



Facility Standard

Transitional Facilities for Animal Products

MPI-STD-ANIPRODS

TITLE

Facility Standard: Transitional Facilities for Animal Products

COMMENCEMENT

This facility standard comes into force on ..

ISSUING AUTHORITY

This facility standard is issued for the purpose of section 39 of the Biosecurity Act 1993.

Dated at Wellington this ... day of 2015

Howard Pharo
Manager, Import and Export Animals
Ministry for Primary Industries
(acting under delegated authority of the Director General)

Contact for further information
Ministry for Primary Industries (MPI)
Regulation and Assurance Branch
Animal Imports
PO Box 2526
Wellington 6140
Email: animalimports@mpi.govt.nz

Draft

Contents

Page

Introduction	3
Part 1: General	5
1.1 Application	5
1.2 Definitions	5
1.3 Implementation arrangements	5
Part 2: Physical and Structural Requirements	6
2.1 Transitional facility location	6
2.2 Transitional facility premises	6
2.3 Signage	7
Part 3: Operational Requirements	8
3.1 Operating manual	8
3.2 Transitional facility access and security	10
3.3 Receipt and movement of uncleared animal products	11
3.4 Product inventory	11
3.5 Segregation of uncleared animal products	12
3.6 Waste disposal	13
3.7 Record keeping	13
3.8 Training	14
3.9 Cleaning and hygiene	14
3.10 Pest control	15
3.11 Contingency plan	15
3.12 Internal audit and quality assurance systems review	16
3.13 External MPI inspection	17
Schedule 1 – Document History	18
Schedule 2 – Definitions	19

Introduction

- (1) This introduction is not part of the facility standard, but is intended to indicate its general effect.

Purpose

- (1) This facility standard relates to transitional facilities for uncleared animal products. The purpose of this standard is to:
 - a) Set out the requirements relating to building, maintaining and operating this kind of facility.
 - b) Describe how a place becomes approved as this kind of transitional facility.

Background

- (1) The Biosecurity Act 1993 (the Act) provides the legal basis for excluding, eradicating and effectively managing pests and unwanted organisms that may cause harm to natural and physical resources and human health. Imported risk goods have the potential to introduce pests and unwanted organisms into New Zealand. For that reason, imported risk goods must obtain biosecurity clearance before they are allowed to enter New Zealand.
- (2) Uncleared animal products must go to a transitional facility on arrival in New Zealand. They must remain there until they are given biosecurity clearance or are transferred or exported.
- (3) A place cannot operate as a transitional facility unless it is approved by the Director-General. In order to be approved, it must comply with the Act and the requirements in this standard. Details about how to apply for facility approval can be found at the following MPI website (<http://www.biosecurity.govt.nz/border/transitional-facilities/registration/application-form>). Facility approvals may be subject to conditions.
- (4) A transitional facility must be operated by an approved operator. The MPI website (<http://www.biosecurity.govt.nz/border/transitional-facilities/registration/application-form>) explains how to become an approved operator. Operator approvals are subject to the condition that the operator will comply with this standard and with any other conditions imposed by the Director-General.

Who should read this facility standard?

- (1) Operators and prospective operators of transitional facilities processing uncleared animal products should read and be familiar with this standard.

Why is this important?

- (1) If a place does not comply with the building, maintenance and operating requirements of this standard, it will not be approved as a transitional facility and, if already approved, the approval may be suspended or cancelled.
- (2) If an operator does not comply with the operating requirements of this standard, the operator's approval may be suspended or cancelled.
- (3) It is an offence to operate a place as a transitional facility if the place is not approved as a transitional facility or the person operating the place is not an approved operator, or if those approvals are suspended. It is also an offence for a person who operates a transitional facility to not comply with the operating standards for the facility.

Document history

-
- (1) This standard was formerly part of the Ministry for Primary Industries (MPI) *Standard for General Transitional Facilities for Uncleared Risk Goods Annex F (Animal Products)*. A new transitional facility standard for animal products was required due to the complexities of managing animal products.
 - (2) Amendments to this standard are listed in Schedule 1.

Other information

Guidance

- (1) Guidance has been prepared to accompany this standard and has been presented as guidance boxes within the standard. The guidance sets out the ways in which the requirements of this standard can be met and contains other useful information. Operators and applicants for approval should read and be familiar with the guidance information.

Costs

- (1) Applicants for a facility approval, and approval to be an operator, must pay an application fee.
- (2) MPI will charge for ongoing monitoring of compliance with this standard and any conditions of an approval. Fees are at the rates set out in the *Biosecurity (Costs) Regulations 2010*.

Part 1: General

1.1 Application

- (1) This standard applies to transitional facilities processing uncleared animal products that have been directed to a transitional facility upon arrival in New Zealand.
- (2) Animal products include but are not limited to animal fibre, bee products (e.g. honey, pollen), hides and skins, horse by-products, salmon and meat (e.g. pork).

1.2 Definitions

- (1) Definitions of terms used in this standard are set out in Schedule 2.
- (2) Terms used in this standard that are defined in the Act have the meanings set out in the Act, unless a different meaning is given in Schedule 2. The Act is available at the following website:
<http://www.legislation.govt.nz/>.

1.3 Implementation arrangements

- (1) The following implementation arrangements apply to transitional facilities already approved to the MPI *Standard for General Transitional Facilities for Uncleared Risk Goods Annex F (Animal Products)*.
 - a) All physical/structural and operational changes as documented in the operating manual must be implemented within six months of commencement of this standard.
 - b) The operator must ensure that all changes related to the transitional facility's approval are submitted to the MPI Inspector at least two months in advance of the implementation deadline to allow the inspector sufficient time to review the operating manual and/or arrange to inspect the facility (if necessary).
- (2) All new transitional facility applications made after the date of commencement of this standard must comply with this standard.

Part 2: Physical and Structural Requirements

2.1 Transitional facility location

- (1) A transitional facility must be located in a place that is provided with suitable services and systems in order to meet the requirements of this standard, and ensure that the biosecurity risks in relation to uncleared animal products are managed at all times.

Guidance 2.1

- Transitional facilities should not be located in areas at risk of flooding (e.g. designated floodplain areas) or areas susceptible to major climatic events (e.g. high winds and significant earthquake activity). Examples of services and systems include access to sewerage systems/treatments and uninterrupted power sources.

2.2 Transitional facility premises

- (1) The area(s) of the transitional facility where the uncleared animal products are stored or processed must securely contain the products and must meet all of the following requirements.
- a) Be an enclosed and covered building with lockable entry points.
 - b) Have sealed floors.
 - c) Have washable surfaces where those surfaces are in contact with uncleared animal products.
 - d) Have storage or processing facilities that allow isolation of uncleared animal products from domestic products or previously cleared products.
 - e) Have a pest control regime such that pests cannot gain entry into the area(s) where the uncleared animal products are exposed.

Guidance 2.2

- Transitional facilities receiving uncleared goods via sea/air containers and facilities holding uncleared animal products will also be approved to the MPI *Standard for General Transitional Facilities for Uncleared Risk Goods* [MPI-STD-TFGEN](#).

- (2) A site plan or map for the entire facility which clearly identifies the area or areas where uncleared animal products are received, stored or processed must be included in the operating manual as set out in clause 3.1.
- (3) When a building approved as a transitional facility is not being used for the purposes of its approval it may be used for other purposes between consignments. Any such use must not compromise the ability of the transitional facility to meet the requirements of this standard when it is being used for the approved purpose.

2.3 Signage

- (1) A transitional facility must have prominent signs at all entrances and areas within the building(s) or premise which are designated as a transitional facility under the Act. Signs must warn that entry is restricted to persons permitted by the operator.
- (2) A copy of the transitional facility sign must be included in the operating manual as set out in clause 3.1.

Guidance 2.3

- Signs may specify that the premises are a “Transitional Facility as Approved by the Ministry for Primary Industries”.
- Signs are not permitted to display the MPI logos as per the Flags, Emblems, and Names Protection Act 1981.

Part 3: Operational Requirements

3.1 Operating manual

- (1) An operating manual must be prepared for each transitional facility and must set out how the facility will be managed and operated to meet the requirements of this standard. The current version of the operating manual must be made available to the MPI Inspector at least three days prior to the external inspection or on request.
- (2) The operating manual must include a description as to how the following standards and requirements will be met in relation to the uncleared animal products, and describe how the efficacy of the systems and procedures will be measured, monitored and determined to be continually effective.
 - a) This standard.
 - b) Any relevant import health standard (IHS).
 - c) Any import permit.
 - d) Any measures approved in a Chief Technical Officer (CTO) direction under section 27(1)(d)(iii) of the Act.
- (3) The operating manual must have the following structure:
 - a) A table of contents with numbered pages and the version number and date on each page.
 - b) The scope of the transitional facility must include:
 - i) The purpose of the transitional facility as set out in the approval.
 - ii) A list of the relevant IHS(s) applicable to the uncleared animal products.
 - iii) A description of the uncleared animal products being imported to or processed at the transitional facility.
 - iv) An estimate of the amount of uncleared animal products per week or per year.
 - c) The management structure and staff responsible for managing the uncleared animal products must include:
 - i) The name and contact details of the transitional facility owner.
 - ii) The name and contact details of the operator and their responsibilities.
 - iii) A list of any staff carrying out management responsibilities including any deputy operators (if applicable), and a description of each person's responsibilities for the physical and operational compliance of the transitional facility.

Guidance 3(c)(iii)

- The operator has an obligation to appoint an individual or individuals as the deputy operator(s) if it is the opinion of the operator that one is needed due to the complexities and particular operating factors of a facility, in the event of the operator's absence, or where contingencies may impact the operator's ability to exercise their responsibilities effectively.
- The operator is accountable for ensuring that the transitional facility is compliant with the requirements of this standard, the relevant IHS, the import permit and/or any measures approved in a CTO direction. While they are not expected to do all the work for the facility to meet compliance, they are responsible for ensuring all the work is done and are satisfied with the information which demonstrates compliance.
- Positions rather than people can be referenced, but provisions should be made to ensure that names and employment dates are kept in company records and are readily accessible.

-
- d) The operating manual must set out the following contact details:
- i) The MPI Inspector with primary responsibility for supervision of the transitional facility.
 - ii) Phone numbers for reporting contamination and email addresses for requesting transfers, etc.
 - iii) The MPI contact person in relation to the inspection of consumer ready cuts of pork (if applicable).
- e) The operating manual must set out the following details of activities undertaken in the transitional facility:
- i) *Transport*: A description of how uncleared animal products are moved from the facility (see clause 3.3 below).
 - ii) *Product inventory*: An outline of the product inventory system for uncleared animal products (see clause 3.4 below).
 - iii) *Product segregation*:
 - 1) A description of how uncleared animal products will be separated from other products, including during movement (if applicable) (see clause 3.5 below).
 - 2) A description of how these measures and procedures will be monitored, maintained and determined to be effective.
 - iv) *Thawing* (for commodities like pork and salmon):
 - 1) A description of how the uncleared animal products are thawed.
 - 2) A description of what happens to the water from thawing.
 - 3) A description of how the potential risks associated with that water are managed.
 - v) *Preparation for processing* (if applicable): A description of how uncleared animal products are prepared for processing and where this occurs in the facility.
 - vi) *Processing*:
 - 1) A description of the processing pathways including the products eligible for clearance (e.g. hams), by-products (see definition in Schedule 2) and waste products (e.g. liquid, trim, contaminated packaging).
 - 2) A description of how the measures (e.g. cooking, scouring parameters) for each processing pathway meets the IHS requirements, import permit and/or any measures approved in a CTO direction.
 - 3) A description of the monitoring procedures used for each pathway to verify that the product complies with the processing measures of the IHS, import permit and/or any measures approved in a CTO direction.
 - vii) *Consumer ready cuts (CRC) of pork processing and reporting* (if applicable):
 - 1) A description of the procedures for processing and releasing CRC under the direct or indirect pathway.
 - 2) An outline of the inventory system (see clause 3.4 below).
 - viii) *Waste disposal*:
 - 1) A description of the disposal or treatment procedures for liquid and solid waste including by-products.
 - 2) A description of how waste disposal measures set in the IHS, import permit and/or any measures approved in a CTO direction are to be met and how the disposal or treatment procedures will be verified.
 - 3) A description of where the waste will be held prior to disposal.
 - 4) The approximate amount of waste generated (see clause 3.6 below).
 - ix) *Transfers or movement*: A description of how uncleared animal products are received from and moved to another facility (see clause 3.3 below).
 - x) *Access and Security*: A description of the access and security procedures (see clause 3.2 below).

-
- xi) *Training*: A description of staff and visitor training (see clause 3.8 below).
 - xii) *Cleaning and hygiene*: A description of the facility's cleaning and personal hygiene regime and how it mitigates risks associated with uncleared animal products (see clause 3.9 below).
 - xiii) *Pest control*:
 - 1) A description of the pest control regime (see clause 3.10 below).
 - 2) Where uncleared animal products are exposed or likely to be exposed, the description must also include what measures will be implemented to ensure that products cannot be accessed by pests and how the efficacy of these measures will be assessed and verified.
 - xiv) *Internal audit and quality assurance systems review*:
 - 1) A description of the scope of the internal audit and quality assurance systems review and the process undertaken for internal audits and quality assurance system review.
 - 2) A description of the procedures for addressing non-compliances (see clause 3.12 below).
 - xv) *Document control*:
 - 1) A description for the process for making changes to the operating manual and how the operating manual will be monitored and checked for relevance.
 - 2) The person(s) responsible for ensuring the operating manual is up to date.
 - 3) A history of the changes to the operating manual.
 - xvi) *Contingency plan*: An outline of potential risks and procedures to be followed in the event of an adverse incident and identification of available resources for the contingency (see clause 3.11).
- (4) The operator must review the operating manual at least once a year to ensure its continuing suitability and effectiveness. The review must take into consideration the following:
 - a) Internal audit and quality assurance systems reports (see clause 3.12 below).
 - b) MPI inspection reports.
 - (5) The operator must inform the MPI Inspector (as soon as practicable) if the transitional facility's operations or activities change from the approved scope of the operating manual.

Guidance 3.1

- An example of an operating manual is available at: [insert web link]

3.2 Transitional facility access and security

- (1) A transitional facility must have access procedures to ensure the security of uncleared animal products. The access and security procedures must be outlined in the operating manual.
- (2) Only persons permitted by the operator are allowed in the transitional facility. The operator must ensure that these persons:
 - a) Adhere to access procedures.
 - b) Are accompanied by a staff member while in the transitional facility (where possible).
 - c) Follow the instructions of the operator at all times.
- (3) The operator must maintain a register of visitors.

-
- (4) The operator must provide access to the transitional facility for the MPI Inspector at any reasonable time or at any other time when provided with 24 hours' notice.

3.3 Receipt and movement of uncleared animal products

- (1) Uncleared animal products must be unloaded at a designated area within the transitional facility.
- (2) The operator must ensure that all uncleared animal products that are received at or moved from the transitional facility have been authorised by the MPI Inspector.
- (3) The operator must ensure that any movement of uncleared animal products is in a secure and contained manner to prevent spillage or contamination of the transporting vehicle, other cargo and/or the environment. The operator must report any spillage or leakage of uncleared animal products that occurs during movement to the MPI Inspector as soon as reasonably possible and must confirm that the MPI Inspector has actually received the notification.
- (4) The transporting vehicle or container must be cleaned and waste must be disposed of as specified in the contingency plan or as directed by the MPI Inspector.

Guidance 3.3

- Biosecurity authorisation from the MPI Inspector may be in the form of a Biosecurity Authority Clearance Certificate (BACC) or movement authorisation form.
- The operator may obtain authorisation to move uncleared animal products by applying to MPI for a BACC redirection or using a movement request form. A written approval from MPI will be given if authorisation requirements have been met.
- Uncleared animal products may only be moved to another transitional facility, containment facility or be exported. If moved to another facility, the operator should demonstrate to the satisfaction of the MPI Inspector that all import requirements in relation to the uncleared animal products can be met at the receiving facility prior to authorisation for the movement being given. Such requirements will include those specified within the relevant IHS(s), the import permit and/or any measures approved in a CTO direction. *Note* that conditions for import or clearance may be specified on the import permit. In order for the receiving facility to be informed of the conditions, the import permit has to accompany the products. Where commercially sensitive information is present on the permit, this information (e.g. exporter details) may be redacted from the document.
- The operator should demonstrate to the satisfaction of the MPI Inspector that the receiving facility is approved to a facility standard that specifies the structural and operational requirements are adequate to manage the risks associated with the uncleared animal products. The scope of the receiving facility's operating manual also needs to cover the nature of the uncleared animal products to be received and the purpose for which they are received.
- Where uncleared animal products arrive without correct MPI documentation, MPI should be notified immediately, and the products held securely until directions are received from MPI as to further actions that need to be taken.
- Movement authorisation forms are available at: <http://www.biosecurity.govt.nz/forms/movement-request-animal-biological-products-peq-plants-seed-stored-products-stock-feed>.

3.4 Product inventory

- (1) The operator must maintain a product inventory of all uncleared animal products received at and moved from the transitional facility. The inventory must include the following (as applicable):
- a) Nature and quantity of the goods received, moved or destroyed.
 - b) Date(s) in which the goods are received, moved or destroyed.

-
- c) Batch numbers of the goods.
 - d) BACC, import permit, any measures approved in a CTO direction and/or movement authorisation form that the products are received or moved under.
 - (2) The product inventory must enable products to be tracked from the point of receipt through each stage of processing until the batch (including by-products and waste) is eligible for one of the following:
 - a) Release (i.e. biosecurity clearance).
 - b) Transfer for further processing, testing or disposal.
 - c) Export.
 - (3) For CRC of pork, the operator must provide a monthly inventory report to the MPI Inspector of all products processed and released under both the direct and indirect CRC pathways. The report must identify the:
 - a) Inspection step the facility is on.
 - b) Amount of product being imported.
 - c) Cut type.
 - d) Number and weights of the batches being released.
 - e) BACC the products are received or moved under.

Guidance 3.4

- Product inventory records should be easily accessible to the MPI Inspector and relevant staff (e.g. keeping all documents for each consignment together).

3.5 Segregation of uncleared animal products

- (1) Uncleared animal products must be effectively segregated from all other products to prevent possible cross contamination. The operating manual must stipulate how this will be achieved, monitored and maintained and be based on the likely risks posed by the uncleared animal products.
- (2) Cleared or domestic products that become contaminated or are suspected to be contaminated from contact with uncleared animal products must be regarded as a biosecurity risk and handled in the same manner as uncleared animal products.

Guidance 3.5

- Storage and management measures should take into account the:
 - Nature of the potential biosecurity contamination associated with the uncleared animal products and how other products could be contaminated.
 - Nature and type of packaging of the uncleared animal products.
- Preventing contamination of cleared and domestic products can be achieved by:
 - Placing products at an adequate physical distance from other products.
 - Separating products using a physical barrier.
 - Secure packaging of uncleared animal products such that any contamination is contained and separated from other products.
- The amount of distance or nature of the physical barrier or packaging will be dependent on the type of animal product and the likely risks associated with it.

3.6 Waste disposal

- (1) The operator must ensure that waste generated from processing be treated or disposed of as specified in this standard, the relevant IHS(s), the import permit and/or any measures approved in a CTO direction, either within the transitional facility or transferred under MPI authorisation to another transitional facility.
- (2) If the uncleared animal products are moved to another transitional facility for treatment or disposal, the operator must provide documented evidence to the MPI Inspector (*see clause 3.3 above*) that the receiving transitional facility and/or operator:
 - a) Has the ability to process the waste as specified in this standard, the relevant IHS(s), the import permit and/or any measures approved in a CTO direction.
 - b) Has undertaken to treat or dispose of the waste as specified in this standard, the relevant IHS(s), the import permit and/or any measures approved in a CTO direction.
- (3) The waste treatment or disposal procedure for each waste stream must be outlined in the operating manual and evidence for its effectiveness must be verified and documented.

Guidance 3.6

- Waste for treatment or disposal might include shipping material (e.g. contaminated pallets, shipping container), contaminated packaging (i.e. packaging that has been in contact with uncleared animal product), trim, by-products and liquid.

3.7 Record keeping

- (1) The operator must implement and maintain an effective record keeping system that allows easy access to records for relevant staff and the MPI Inspector.
- (2) The operator must maintain records of the following:
 - a) All uncleared animal products entering the transitional facility with the accompanying approval documents.
 - b) Official documents verifying compliance with the relevant IHS(s), the import permit and/or any measures approved in a CTO direction.
 - c) All uncleared animal products being moved to another transitional facility with the approval documents.
 - d) All products that have been processed to the requirements of the relevant IHS(s), the import permit and/or any measures approved in a CTO direction.
 - e) All uncleared animal products that have been exported.
 - f) Training and assessment records.
 - g) Internal audit reports, quality assurance systems review reports and close out records.
 - h) MPI inspection reports.
- (3) Records must include dates and signatories of persons responsible.
- (4) Records must be legible, readily identifiable, and must be kept for a minimum of seven years from receipt, preparation or amendment.

Guidance 3.7

- The record keeping system should be electronic and incorporated into a wider records management system, if possible. This allows easier entry sorting and retrieval of specific information related to goods, transfers or processing.

3.8 Training

- (1) The operator must nominate a person or position within the company who is responsible for training of staff and visitors.
- (2) A training programme must be developed and implemented for all staff working at the transitional facility that will be handling uncleared animal products, and for visitors to the facility. The programme must describe the following:
 - a) How the training is to be implemented.
 - b) How the effectiveness of training is assessed.
 - c) The time scales for implementation and refresher courses.
- (3) The training programme must be described in the operating manual.
- (4) The operator must ensure that persons likely to be handling uncleared animal products are aware of and understand the following:
 - a) The requirements of this standard.
 - b) The documentation related to the management of uncleared animal products.
 - c) Their responsibilities and obligations while in the transitional facility in relation to the management of uncleared animal products.

Guidance 3.8

- Visitors to the transitional might include contractors undertaking repairs and maintenance work, persons delivering or removing goods, local body inspectors, members of the public, and persons within the company who may not be in the transitional facility on a regular basis and do not have direct responsibilities for operations.
- The training provided for each person should only address what is needed in order for the requirements of this standard to be met. Contractors, for example, may only need to be provided with information about the facility and the precautions they must take to ensure the safe and secure management of uncleared animal products they may come in contact with.

3.9 Cleaning and hygiene

- (1) The operator must have a cleaning and hygiene system in place that ensures the transitional facility is kept clean at all times and activities undertaken by personnel do not compromise the management of the uncleared animal products.
- (2) The operating manual must specify the cleaning and hygiene procedures, measures and equipment that will be employed, how these will be assessed as being effective, and what evidence will be provided to verify this.

Guidance 3.9

- Cleaning and hygiene procedures should take into account prevention of accumulation of waste and debris, prevention of possible refuge areas for pests and the disposal of contaminated packaging, sweepings, dunnage or any other waste that might pose a biosecurity risk.
- Personal hygiene procedures should include measures that reduce the likelihood of biosecurity contaminants being removed from the facility or transferred to domestic and cleared goods (e.g. on contaminated clothing, hands and equipment in contact with uncleared animal products).

3.10 Pest control

- (1) The operator must ensure that pests (*see definition in Schedule 2*) which present a risk to the safe and secure management of uncleared animal products are effectively controlled. The operating manual must describe the process that will be undertaken.
- (2) The management plan must take into consideration:
 - a) The pests that present a risk to the uncleared animal products at the transitional facility.
 - b) The procedures, measures and equipment that will be used to control the pests.
 - c) How the control measures will be monitored and determined to be effective, and what information will be provided to verify this.
- (3) The operator must ensure that transitional facilities processing bee products and other products that may attract flying or crawling insects must be fitted with insect proofing to prevent entry into the transitional facility where uncleared goods are exposed or likely to be exposed.
- (4) The operator and any staff must inform MPI as soon as practicable of the presence of any organism not normally seen or otherwise detected in New Zealand, in accordance with Section 44(1) of the Act.

Guidance 3.10

- The management should take into account the nature of the pests to be controlled, the type of uncleared animal products being received and processed, the nature of the processing, by-products and waste, and the location of the transitional facility.
- The management of pests should also take into account and align with the cleaning and hygiene procedures.
- Insect proofing may include screens over windows and vents, doors flush with the floor, ceiling and walls, ensuring that the interior of the building is free from cracks or holes that would allow entry of insects, or a combination of these measures.

3.11 Contingency plan

- (1) The operator must ensure that contingency plans are in place to manage any situation or incident which may compromise the biosecurity of uncleared animal products. The contingency plan must be included in the operating manual.
- (2) The contingency plan must include:
 - a) The procedures to be followed in the event of an identified situation occurring.
 - b) The resources required and available to effectively manage these situations.
 - c) A description of how the contingency plan will be verified to ensure that it is effective and can be immediately implemented for each situation.

- d) Evidence to verify the effectiveness of each contingency plan.

Guidance 3.11

- Examples of events which may compromise the biosecurity of uncleared animal products include fire, natural disasters (e.g. earthquakes, flood), loss of operator, breaches of security (e.g. theft, containment), unexpected arrival of uncleared animal products, loss of essential services (e.g. electrical power, equipment malfunction), cancellation of facility approval, or inability to operate due to lack of financial resources.
- Contingency plans need to contain sufficient information to enable persons responsible for implementing the plan to respond as quickly as possible. The information needs to be clear and complete, including up to date contact details of key individuals and emergency services (if applicable)
- Testing of contingency plans should be carried out on a regular basis to ensure a smooth implementation of each plan. Testing should also ensure that equipment and other resources are operational and staff know how to use it.

3.12 Internal audit and quality assurance systems review

- (1) The operator must carry out an internal audit and quality assurance systems review at least once every six months. The internal audit and quality assurance systems review report must be included in the operating manual.
- (2) The internal audit must verify that the transitional facility's activities continue to comply with the:
 - a) Transitional facility approval, including the requirements of this standard and any conditions placed on the approval.
 - b) Operator approval, including any conditions placed on the approval.
 - c) Any conditions and requirements in the operating manual.
- (3) A review of the quality assurance systems must be focused on:
 - a) Ensuring that the most appropriate and effective systems, procedures and processes are in place to meet the regulatory requirements.
 - b) Ensuring that there are effective methods to monitor, assess and evaluate those systems, procedures and processes.
 - c) Ensuring that those systems, procedures and processes are being complied with.
 - d) Identifying how the quality assurance system can be improved and how non-compliances can be corrected and prevented.
- (4) The operator must document all audit and review findings in a written report and provide the report to the MPI Inspector within five days of being completed. The report must include:
 - a) The scope and date of the audit.
 - b) The names of the auditors and auditees.
 - c) Any recommendations, non-compliances or corrective actions, and the timeline for their completion.
 - d) The overall conclusions as to whether compliance has been met.
 - e) Signature of the operator and acknowledgement that they agree with the conclusions of the audit and review.

Guidance 3.12

- An example of an internal audit check list is available at: [insert web link]. This internal audit check list is only meant to be a template and needs to be customised to fit the specific requirements of each transitional facility.

3.13 External MPI inspection

- (1) The operator must provide the MPI Inspector access to the transitional facility and all records and documents when requested to verify compliance with this standard. The operator must be present to facilitate the inspection.
- (2) The MPI inspection reports must be included in the operating manual.

Guidance 3.13

- Transitional facilities are assessed by the MPI Inspector to ensure the transitional facility's approval and/or operator's approval, and any other regulatory requirements in relation to uncleared animal products are being complied with. Part of the inspection is ensuring that the provisions in the operating manual are being complied with because those provisions have been approved by MPI as meeting the requirements of this standard.
- The transitional facility will be inspected at least annually by the MPI Inspector. MPI reserves the right to inspect at any time and inspections may be unscheduled.
- Where a transitional facility is not compliant with this standard, the MPI Inspector may recommend the approval for that transitional facility and/or operator be suspended or cancelled. Where non-compliances are found but suspension or cancellation is not initially recommended, inspection frequencies will increase until the MPI Inspector is confident the facility is fully compliant.
- Details of any non-compliances will be given to the operator on a MPI corrective action request (CAR). The CAR details the non-compliance, lists the corrective action(s) and the timeframe that these actions must be completed or resolved.

Schedule 1 – Document History

Date First Issued	Title	Shortcode
TBA	Transitional Facilities for Animal Products	MPI-STD-ANIPRODS
Date of Issued Amendments	Title	Shortcode

Schedule 2 – Definitions

Terms used in this standard that are defined in the Act have the meanings set out in the Act, unless a different meaning is given below.

The Act

Biosecurity Act 1993.

BACC

A biosecurity authority clearance certificate, which is a document given by an Inspector that certifies that the Inspector has given a clearance or a biosecurity authorisation for the goods it relates to.

Biosecurity authorisation

An authorisation given by an Inspector under section 25 of the Act permitting uncleared goods to be moved from a transitional facility or biosecurity control area to another transitional facility, biosecurity control area, containment facility, or to be exported.

By-products

An incidental or secondary product made in the manufacture or process of something else.

CTO

A Chief Technical Officer.

CTO direction

A guideline or direction given by a CTO under section 27(1)b(iii) or 27(1)d(iii) of the Act on measures that may be applied to risk goods to effectively manage risks.

Import permit

A certificate given by the Director-General of MPI under section 24D(2) of the Act.

MPI

Ministry for Primary Industries.

Pest

Includes but is not limited to insects and other invertebrates, birds, rodents, cats, dogs, weeds and microorganisms for the purpose of this standard.