Australian Government
Department of Agriculture, Water and the Environment

GUIDELINE

Third party audits of processed plant-based stockfeed facilities

Direction to industry

This document outlines the requirements for engaging and undertaking third party site audits of facilities used in the manufacture and export of processed plant-based stockfeed to Australia. All parties with roles and responsibilities explicit in this guideline must comply with it.

Summary of main points

This document outlines the processes and requirements for engaging and undertaking third party site audits of facilities used in the manufacture and export of processed plant-based stockfeed to Australia. This includes processes for:

- Engaging and evaluating a third party auditor
- Third party site audit preparation
- Third party site audit

In this document

Purpose of this document

This document outlines the processes and requirements for engaging and undertaking third party site audits of facilities used in the manufacture and export of processed plant-based stockfeed to Australia. It is designed to assist importers and third party auditors understand the requirements and their roles and responsibilities in the process.

Definitions

The following table defines terms used in this document.

Term	Definition
Audit	An activity to verify, by examination and evaluation of objective evidence, that applicable elements of an offshore facility's quality management system are appropriate, effective and conform with the department's requirements including the *Requirements for facilities manufacturing and exporting processed plant-based stockfeed and their ingredients to Australia*.
Audit plan	A plan developed by the auditor which includes (but is not limited to): • audit objectives • audit scope • audit criteria • dates and sites where the onsite activities will be conducted • roles and responsibilities of the audit team members
Audit questionnaire	A form completed by an overseas facility that is used to determine compliance with the *Requirements for facilities manufacturing and exporting processed plant-based stockfeed and their ingredients to Australia*.
Corrective action plan	A documented plan to capture the actions to be taken to address non-conformances identified at audit. The plan details actions and timelines for implementation.
Desk audit	An assessment by the department of the audit questionnaire, quality management system and completed records provided by an offshore facility.
Livestock	Animals that are kept for production or lifestyle, such as cattle, sheep, pigs, goats, horses or poultry.
Overseas facility	An overseas establishment involved in the manufacture, storage and export of processed plant-based stockfeed to Australia.
Processed plant-based stockfeed	Any single material, or multiple materials, whether processed or semi-processed intended to be fed directly to livestock for the maintenance of life, normal growth, production, work and re-production. A stockfeed comprises one or more stockfeed ingredients and may also contain one or more stockfeed additives.

Term	Definition
Production questionnaire	A form completed by an overseas facility that is used by the department to assess the level of biosecurity risk of a plant-based animal feed. The department will use this assessment to decide whether: • a permit can be issued • further information is required; or • an audit of the overseas facility is required.
Requirements for facilities manufacturing and exporting processed plant-based stockfeed and their ingredients to Australia (the *Facility requirements*)	The department's requirements for facilities sourcing inputs, manufacturing, storing, handling, transporting and exporting processed plant-based stockfeed and stockfeed ingredients to Australia. The *Facility requirements* may also be applied to pet food ingredients and aquaculture feed, depending on the level of biosecurity risk, and the potential for diverting that commodity for stockfeed use. The *Facility requirements* are to be used by overseas facilities in developing systems, processes, and procedures to manage contamination risks and ensure that products are sufficiently processed according to Australia's import conditions for processed plant-based stockfeed. The *Facility requirements* will be referenced by the department during desk and site audits undertaken as part of assessing an importer's permit application to import processed plant-based stockfeed.
Site audit	An audit conducted on the premises of an offshore facility involving observation of procedures, inspection of facilities, inputs and finished products, interview of personnel and examination of completed records.
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. It includes enzymes, acidity regulators, trace elements, vitamins, macro minerals, preservatives, colouring agents, binders, dust suppressants, carriers and flavours.
Stockfeed ingredient	A nutritive component, part or constituent of any combination or mixture making up a stockfeed. Examples of ingredients contained in plant-based stockfeed include soybean meal, palm kernel expeller and copra meal.
Third party site audit brief	An outline of the required site audit, including objectives, scope, criteria, preparation, resources and types of evidence to be collected. The purpose of the "audit brief" is to ensure that the exact terms and details of the audit are understood by the third party auditor.
Third party auditor	An independent auditor employed by an accredited certification body.
Import permit application	An application to import goods into the Australian Territory

Policy statement

Management of biosecurity risks

The department imposes strict controls on the importation of processed plant-based stockfeed and their ingredients to ensure that the associated biosecurity risks are managed to provide an appropriate level of protection for Australia (ALOP), which according to the *Biosecurity Act 2015* is to a very low level of risk, but not to zero.

An Australian importer must apply for a permit to import processed plant-based stockfeed and their ingredients and have the permit approved before shipping product to Australia.

Certain stockfeed and stockfeed ingredients require an audit of facilities used in the manufacture and export of the goods to Australia prior to the issuance of an import permit.

The *Facility requirements* form the basis of audits of the facilities conducted during import permit application assessments.

Third party audits

In accordance with ISO/IEC 17021-1:2015, the department has determined that in certain circumstances, site audits of facilities used in the manufacture and export of processed plant-based stockfeed to Australia may be outsourced to third parties.

Third party auditors must be accredited as a FAMI-QS, GMP+ international, ISO/IEC 17021-1:2015 or ISO/TS 22003:2013 certification body:

- FAMI-QS is a quality and safety system for specialty feed ingredients. The FAMI-QS code of practice includes requirements on Good Manufacturing Practices, HACCP programme and continuous improvement, management of operations and risks with a goal of maintaining feed safety and quality. FAMI-QS certification bodies audit and certify companies against the code and must be ISO/IEC 17021-1:2015 and ISO/TS 22003:2013 accredited, work in the animal feed and food sector, and meet the requirements for competence, impartiality and confidentiality.
- The GMP+ Feed Certification scheme administered by GMP+ International includes modules for Feed Safety Assurance (FSA) and Feed Responsibility Assurance. The FSA module is focussed on animal feed safety and includes requirements for a feed safety management system, application of HACCP principles, traceability, and monitoring. GMP+ accepted certification bodies audit and certify companies against the requirements of the scheme and must be ISO/IEC 17065, ISO/IEC 17021 and/or NPR-ISO/TS 22003 accredited, and meet the requirements for auditor competence, experience impartiality and confidentiality.
- ISO/IEC 17021-1:2015 outlines the requirements for bodies providing audit and certification of management systems. The standard includes requirements for impartiality, confidence, and competence and consistency.
- ISO/TS 22003:2013 is a technical specification that outlines the requirements for bodies providing audit and certification of food safety management systems. The standard includes requirements for impartiality, confidence, competence, and consistency.

Third party auditors must conform to the provisions of ISO/IEC 17021-1:2015 or ISO/TS 22003:2013 including competence, impartiality and confidentiality:

- Third party auditors shall not allow commercial, financial or other pressures to compromise their impartiality, and shall have in place a policy for managing impartiality and processes to manage and address conflicts of interest. In addition, the third party auditor must not have undertaken audits of the facility for a minimum of two years from the point of application to conduct third party audits on behalf of the department.
- Third party auditors must have a process for determining and evaluating the competency of personnel involved in audits at the overseas facility.

- Third party auditors shall keep confidential all information obtained or created during the audit except as required by law.

Third party auditors must have experience auditing the animal feed sector or food safety management systems. As a minimum, the department requires evidence that potential auditors are qualified and have undertaken 3 audits in animal feed/food safety within the last 3 years.

Costs borne by the third party auditor are to be met by the applicant.

Legislative framework

The following table outlines the specific sections of *the Biosecurity Act 2015* (the Act) that applies to engaging and undertaking third party site audits of facilities used in the manufacture and export of processed plant-based stockfeed to Australia.

Relevant section of the *Biosecurity Act 2015*:	**How it applies**
Section 5	Definition of Appropriate Level of Protection (ALOP)
Section 9	Definition of biosecurity risk
Section 174	The Director of Biosecurity and the Directory of Human Biosecurity may jointly determine specified goods or class of goods that must not be brought or imported into Australian territory unless specified conditions are complied with (conditionally non-prohibited goods)
Section 176	Application of Division 3 – import permits to bring or import goods into Australian territory
Section 177	Person may apply for an import permit
Section 178	Sets out the time in which a decision related to an import permit application must be made and allows for the Director of Biosecurity to request further information in order to make a decision
Section 179	Sets out the things the Director of Biosecurity must consider when deciding whether to grant an import permit
Chapter 11, Part 2	Governs the use and disclosure of information that is obtained under, or in accordance with the Act, including records made

Roles and responsibilities

The following table outlines the roles and responsibilities undertaken in this guideline.

Role	**Responsibility**
Applicant	• lodging an import permit application • engaging a potential third party auditor • submitting an audit questionnaire • liaising with overseas facilities and third party auditor in relation to audit preparations • liaising with overseas facilities regarding corrective actions to address non-conformances

Role	Responsibility
Department of Agriculture, Water and the Environment officer (DO)	• determining whether a third party audit arrangement is acceptable • determining the suitability of third party auditors • communicating site audit requirements including preparing third party site audit briefs • approving third party site audit plans • approving third party site audit reports • assessing corrective actions applied by an overseas facility to address non-conformances • making decisions on import permit applications
Overseas facility	• completing the audit questionnaire • facilitating site audits • applying corrective actions to address non-conformances
Third party auditor	• completing the third party auditor application form • developing audit plans • scheduling site audits • conducting site audits • reporting site audits

Engaging and evaluating a third party auditor

Following submission of the import permit application and production questionnaire by the applicant, the department assesses the documents and advises the applicant if a site audit is required and if that site audit can be conducted by a third party auditor.

Note: Site audits cannot be conducted until desk audits have been undertaken by the department. In some instances, the desk audit phase can take some time to complete depending on a range of factors including the time it takes to implement corrective actions.

The following table outlines the process for engagement of a third party auditor.

Stage	What happens	Responsible party
1.	Identifies a potential third party auditor and provides the third party auditor with: • the infographic - importing processed plant-based animal feed • this guideline • the Facility requirements, • the third party auditor application form: processed plant-based stockfeed	Applicant
2.	The facilities are advised that a third party auditor will conduct a site audit of the facility; and that documentation about the facility will be passed onto the third party auditor as part of the audit.	Applicant

<table>
<tr><th>Stage</th><th>What happens</th><th>Responsible party</th></tr>
<tr><td>3.</td><td>A third party auditor application form: processed plant-based stockfeed is completed and submitted directly to the department or through the applicant.

Note: Third party auditors previously found to be suitable by the department are not required to complete all sections of the application form.</td><td>Third party auditor</td></tr>
<tr><td>4.</td><td>The application is assessed to determine if the potential third party auditor is:

1. competent
2. impartial
3. accredited
a. as a FAMI-QS certification body, or
b. as a GMP+ certification body, or
c. against ISO/IEC 17021-1:2015 or ISO/TS 22003:2013 and is experienced auditing the animal feed sector or food safety management systems.

<table><tr><th>When…</th><th>Then…</th></tr><tr><td>Further information is required to complete the assessment</td><td>the third party auditor is contacted and asked to provide the information required to complete the assessment.</td></tr><tr><td>The third party auditor is assessed as suitable</td><td>• the third party auditor and applicant are notified of the outcome
• Go to section: Third party site audit preparation</td></tr><tr><td>The third party auditor is assessed as not suitable</td><td>• the third party auditor and applicant are notified of the outcome
• the applicant is asked to engage a new third party auditor</td></tr></table></td><td>DO</td></tr>
</table>

Third party site audit preparation

The department undertakes a desk audit of the audit questionnaire and associated documentation. Any non-conformances identified through the desk audit are provided to the applicant and the overseas facility for rectifying before proceeding to site audit.

The following table outlines the process for preparing for the third party site audit.

Stage	What happens	Responsible party
1.	A third party site audit brief is prepared.	DO

<table>
<tr><th>Stage</th><th>What happens</th><th>Responsible party</th></tr>
<tr><td>2.</td><td>The third party auditor is provided the following documents:
Third party site audit brief
Finalised desk audit report
The Facility requirements
Audit questionnaire and associated attachments/records</td><td>DO</td></tr>
<tr><td>3.</td><td>The third party site audit documents are reviewed.<table><tr><th>When there are…</th><th>Then…</th></tr><tr><td>Questions</td><td>these are resolved by the DO through email or phone</td></tr><tr><td>No questions</td><td>continue to stage 4</td></tr></table></td><td>Third party auditor</td></tr>
<tr><td>4.</td><td>A draft audit plan is submitted to the DO.</td><td>Third party auditor</td></tr>
<tr><td>5.</td><td>The audit plan is reviewed against the requirements of the third party site audit brief.<table><tr><th>When the audit plan…</th><th>Then…</th></tr><tr><td>Meets requirements</td><td>the third party auditor is notified
continue to stage 6</td></tr><tr><td>Does not meet requirements</td><td>the third party auditor is advised of the deficiencies and asked to submit an updated plan.
Note: Any follow up questions from the third party auditor are resolved by the DO through email or phone.</td></tr></table></td><td>DO</td></tr>
<tr><td>6.</td><td>A pre-audit meeting is held to discuss the audit including common issues with site audits of stockfeed facilities.</td><td>DO/third party auditor</td></tr>
<tr><td>7.</td><td>The site audit is scheduled.</td><td>Third party auditor/Overseas facility</td></tr>
</table>

Third party site audit

The following table outlines the process for conducting a third party site audit.

<table>
<tr><th>Stage</th><th>What happens</th><th>Responsible party</th></tr>
<tr><td>1.</td><td>The site audit is conducted in accordance with the audit plan.
Note: Preliminary audit findings are shared with the facility at the exit meeting with advice that final outcomes including acceptable corrective actions need to be approved by the department.</td><td>Third party auditor</td></tr>
<tr><td>2.</td><td>A draft audit report and associated audit evidence are submitted to the DO.</td><td>Third party auditor</td></tr>
<tr><td>3.</td><td>Draft audit report and audit evidence are reviewed within 20 business days.
<table><tr><th>When…</th><th>Then…</th></tr><tr><td>Further evidence or clarification is needed</td><td>the third party auditor is contacted and asked to provide the information required or amend the audit report
Note: this may include the requirement to redo the site audit of the facility.</td></tr><tr><td>The draft audit report is sufficient</td><td>• The third party auditor is contacted and asked to finalise and submit the audit report.
• go to stage 4</td></tr></table></td><td>DO</td></tr>
<tr><td>4.</td><td>Final audit report received from the third party auditor is provided to the applicant and the overseas facility.
<table><tr><th>When there are…</th><th>Then…</th></tr><tr><td>No non-conformances</td><td>A permit may be granted</td></tr><tr><td>Non-conformances that cannot be corrected</td><td>A permit may be refused</td></tr><tr><td>Non-conformances that could be corrected</td><td>• the applicant and overseas facility are asked to provide a corrective action plan within 30 days.
• continue to stage 5.</td></tr></table></td><td>DO</td></tr>
<tr><td>5.</td><td>Corrective action plan and evidence of corrective actions are provided to the DO.</td><td>Overseas facility/Applicant</td></tr>
</table>

<table>
<tr><th>Stage</th><th>What happens</th><th>Responsible party</th></tr>
<tr><td>6.</td><td>The corrective actions are assessed to verify completion and effectiveness.
<table>
<tr><th>When the corrective actions are…</th><th>Then…</th></tr>
<tr><td>Complete and effective</td><td>• the applicant and overseas facility are notified of the outcome
• a permit may be granted</td></tr>
<tr><td>Complete but require another site audit to verify effectiveness</td><td>• the applicant and overseas facility are notified of the outcome
• return to Section: Third party site audit preparation</td></tr>
<tr><td>Not complete or not effective</td><td>• the applicant and overseas facility are notified of the outcome and are asked to provide a revised corrective action plan
• a permit may not be granted if a revised corrective action plan is not provided or considered to be incomplete or ineffective</td></tr>
</table></td><td>DO</td></tr>
</table>

Version history

The following table details the published date and amendment details for this document.

Version	Date	Amendment details
1.0	14/09/2020	First publication of this guideline.