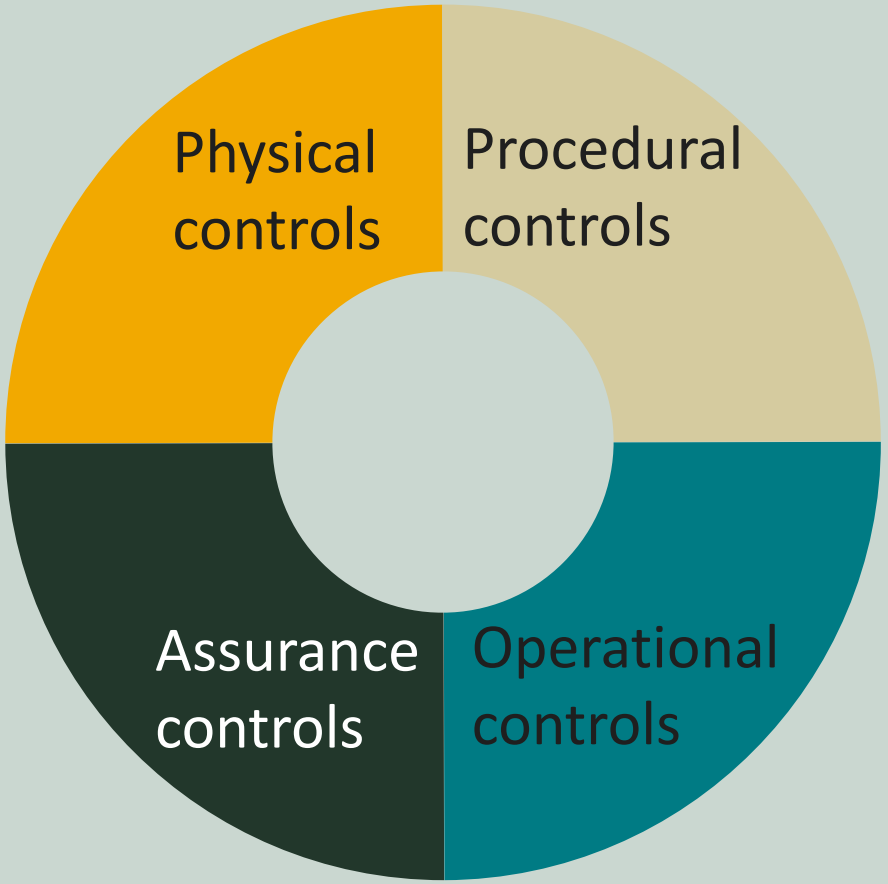
Supports a case-by-case approach for goods presenting higher or more complex risks.

Measures included as import permit conditions are legally enforceable

- Issued to a particular entity
- Restrict establishments, suppliers or facilities in the import pathway
- Restrict how goods are imported, handled, stored, used or disposed of
- Can be amended, suspended or revoked as circumstances change.

Approved Arrangements

- Secure storage of imported goods
- Restricted access areas
- Segregation from non-regulated material
- Containment facilities



- Receipt and inventory procedures
- Record keeping
- Traceability
- Incident reporting
- Personnel training and competency

- Auditing
- Monitoring
- Compliance verification
- Reporting to DAFF where required

- Handling and transport requirements
- Treatment or processing requirements
- Waste management and disposal requirements
- Decontamination procedures

Frontier AI and biological risk

- Frontier AI may change the accessibility and nature of biological risks.
- AI and synthetic biotechnology are increasingly converging.
- External stakeholders and parliamentary witnesses have called for screening of imported synthetic nucleic acids for sequences of concern.
- The department works across government to assess whether existing settings remain appropriate.

Emerging technologies may change both the risks and the safeguards needed.

Evolving regulatory settings

Imported veterinary vaccines

- Reviewing policy for imported veterinary immunobiologicals, including vaccines.
- Considering established and emerging technologies.
- Keeping risk management contemporary and evidence based.

Synthetic biotechnology

- Reviewing arrangements for imported synthetic nucleic acids.
- Considering whether controls remain appropriate as technologies evolve.
- Engaging across government on cross-cutting risks.

Register as a stakeholder at https://www.agriculture.gov.au/biosecurity-trade/policy/risk-analysis/stakeholder

Regulatory settings must evolve with the science.

Take-home messages

- The OGTR regulates risks arising from gene technology and proposed dealings.
- DAFF regulates biosecurity risks associated with imported goods.
- The regulators may consider the same goods through different legislative frameworks.
- Regulatory controls are complementary and may operate at the same time.
- Institutions need to identify and implement all applicable requirements.
- Early engagement supports clear, coordinated and effective regulation.

Same products. Different risk questions. Complementary regulation.