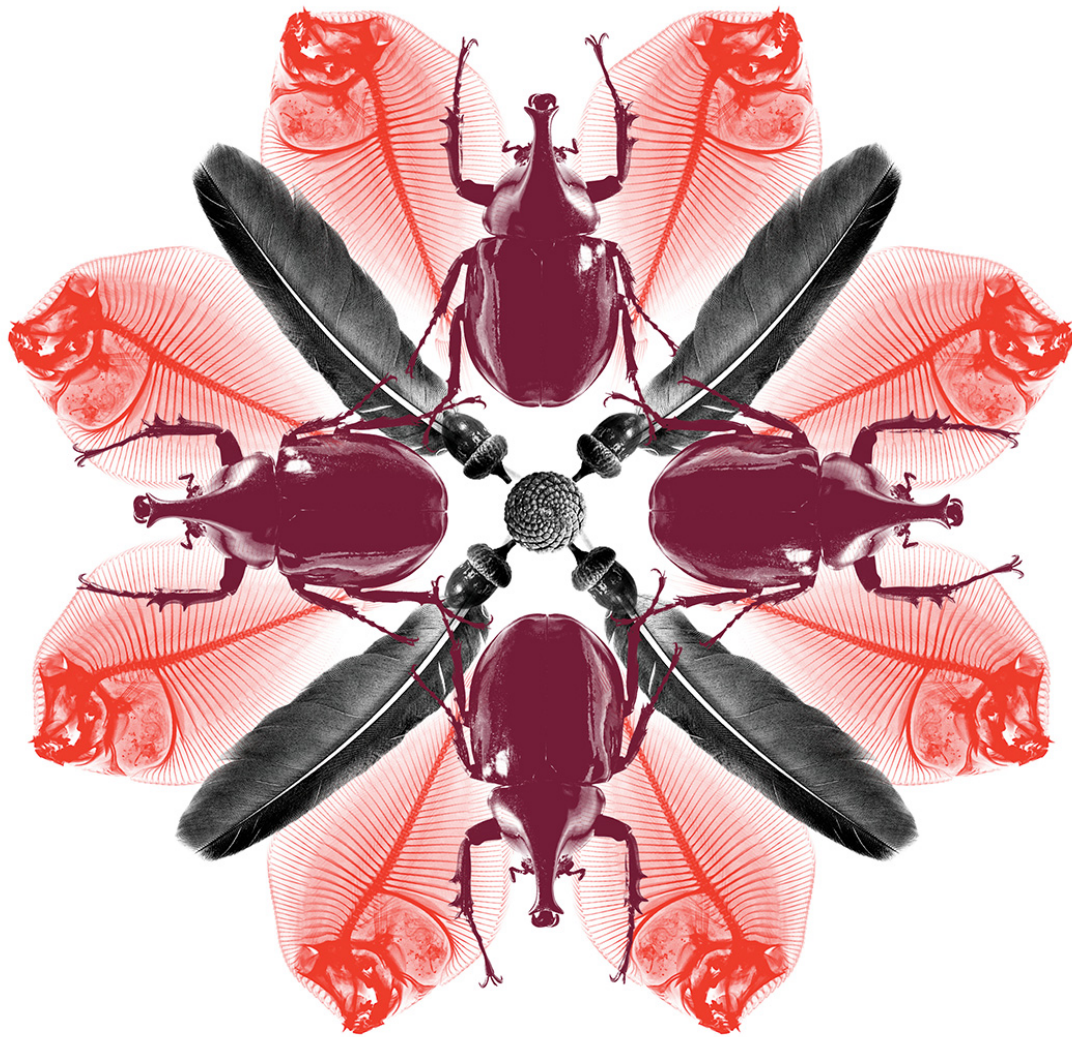




Australian Government
Department of Agriculture,
Water and the Environment

Requirements for facilities manufacturing and exporting processed plant-based stockfeed and their ingredients to Australia

Version 1.0



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The Department of Agriculture, Water and the Environment may make changes to this document from time-to-time. To download the latest version visit:

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1 Introduction

This document provides the Australian Government's general requirements for overseas facilities that manufacture, store, handle, transport or export processed plant-based stockfeed and stockfeed ingredients to Australia.

Australia imposes strict controls on the [importation of processed plant-based stockfeed and their ingredients](#) to ensure that the associated risks are managed to keep [Australia's biosecurity protected](#).

This document is designed to assist facilities in developing systems, processes and procedures to manage contamination risks and ensure that products are sufficiently processed to meet Australia's import conditions.

The department will also reference this document when conducting audits as part of assessing applications to import processed plant-based stockfeed.

Imported processed plant-based stockfeed and their ingredients may provide a pathway for exotic animal and plant diseases and insect pests to be introduced into Australia. Stockfeed and their ingredients may be contaminated with biosecurity risk material:

- via substitution of raw materials with animal derived material
- during on farm production
- during processing at a manufacturing facility
- during storage and packaging
- during transport to the point of export
- during transportation to Australia.

[Animal diseases of concern](#) include:

- Bovine spongiform encephalopathy (BSE) and other transmissible spongiform encephalopathies (TSEs)
- Foot-and-mouth disease
- Infectious bursal disease
- Newcastle disease
- African swine fever

[Plant pests and diseases of concern](#) include pathogens such as karnal bunt (*Tilletia indica*), insects such as khapra beetle (*Trogoderma granarium*), and contaminant seeds. Seeds can be devastating to the Australian environment and agricultural production areas due to the pathogens they host and risk of becoming weeds.

1.1 Scope

This document provides general requirements for overseas manufacturers and facilities that export processed plant-based stockfeed and their ingredients to Australia. These are in addition to any specific [import](#) conditions set by the department.

This document may also be applied to other plant-based animal feed products, depending on the level of biosecurity risk including the potential for diverting that product for stockfeed use.

The requirements provided in this document do not apply to overseas facilities manufacturing and exporting:

- animal feeds containing ingredients of animal or microbial origin (including those produced by fermentation)
- whole grain and seed
- small samples of stockfeed for laboratory analysis.

2 Definitions and glossary

2.1 Key definitions

The following words are used throughout this document to describe requirements, recommendations, allowances and guidance for offshore facilities wishing to manufacture and/or export plant-based stockfeed for the Australian market.

- 'must' indicates a mandatory requirement.

Failure to meet these will be considered a non-conformance.

- 'should' indicates that the requirement is expected to be implemented unless there is a valid reason for not implementing it. A valid reason could be that it is not applicable to the facility or has been replaced by an alternative demonstrated to provide an equivalent alternative.

Failure to meet these requirements will result in a non-conformance unless demonstrated to be inapplicable or an acceptable alternative is in place.

- 'may' indicates an allowance for the facility to decide how to achieve the desired outcome of a requirement.

How the facility chooses to meet the desired outcome will be assessed at audit and may result in a non-conformance being issued if the desired outcome is not met.

2.2 Glossary

Term	Definition
biosecurity	Managing risks to Australia’s economy, environment and community of pests and diseases entering, emerging, establishing or spreading in Australia.
biosecurity integrity	Where inputs and finished products are not contaminated with biosecurity risk material at any point during the primary production, manufacturing and handling phases.
biosecurity risk material	Any material with the potential to introduce a pest or disease. Examples of biosecurity risk material includes, but is not limited to: <ul style="list-style-type: none"> • animals e.g. rodents, birds and insects • animal parts and animal products e.g. feathers, faeces • plants and plant parts including seeds • soil
biosecurity specifications	These are the specifications set by the facility to ensure biosecurity risks are managed in accordance with Australia’s import conditions. See section 3 for a description of these requirements.
calibration	A demonstrated comparison of a measurement device against a more accurate traceable reference or standard device.
contamination	The undesired introduction of biosecurity risk material, into or onto inputs or finished products.
cross-contamination	Contamination of an input or finished product with another input or finished product.
finished product	A stockfeed or stockfeed ingredient that it is to be exported to Australia and has met biosecurity specifications.
facility	An overseas establishment that manufactures, stores, handles, transports or exports processed plant-based stockfeed and stockfeed ingredients to Australia.
inputs	Any materials required for the manufacture of the finished product. For manufacturing facilities inputs may include raw materials, stockfeed ingredients or additives, intermediate products, or packing materials. For offsite handling facilities, inputs may include finished products and packing materials.
livestock	Animals that are kept for production or lifestyle, such as cattle, sheep, pigs, horses or poultry.
non-conforming products	Inputs and finished products that do not meet the biosecurity specifications.
potable water	Water that is processed and treated to meet standards for human consumption.
processed plant-based stockfeed	One or more processed or semi-processed plant materials for feeding directly to livestock, for the maintenance of life, normal growth, production, work and reproduction. A stockfeed comprises one or more stockfeed ingredients and may also contain one or more stockfeed additives. Examples include soybean meal, palm kernel expeller, copra meal, corn gluten meal, dried distiller’s grains, sugar beet pulp, and compound feeds.
quality management system	A document or a series of documents that describe the policies and objectives as well as the processes to achieve those policies and objectives. A quality management system is required by most feed safety certification schemes including FAMI-QS and GMP+FSM.
stockfeed additive	Any intentionally added component of feed not normally consumed as a stockfeed ingredient, which affects the characteristics of feed or animals fed with it e.g. enzymes, acidity regulators, trace elements, vitamins, preservatives, colouring agents, binders, dust suppressants, carriers, flavours.
stockfeed ingredient	A nutritive component, part or constituent of any combination or mixture making up a stockfeed.

3 Biosecurity specifications

Desired outcome: Biosecurity specifications for inputs and finished products are clearly defined to ensure biosecurity risks are managed in accordance with Australia's import conditions.

- a) The facility must document critical parameters for managing biosecurity risk material in all inputs and finished products.
 - i) There must be a nil tolerance for vertebrate animal material in all inputs and finished products.
 - ii) There must be a nil tolerance for whole seeds, live insects, unprocessed plant material and soil in all finished products.
 - iii) Finished products must be processed to achieve Australia's import requirements as determined by the department during assessment of the importer's permit application. This includes requirements for treatment temperature and time which are determined by the animal health status of the country of origin, the types of inputs and how they are grown.
- b) Inputs and finished products must be transported in:
 - i) packaging that is clean and new; OR
 - ii) enclosed containers or covered conveyances that:
 - 1) are free of residues from previous cargoes; and
 - 2) have not previously carried animal material in the previous three cargoes.

4 Quality management system

Desired outcome: the facility has a quality management system in place that ensures all activities contribute to managing the biosecurity risk of the product and are consistently defined, implemented and maintained at all levels.

- a) The facility must have, maintain and continually improve a documented quality management system. The system must include:
 - i) a manual which lists all processes and activities that can affect the biosecurity integrity of finished products.
 - ii) an organisational structure and clearly defined responsibilities for all roles involved in the production, handling, storage and distribution of finished products.
 - iii) processes for document control, internal auditing and management review.
 - iv) documented procedures for all processes and activities relevant to this document.
 - v) staff training requirements including how staff will be verified as competent in their roles and responsibilities.
- b) A record keeping system must be in place.
 - i) Activities and processes relevant to this document must be recorded without delay after they have been performed.
 - ii) Records should be kept for a minimum of 2 years.
- c) Facilities must immediately notify the department through the importer of any changes that impact the ability of the facility to meet the requirements provided in this document and import permit conditions.

5 Infrastructure and security

Desired outcome: the facility is constructed and managed to ensure that the biosecurity integrity of inputs and finished products can be maintained; and that the facility is geographically isolated from animal production systems.

- a) Buildings and equipment used for storage, handling and production must be designed and constructed to:
 - i) eliminate or minimise the risk of contamination and cross-contamination; and
 - ii) allow for adequate cleaning and maintenance.
- b) Manufacturing equipment must be capable of achieving and maintaining the minimum parameters prescribed in the biosecurity specifications.
- c) There must be no animals kept on site at the facility.
- d) There should be no animals kept in close proximity to the facility. Where there are animals in close proximity to the facility, the department will consider whether these are a potential source of product contamination.
- e) The perimeter of the facility must be secured in such a manner as to prevent the entry of wild animals and unauthorised personnel or vehicles onto the site.
- f) Procedures must be in place to control access to the facility in order to eliminate or minimise the risk of contamination.

6 Supply, transport and receipt of inputs

Desired outcome: the inputs meet biosecurity specifications and can be traced back to the point of origin.

- a) The manufacturing facility should document the following information for each of their suppliers:
 - i) Geographic location
 - ii) Crop production system. This includes whether the crops are grown:
 1. organically or conventionally
 2. in broad acre farming using mechanical harvesting or a household/small-acre production system or combination of the two
 3. on land also used for other agricultural purposes such as livestock grazing.
 - iii) Use of animal-derived fertilisers
 - iv) Crop harvest method
 - v) Storage methods of raw products
- b) The facility must establish arrangements with transport providers to ensure they comply with biosecurity specifications.
- c) The manufacturing facility must undertake appropriate sampling and analysis to confirm that inputs meet biosecurity specifications.
- d) The facility must have procedures in place to prevent contamination during receipt of inputs.

7 Product handling and traceability

Desired outcome: systems and procedures prevent contamination and cross-contamination during handling of inputs and finished products and allow trace-back to the source.

- a) Inputs and finished products must be stored in a manner that:
 - i) allows for their identification
 - ii) prevents contamination and cross-contamination.
- b) Procedures must be in place to prevent contamination and cross-contamination during storage, handling and manufacturing.
- c) The facility must keep records of the origin of inputs, batch / lot records and distribution records of finished products to facilitate a full trace-back, trace-forward or recall if required.

8 Manufacturing process: monitoring and control

Desired outcome: the facility has appropriate measures in place to ensure that finished products meet biosecurity specifications.

- a) Only potable water should be used in feed manufacture.
- b) Processing equipment must allow for monitoring of processing parameters prescribed in the biosecurity specifications.
 - i) Temperature monitoring equipment must be validated to be of a sufficient type, resolution and accuracy to provide certainty that the prescribed core product temperature(s) have been met.
 - ii) Temperature monitoring equipment must be placed in an appropriate location to provide assurance that core product temperatures have been met for the required duration.
 - iii) There must be a mechanism, such as a mechanical alarm or procedure, which alerts when the minimum temperature has failed during processing.
- c) Temperature monitoring equipment must be calibrated prior to first use and at periodic intervals during processing to ensure acceptable accuracy and reliability. Calibration activities must be supported by a documented procedure.
 - i) The calibration interval should be determined based on recommendations from the equipment manufacturer, the results of previous calibrations and other factors such as frequency of use and the operating environment. Calibration intervals should be no longer than 12 months.
 - ii) Calibration activities must be documented with results recorded.
- d) Processing parameters must be monitored to ensure compliance with biosecurity specifications. Processing activities must be supported by documented procedures.
 - i) The frequency of temperature recording must provide a high level of assurance that the minimum temperature requirements are maintained during production.
 - ii) The frequency should be determined based on the variability of the applied heat treatment and the amount by which such a heat treatment exceeds the minimum requirements defined in the biosecurity specifications.
 - iii) Recording of processing parameters may be automated provided that records are retained and are accessible.
 - iv) The amount of time processed product has been maintained at the minimum temperature should be monitored and recorded. Alternatively, process validation and verification may be conducted to demonstrate that resulting products can meet the minimum processing times.

9 Release of finished products

Desired outcome: the facility has procedures in place to ensure that finished products leaving the facility meet biosecurity specifications.

- e) The facility must have procedures in place to verify all biosecurity specifications have been met before release of products to an Australian importer.
 - i) These procedures must include sampling and inspection of finished product to verify freedom of visually detectable biosecurity risk material.

10 Non-conforming products

Desired outcome: the facility has systems in place to identify and manage non-conforming inputs and finished products.

- a) The facility must have procedures to prevent the unintended use or delivery of non-conforming inputs and finished products.
 - i) Re-work of non-conforming finished products should only occur if the biosecurity specifications can be met.
- b) The facility must implement and record all corrective actions to prevent recurrence of non-conforming products.
- c) The Australian importer must be notified if non-conforming products have been exported to Australia.

11 Cleaning and maintenance

Desired outcome: the facility has maintenance and cleaning practices in place to ensure that the biosecurity integrity of inputs and finished products is not compromised.

- a) The facility must undertake regular cleaning of all areas to remove sources of potential contamination and to prevent accumulation of residues and waste products that may attract and harbour pests.
 - i) Documented cleaning procedures must include the frequency of cleaning, area to be cleaned and the method of cleaning. The frequency of cleaning may vary depending on individual facilities and the rate of accumulation of residues and waste products.
 - ii) Records must be kept verifying the completion and effectiveness of cleaning activities.
- b) The facility should only use potable water to undertake cleaning of areas where inputs and finished products are handled.
- c) The facility and equipment must be maintained in a good state of repair.
 - i) Documented maintenance procedures must include the frequency of maintenance, equipment, area to be maintained and the method of maintenance. The frequency of maintenance may vary depending on the nature of the equipment, level of use and/or the manufacturer's specifications.
 - ii) Records must be kept verifying the completion and effectiveness of maintenance activities.
- d) Maintenance and construction operations must not present any potential for contamination of product.

12 Pest management

Desired outcome: the facility has appropriate procedures in place to monitor and control pests to prevent contamination and infestation of inputs and finished products.

- a) The manufacturing facility must have monitoring and control procedures for pests including rodents, birds and insects.
 - i) Pest monitoring and control activities may include inspections, exclusion, trapping, deterrents, baiting and pesticide application.
- b) Pest monitoring and control procedures must be supported with appropriate policies, documentation, records and verification activities.
- c) The results of pest monitoring and control activities must be regularly reviewed for effectiveness and adjusted as required.