

Guidelines for Engaging Third-Party Audit Service Providers



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Introduction

Biosecurity policies of the Department of Agriculture, Fisheries and Forestry (DAFF, the department) require that certain biological goods¹ can only be exported to Australia following satisfactory completion of:

- An assessment of an application for import permit for the specific biological goods²
- A desktop audit of the offshore manufacturer of the goods, and
- A site audit that includes an assessment of the offshore manufacturer's premises and procedures.

The site audit of the offshore manufacturer can be undertaken by the department's biosecurity officers or by a third-party audit service provider. Audit service providers must be independent of the auditee with no perceived or actual conflict of interest. They must also have been assessed by the department's biosecurity officers as being capable and suitable to perform this function.

This Guideline document contains information relevant to Australian importers that are considering engaging independent audit service providers to perform site audit functions as part of the import permit application process. Importers should consider this information before nominating their selected audit service provider to the department for assessment.

¹ Biological goods are goods that contain ingredients originating or derived from an animal, plant, microorganism, or microbial source.

² This application is submitted by the importer to the permit issuing areas of the department through the [BICON](#) system.

Roles and responsibilities

The following table identifies entities involved in this process and the responsibilities of each entity:

Role	Responsibilities
Import permit applicant i.e. the Australian importer	<ul style="list-style-type: none"> • Lodging the import permit application. • Seeking the services of an independent audit service provider. • Nominating the audit service provider to the department. • Liaising with representatives of the offshore manufacturer and the audit service provider to facilitate site audit preparations. • Liaising with representatives of the offshore manufacturer to implement corrective actions to address audit non-conformances.
DAFF biosecurity officer	<ul style="list-style-type: none"> • Assessing applications from audit service providers. • Communicating assessment findings to affected parties. • Hosting audit briefing sessions with successful auditors • Approving audit plans and reports from auditors. • Assessing auditee's plans for corrective action in response to audit non-conformances. • Making decisions on import permit applications.
Auditee i.e. the offshore manufacturer	<ul style="list-style-type: none"> • Providing information to support the permit application. • Facilitating the site audit. • Applying corrective actions to address non-conformances.
Auditor(s) from the third-party audit service provider	<ul style="list-style-type: none"> • Completing the third-party auditor application form. • Participating in audit briefing sessions with DAFF biosecurity officers. • Audit preparations i.e. developing audit plans, scheduling the site audit. • Doing the site audit. • Drafting audit reports and submitting reports to the department.

Terms for Engaging Third-Party Audit Service Providers

The following are terms under which Australian importers can seek to engage independent, third-party audit service providers to provide biosecurity audit functions in support of their import permit application:

1. Site audits of offshore manufacturers will be preceded by a desktop audit undertaken by a biosecurity officer from a permit issuing area of the department. Offshore manufacturers deemed non-compliant during the desktop audit will not be eligible for site audit without effective corrective actions.
2. Biosecurity officers from the department will conduct the first site audit of a facility that has not previously exported goods to Australia.
3. For subsequent audits, the Australian importer is responsible for:
 - Seeking potential audit service providers to undertake biosecurity audits, and
 - Nominating candidate audit service providers to the department for assessment.

The nominated audit service provider will be assessed by the department for accreditation, competence, impartiality and confidentiality (see section below for further information).

4. Nominated audit service providers will need to complete the **Third-party audit service provider application form** published by the department to support their candidacy for provision of audit services.
5. Audit service providers must conform to the provisions of ISO/IEC 17021-1:2015 or ISO/TS 22003:2013 standards, including competence, impartiality and confidentiality.
6. Only those audit service providers that have suitable accreditation and are deemed competent and impartial by the department will be approved for provision of audit services.
7. Candidate audit service providers will be notified of the outcome of the department's assessment for suitability. The department will provide those candidates deemed unsuitable with a rationale for this decision. The department's decision on a candidate's suitability is final and not contestable.
8. Audit service providers deemed unsuitable by the department will be ineligible for provision of audit services on behalf of the Australian importer.

9. Audit service providers deemed unsuitable by the department may be subsequently deemed suitable if corrective actions are implemented and the candidate is assessed to be compliant with the department's accreditation, competence, impartiality and confidentiality requirements.
10. Terms of the contract for provision of audit services, including terms for payment of fees for service, are negotiated between the Australian importer and the audit service provider. The department will not moderate in any way between the importer and the service provider on contract terms.
11. The Australian importer is liable for all costs associated with the provision of biosecurity audit services, including time taken by biosecurity officers to:
 - Assess the nominated audit service provider for compliance with the department's accreditation, competence, impartiality and confidentiality requirements
 - Brief the audit team prior to conducting the biosecurity audit
 - Review the audit team's report and findings, and
 - Support the audit team with any follow-up actions (e.g. issuance of corrective action requests, assessment of the auditee's corrective action plan, reviewing evidence of corrective actions)
12. Costs to the department associated with all audit-related activities will be fully cost-recovered by the department. Fees will be charged to the Australian importer in accordance with the department's current [Charging Guidelines](#). All desk-based activities undertaken by biosecurity officers will be charged at the quarter hour in-office assessment rate.
13. Biosecurity officers will maintain a record of time taken for all audit-related activities and this record will be provided to the Australian importer upon request.
14. The Australian importer will be invoiced by the department for provision of specific services immediately following provision of those services.
15. External audit teams endorsed by the department will receive a pre-audit briefing from the relevant permit issuing area in preparation for their audit activities. External audit teams will then prepare an audit plan in consultation with the auditee.
16. Audit teams must have a physical presence at the manufacturing site. The department does not endorse remote/virtual audits to be performed by audit service providers.
17. Following the department's accreditation of an audit service provider, the Australian importer is responsible for liaising with the overseas manufacturer to facilitate the activities of the audit team. This includes finalising dates for the audit, accommodation for the audit team, transfers to and from the manufacturing premises, and access to the site during the audit.

18. Biosecurity officers from the department will conduct audits of facilities where there has been a change that has a significant impact on the inherent level of risk associated with goods exported to Australia. This includes, but is not limited to, changes to infrastructure at the manufacturing site that impact production lines, changes to company ownership, and changes to the status of quality management at the manufacturing site.
19. Audit service providers will be subject to ongoing assessment by the department for accreditation, competence, impartiality and confidentiality.
20. An audit service provider that has been approved by the department subject to conditions is approved for provision of services for other Australian importers subject to those same conditions.

For example, an audit team that is nominated by an importer and approved by the department for provision of audit services for pet food production facilities is eligible for provision of those services for other importers subject to ongoing compliance with the department's requirements.

21. Biosecurity officers from the department will continue to conduct biosecurity audits where the decision of the Australian importer is not to engage an audit service provider.

Criteria for Suitability of Third-Party Audit Service Providers

Accreditation, competence, impartiality and confidentiality

Audit service providers must operate to one of the following standards:

- [ISO/IEC 17021-1:2015](#) outlines the requirements for bodies providing audit and certification of management systems, or

- [ISO/TS 22003:2013](#) is a technical specification that outlines the requirements for bodies providing audit and certification of food safety management systems.

These standards include requirements for impartiality, confidence, competence and consistency.

Service providers that can demonstrate competence as auditors against the following standards/systems will be considered by the department:

- [bsi](#) standards for Quality Management Systems (ISO 9001), HACCP & GMP, Food Safety.
- [Bureau Veritas](#) who provide inspection and certification services allowing businesses to demonstrate that they comply with standards and regulations. BV offer in-depth knowledge of the standards applicable to company operations and provide independent third-party verification of compliance.
- [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.
- [FeedSafe](#)[®], which is operated by the Stock Feed Manufacturers' Council of Australia, is the Quality Assurance Accreditation Program for the Australian stock feed industry.
- [FSSC](#) 22000 Food Safety Management Systems.
- Good Manufacturing Practice ([GMP](#)) as regulated by the Australian Pesticides and Veterinary Medicines Authority

- 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.
- [LRQA](#) – ISO 9001 Quality Management Systems.
- [SGS](#) provide a comprehensive range of assurance and advisory services to help food businesses deliver high quality, safe and compliant products to market. Their highly qualified auditors and food safety specialists provide independent solutions covering risk management and compliance.

Third party auditors must 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, individuals auditing the manufacturer must not have audited the facility for at least two years prior to the application to conduct third party audits on behalf of an Australian importer.

Third party auditors must have a process for determining and evaluating the competency of personnel involved in audits at offshore manufacturing sites.

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 invoiced directly to the Australian importer.