

Identification of organisms

155.04.03

18 December 2023

New Zealand Government

TITLE

Facility Standard: Identification of organisms

COMMENCEMENT

This Facility Standard comes into force on 18 December 2023

REVOCATION

This Facility Standard revokes and replaces the Facility Standard Identification of Organisms, 28 April 2022.

The amendment history to this Facility Standard is set out in Appendix 1: Amendment Record.

ISSUING AUTHORITY

This Facility Standard is issued under section 39(10) of the Biosecurity Act 1993 to incorporate amendments made pursuant to section 166A of that Act.

Dated at Wellington, 18 December 2023

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Introduction

This introduction is not part of the Facility Standard, but is intended to indicate its general effect.

Purpose

This Facility Standard applies to transitional facilities that undertake the identification of vertebrates, invertebrates, microorganisms, and plants associated with uncleared goods for MPI.

Background

The process of identification requires recognised expertise in various scientific disciplines (bacteriology, entomology, mycology, nematology, virology, etc.) and often requires specialised laboratory equipment. Accurate identification is important for biosecurity.

The key elements of a transitional facility approved to this Facility Standard are the effective implementation of a quality management system and the ability of the facility to demonstrate technical competence and generate technically valid results.

Who should read this Facility Standard?

This Facility Standard should be read by operators or prospective operators of transitional facilities that undertake the identification of vertebrates, invertebrates, microorganisms, and plants.

Why is this important?

If a transitional facility does not comply with the requirements of this Facility Standard, it will not be able to undertake organism identifications for MPI.

It is an offence to operate a place as a transitional facility if it is not approved as a transitional facility, or if the person operating the place is not an approved operator of that transitional facility, 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 transitional facility.

Part 1: General Requirements

1.1 Application

- (1) This Facility Standard applies to transitional facilities that undertake the identification of invertebrates, microorganisms, and plants associated with uncleared goods for MPI. This includes:
 - a) Live organisms;
 - b) Dead organisms or parts thereof; and
 - c) Organic material.

Guidance

- This Standard applies to imported commodities that have not received biosecurity clearance and where MPI border staff identify invertebrates, symptoms of pathogens, seeds and other foreign plant material suspected to be a contaminant of biosecurity concern.
- Organisms that have been intentionally imported are not in scope of this Standard and not subject to any of the specified requirements.
- Organisms detected on goods that have received biosecurity clearance, or organisms found within the New Zealand environment are not in scope of this Standard and are not subject to any of the specified requirements.

1.2 Incorporation by reference

- (1) The following documents are incorporated by reference in this Facility Standard under section 142M(1)(a) of the Biosecurity Act 1993 (the Act):
 - a) New Zealand Standard ISO/IEC 17025 General requirements for the competence of testing and calibration laboratories;
 - b) ISTA Accreditation Standard for Seed Testing and Seed Sampling
 - c) Official New Zealand Pest Register (ONZPR).
- (2) Under section 142O(3) of the Act, it is declared that section 142O(1) does not apply. That is, a notice under section 142O(2) of the Act is not required to be published before material that amends or replaces the above listed standards, guideline or lists has legal effect as part of these documents.

1.3 Definitions

Formal identification – The taxonomic classification for an organism to a level sufficient to determine if it is a regulated pest.

ISO – International Organization for Standardization.

ISTA – International Seed Testing Association.

MPI – Ministry for Primary Industries.

Microorganism – A microscopic organism, including protozoa, fungi, archaea, bacteria, viruses, and unicellular algae.

New organism – As defined in the Hazardous Substances and New Organisms Act 1996.

Organism – As defined in the Biosecurity Act 1993. For the purposes of this Facility Standard, organism includes:

a) dead organisms.

Organic material – As defined in the Biosecurity Act 1993.
Plant – Living plants and parts thereof, including seeds and germplasm.
Sample – A small part intended as a representative of the whole.
Uncleared goods – As defined in the Biosecurity Act 1993.
Transitional Facility – As defined in the Biosecurity Act 1993.

Part 2: Operational Requirements

2.1 Organisms and/or organic material to be retained in the facility

- (1) Organisms and/or organic material used for identification purposes must not be destroyed until either a month has elapsed since receipt or the uncleared goods the organisms were taken from are:
 - a) Granted biosecurity clearance; or
 - b) Exported; or
 - c) Disposed of.

Guidance

- Live organisms may be maintained indefinitely but must remain in an appropriate transitional facility unless biosecurity clearance is granted by an MPI inspector.
- Live organisms may be rendered non-viable in which case, refer to the row 'Dead organisms and organic material' in Table 1. Following identification these may be archived.
- If a laboratory receives a non-viable specimen, refer to the row 'Dead organisms and organic material' in Table 1. Following identification these may be archived.
- Archived material is no longer subject to this standard and no longer needs to be secured in a Transitional Facility. e.g., retaining insects as pinned specimens in a collection.
- (2) Organisms and/or organic material can only be directed to facilities approved to this Facility Standard and the relevant facility standards prescribed in Table 1.
- (3) Live organisms may be moved within New Zealand to a facility other than that prescribed in clause 2.1(2) when the receiving facility is a transitional or containment facility specifically approved by the Director-General under the Act for receipt of the organism.

2.2 Competence of laboratory

(1) Facilities must be approved to the standard(s) as prescribed in Table 1.

| Туре | Accreditation Standards | Transitional or Containment Facility Standard |
|----------------|---|--|
| Invertebrates | ISO/IEC 17025 | Identification of Organisms AND Transitional and Containment Facilities Standard for Invertebrates |
| Microorganisms | ISO/IEC 17025 | Identification of Organisms AND Facilities for Microorganisms and Cell Cultures: 2007a |
| Plants (seeds) | ISO/IEC 17025 OR ISTA Accreditation Standard for Seed Testing and Seed Sampling | Identification of Organisms AND Standard for Transitional Facilities for General Uncleared Risk Goods OR Containment Facilities for Plants: 2007 OR Transitional Facilities for Biological Products |

Table 1. Required approvals by type of identification to be undertaken

| Туре | Accreditation Standards | Transitional or Containment Facility Standard |
|-------------------------------------|-------------------------|---|
| Plants (not seeds) | ISO/IEC 17025 | Identification of Organisms AND Containment Facilities for Plants: 2007 |
| Dead organisms and organic material | ISO/IEC 17025 | Identification of Organisms |

2.3 Records and reporting to Ministry for Primary Industries

- (1) Records must be retained for a period of at least seven years and must be available to MPI on request.
- (2) The transitional facility must provide a monthly report to MPI of identifications undertaken in accordance with this Facility Standard for risk management purposes.
- (3) The records to be retained and the reporting to MPI must include the information prescribed in Table 2.

Table 2. Records to be retained and reported

| Records to be retained | Monthly reporting to MPI |
|---|---|
| Description of the received materials | |
| Date of receipt into the transitional facility | |
| Name of the submitting person/organisation | |
| Details of consignment, including: i) Nature of the uncleared good; ii) Country of origin; iii) Consignment or MPI reference number; and iv) Line item number, if supplied. | Details of consignment, including: i) Nature of the uncleared good; ii) Country of origin; iii) Consignment or MPI reference number; and iv) Line item number, if supplied. |
| Lab submission reference number | |
| Third-party consultations (i.e., identifications by subject matter experts, if applicable) | |
| Diagnostic tests/examinations applied | |
| Formal identification of the organism | Formal identification of the organism |
| Number of organisms of each species in sample | |
| Life stages in sample (if applicable) | Life stages in sample (if applicable) |
| Viability of organisms and/or organic material (e.g., living/dead) in sample | Viability of organisms and/or organic material (e.g., living/dead) in sample |
| Date and method of disposal (if applicable) | |
| Associated documentation (e.g., submission form, movement authorisation, etc., if applicable) | |

Guidance

- All reports should be sent to <u>plantimports@mpi.govt.nz.</u>
- The requirements in this Facility Standard are in addition to other record management requirements specified in other standards.
- Laboratories should not provide advice on whether an organism is a:
 - regulated organism
 - unwanted organism
 - notifiable organism
 - new organism.
- The regulatory status of an organism can be found in the <u>Official New Zealand Pest Register</u> (ONZPR).
- If it is not possible to make a conclusive identification of the organism, provide details of the consignment and the best available identification.

2.4 Facility waste

- (1) Facility waste must be:
 - a) securely transported to an approved facility for treatment and disposal following movement authorisation from the MPI Inspector; OR
 - b) destroyed within the facility prior to disposal using any of the following methods:
 - i) a method specified in the relevant transitional facility standard specified in Table 1; OR
 - ii) pressure steam sterilisation for a minimum of 15 min at 121°C or 4 min at 134°C; OR
 - iii) incineration; OR
 - iv) appropriate chemical treatment from the standard AS/NZS 2243:3; OR
 - v) appropriate chemical treatment from the <u>Approved Disinfectants for General Transitional</u> <u>Facilities for Uncleared Goods;</u> OR
 - vi) freezing until the core temperature has been held at (or below) minus 18°C for a minimum of 7 days for fruit fly host material; OR
 - vii) freezing until the core temperature has been held at (or below) minus 10°C for a minimum of 7 days for non- fruit fly host material; OR
 - viii) another approved method listed in <u>Approved Biosecurity Treatments</u>.

2.5 Approval costs

- (1) Facilities must pay fees to obtain transitional facility approval and operator approval, and for the ongoing monitoring and inspections that ensures compliance with this Facility Standard. For current rates, see the <u>Biosecurity (Costs) Regulations 2010</u>.
- (2) Facilities will be subject to annual audits.

Appendix 1: Amendment Record

| | Date | Part Changed | Description |
|---|------------------|-------------------------------|---|
| 0 | 28 April 2022 | | Facility Standard: Standard for Transitional Facilities for the Identification of Organisms revoked. Facility Standard: Identification of organisms issued. |
| 1 | 18 December 2023 | 2.1(1) 2.4 1.1, 2.1-2.3 | Timeframe for keeping specimens added. Additional methods of destruction added. Guidance added for clarity. |
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