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SITE AUDIT CRITERIA FOR OFFSHORE MANUFACTURING FACILITIES EXPORTING BIOLOGICAL GOODS TO AUSTRALIA

Introduction

Importers require a permit to bring many biological goods[1] into Australia. Applications for import permit are assessed by officers from the Animal and Biological Imports Branch (ABIB) of the Department of Agriculture, Fisheries and Forestry (the department). These are evaluated against the requirements of the relevant biosecurity policies, guidelines, and import risk analyses.

Before a site audit of the manufacturing facility can be done, ABIB assessors must complete a desktop audit. This is to ensure there are documented systems in place within the facility to support the production of product that is compliant with Australia's biosecurity requirements. Following completion of a successful desktop audit, ABIB officers will contact applicants to organise a site audit of the manufacturing facility.

The objective of the site audit will be to ensure that the processes, systems and procedures reviewed as part of the desktop audit are implemented as standard work practices by employees within the manufacturing facility. Critical procedures such as the sourcing and processing of starting materials, recording of production steps, movement and storage of materials/finished products, and document management are covered during the site audit. Auditors must be confident that products manufactured offshore do not act as a vector for the introduction of pests or diseases of biosecurity concern into Australia.

Auditors must be satisfied that facilities have established systems that support traceability of final product to the source of starting materials of animal origin. Auditors must be assured that existing documentary evidence indicates that the product satisfies the department's requirements for sourcing and treatment in every instance. The audit will also include an assessment of procedures that are in place to ensure that the risk of contamination of product, either through cross-contamination or environmental contamination, is acceptably low.

The scope of the site audit includes:

1. **Premises and Equipment**
2. **Personnel**
3. **Documentation**
4. **Production**
5. **Quality Assurance and Continuous Improvement**

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

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1. PREMISES AND EQUIPMENT

General

a) Premises must be situated in an environment that presents minimal risk of causing contamination of materials or products. The biosecurity risk of agricultural production facilities, such as abattoirs or farms, in proximity to the site will be assessed.

b) Premises must be maintained to a very high standard of cleanliness. Repair and maintenance operations must not present any potential for contamination of product.

c) Settings for lighting, temperature, humidity and ventilation must be such that they allow for the manufacture of product free from contamination.

d) Premises must be designed and equipped to afford maximum protection against the entry of insects, vermin, and other animals.

e) Steps must be taken to prevent the entry of unauthorised people. Documented security procedures must be maintained. Production, storage, and quality control areas must not be used as passageways by personnel who do not work in them.

f) Site maps of the manufacturing plant must be provided and must include detail of the activities undertaken in each area. A list of all the products stored and produced at the manufacturing site must be provided.

g) An effective pest control program must be in place. Traps must be located at strategic points throughout the facility and be recorded on a site map. The traps must be regularly checked and maintained.

Equipment

h) Equipment repair and maintenance operations must not present any hazard to the integrity of the product. Procedures must be in place to ensure that environmental contamination or cross-contamination from within the plant will not occur.

i) The system, including chemicals, used for washing and cleaning of equipment must ensure that equipment is not a source of product contamination. Cleaning procedures, including the use of cleaning agents, must be documented and compliance recorded. Cleaning procedures employed between batches must be closely scrutinised.

j) Defective equipment must be removed from production or clearly labelled as defective. Replacement equipment must be fit for purpose.

k) Relevant equipment, such as that requiring temperature control, must be fitted with recording and/or alarm systems. Records must be maintained for the performance and calibration of this equipment.

2. PERSONNEL

General

a) The manufacturer must have an adequate number of personnel with the necessary qualifications and practical experience.

b) The manufacturer must provide an organisation chart. People in responsible positions must have specific duty statements recorded in writing that describe their responsibilities.

c) Prevention of contamination of product from environmental elements by personnel must be achieved through the delivery of effective washing and hygiene processes and appropriate barrier clothing is worn by staff during the production process.

Training

d) The manufacturer must provide training for all personnel whose duties take them into production areas (including maintenance and cleaning personnel), and for other personnel whose activities could affect the integrity of product. The training curriculum must include elements covering microbial contamination and the necessity of ensuring that the biosecure status of product is not compromised at any time.

e) Newly recruited personnel must receive training appropriate to the duties assigned to them. Ongoing training must be given and its practical effectiveness assessed.

f) Training records must be kept for all personnel and must be available upon request.

Personal Hygiene

g) Detailed hygiene programs must be established and adapted to the different needs within the manufacturing facility.

3. DOCUMENTATION

Document management and storage

a) Documents must be designed, prepared, reviewed, and distributed under a defined control system. Current versions of documents must be approved, signed, and dated by appropriate and authorised persons.

b) Documents must be laid out in an orderly fashion and be easy to check. Reproduced documents must be clear and legible. The reproduction of working documents from master documents must not allow any error to be introduced through the reproduction process.

c) Documents must be reviewed regularly and kept up to date through a defined control system. When a document has been revised, systems must be in place to prevent inadvertent use of superseded documents.

d) Records must be made at the time each action is taken and in such a way that all significant activities concerning the manufacture of product are traceable. They must be retained for at least two years after the expiry date of the finished product.

e) There must be appropriately authorised and dated specifications for starting materials, packaging materials and finished products. The specifications must include the sourcing of the starting materials as approved by the department. The specifications must include all alternative suppliers that have been approved.

f) Manufacturers must maintain formally authorised manufacturing formulas for each product exported to Australia. This must reference all materials of biosecurity concern (e.g., animal materials, enzymes) used in production. The formula must include all alternatives approved by the department.

g) A clear and accurate batch processing record must be kept for each batch. It must be based on the relevant parts of the currently approved manufacturing formula, including all starting materials of animal origin used. The record must include the number of the batch being manufactured for auditing purposes.

h) Details of finished product destined for Australia and the name/s of the Australian importer/s must be recorded to support product recall, if necessary.

i) Standard operating procedures (SOP) must be in place for:

- the receipt of each delivery of all starting or primary materials for use in production and any packaging materials

- quarantine/release procedure for starting materials

- internal labelling, quarantine and storage of starting materials, packaging materials and other materials

- sampling, which would include the person(s) authorised to take samples, the methods and equipment to be used, and any precautions to be observed to avoid contamination of the material

- release and rejection procedures for materials and products, specifically for the release for sale of the finished product by a qualified person

- the distribution of each batch of a product that facilitates recall of the batch, if necessary, and

- maintenance, cleaning, sanitisation, and pest control.

The position of the person(s) responsible for each step in the SOP must be listed in the SOP.

j) Documents must be signed by authorised personnel with responsibility for the operation.

4. PRODUCTION

General

a) Production must be performed and supervised by competent people. Production must be done in accordance with written procedures/instructions and must be recorded.

b) At every stage of processing, products and materials must be protected from cross-contamination within the plant and external contamination from the environment.

c) At all times during processing, all materials, bulk containers, major items or equipment and rooms used should be labelled or otherwise identified with an indication of the product or material being processed, the finished product and the batch number.

d) Access to production areas must be closely monitored and restricted to authorised personnel only.

e) Measures to prevent cross-contamination and their effectiveness must be checked periodically according to set procedures.

Storage Areas

f) Storage areas must be of sufficient capacity to allow orderly storage of the various categories of materials and products. The storage areas must be designed to support effective storage conditions.

g) Access to storage areas must be restricted to authorised personnel only.

h) Printed packaging materials and labels must be securely stored. The person responsible for security around the storage of printed packaging materials and labels must be identified.

Production Areas

i) Where manufacturers do not have dedicated facilities for production of product for the Australian market, appropriate cleaning procedures between batches must be in place. Cleaning procedures must be documented and recorded.

j) Premises should be laid out in a way as to allow production to take place in areas connected in a logical order corresponding to the sequence of operations. Efforts should be made to minimise unnecessary movement by personnel to minimise the risk of environmental contamination or cross-contamination in the plant.

k) Pipework, light fittings, ventilation points and other services must be designed and situated to avoid the creation of recesses which are difficult to clean.

l) Drains must be of adequate size to prevent the build-up of waste but not of a size that allows contamination to enter the facility from the external environment.

m) Premises for the packaging and dispatch of finished product must be specifically designed and laid out to avoid cross-contamination.

n) Production areas must be illuminated to a sufficient degree.

Starting Materials

o) The suitability of starting materials must be clearly defined in written specifications and must include approved sources of starting materials of biosecurity concern (e.g., material derived from animals). These must include details of the supplier, the geographical origin, any testing or treatment of the material as required by the department, and the animal species from which the material is derived.

p) Procedures must be in place to support the quarantine and release of incoming starting materials.

q) All incoming starting materials must be checked to ensure that the consignment corresponds to the order. Incoming materials must be physically or administratively quarantined immediately after receipt, until they have been released for use in production. The origin of animal derived starting materials used in production of product for Australia must be verified. Government certification is required for verification in most cases. These documents must be produced upon request.

Finished products must also be physically or administratively quarantined immediately after processing, until they have been released for distribution.

r) The compliance of incoming starting materials with specifications must be verified. Written attestations provided by material suppliers must be a contemporary reflection of the conditions of manufacture of that material. Documents should be signed and dated within 6 months of receipt of the batch of starting material.

5. QUALITY ASSURANCE AND CONTINUOUS IMPROVEMENT

a) In-process controls must be in place to maximise product quality and reduce the risk of product contamination. A consistent application of quality standards is required to build confidence in the ability of the manufacturer to produce product that is compliant with Australia's biosecurity requirements.

b) A system for accreditation of new suppliers of starting materials and products must be in place. The approval, continual oversight, and audit of suppliers should be based on quality risk management**.**

c) Finished product assessment should include all relevant factors, including the origin of starting materials used in production, the processes in place to prevent environmental or cross contamination from occurring, the protocols and results of any testing or treatments of starting materials, details of labelling and storage, and the specific destination of finished product.

c) Management must be able to comply with the department's requirements by ensuring that finished product can be traced from the origin of starting materials through to the finished product by batch number or any other appropriate identification. Government certification must be on file to verify the origin of any starting materials, if required.

d) There must be a focus on continuous improvement which strengthens quality systems and processes, leading to increased levels of compliance with regulatory obligations. This will include having systems in place for review of customer complaints, management of non-conforming product (including product recalls), and periodic quality review of product.

e) A formal change control system, which includes a regulatory impact assessment, should be in place. The system must incorporate processes for:

- Notification to the Australian importer of proposed changes

- Review of the change with opportunity for the provision of feedback, and

- Formal approval of the proposed change by the Australian importer.