



Ornamental Fish and Marine Invertebrates

MPI-STD-ORNAFISH

TITLE

Facility Standard: Ornamental Fish and Marine Invertebrates

COMMENCEMENT

This Facility Standard comes into force on ..

REVOCATION

This Facility Standard revokes and replaces:

Standard for Transitional Facilities for Ornamental Fish and Marine Invertebrates 154.02.06, 20 April 2011

ISSUING AUTHORITY

This Facility Standard is issued

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

Contents	Page
Introduction	3
Part 1: General Requirements	5
1.1 Application	5
1.2 Definitions	5
Part 2: Physical and Structural Requirements	6
2.1 Transitional Facility location	6
2.2 Transitional facility premises	6
2.3 Signage	6
Part 3: Operational Requirements	7
3.1 Operating manual	7
3.2 Transitional facility access and security	9
3.3 Receipt and movement of animals	9
3.4 Water treatment and disposal	10
3.5 Record keeping	11
3.6 Disease surveillance	12
3.7 Training	14
3.8 Cleaning and hygiene	14
3.9 Pest control	15
3.10 Contingency plan	15
3.11 Biosecurity clearance	15
3.12 Internal audit and quality assurance system review	16
3.13 External MPI audit	17
Schedule 1 – Document History	19
Schedule 2 – Definitions	20

Introduction

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 holding uncleared ornamental fish and marine invertebrate species.
- (2) 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.
 - c) Specify quarantine requirements intended to minimise the risk of introducing infectious agents and their transmission to susceptible species in New Zealand.
 - d) Prevent the introduction of ornamental fish and marine invertebrate species that have not been cleared for importation.

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) The risk goods that this standard relates to must go to a transitional facility on arrival in New Zealand. They must remain there until they are given biosecurity clearance or are re-shipped or destroyed.
- (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 Inspectors of facilities holding ornamental fish and marine invertebrates that have been directed on arrival in New Zealand to a transitional (quarantine) facility as a requirement of an import health standard (IHS).

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) Refer to 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) Amendment Regulations 2015*.

Draft for Consultation

Part 1: General Requirements

1.1 Application

- (1) This facility standard applies to transitional facilities holding ornamental fish and marine invertebrates that have been directed to a transitional facility upon arrival in New Zealand.

1.2 Definitions

- (1) For the purposes of this standard, terms used that are defined in the Act have the meanings set out there. The Act is available at the following website: <http://www.legislation.govt.nz/>.
- (2) See Schedule 2 for additional definitions that apply.

Draft for Consultation

Part 2: Physical and Structural Requirements

2.1 Transitional Facility location

- (1) The 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 ornamental fish and marine invertebrates are managed at all times and that adequate provision can be made for the management of contingencies in the event of an incident or containment breach.

2.2 Transitional facility premises

- (1) A fully enclosed building must be provided for the access of people and the holding of ornamental fish and marine invertebrates.
- (2) Floors, walls, ceiling, shelves, benches and all other fixtures must be constructed of materials that can be effectively cleaned and disinfected. They must be maintained so that free water does not lie on the surface.
- (3) The ornamental fish and marine invertebrates must be held in tanks. The tanks must be kept clean and have at least one clear glass side for easy inspection of the fish and marine invertebrates. There must be sufficient lighting to clearly observe their contents. Tanks must be permanently identified so that records of the fish and marine invertebrates can be correlated with each tank.
- (4) Tank lids (or equivalent approved by the Inspector) prevent fish jumping out of tanks and minimise splash contamination must be used, and the Inspector must determine if this is required for fish to be considered as in a separate water system.
- (5) A site plan or map for the entire facility which clearly identifies the area or areas where uncleared animals are received or held must be included in the operating manual as set out in Clause 3.1.
- (6) The quarantine facility must be constructed and operated in a manner that contain in isolation the imported ornamental fish and marine invertebrates.
- (7) During the quarantine period:
 - a) The operator must ensure that no ornamental fish, equipment, or materials are removed from the facility without approval of the Inspector, unless allowed in the current *IHS: Ornamental Fish and Marine Invertebrates from All Countries*.
 - b) The facility must not be used for any purpose other than the quarantine of imported ornamental fish except that scavenger fish and snails may be kept in the tanks for hygiene purposes.

2.3 Signage

- (1) A transitional facility must have prominent signs at all entrances and areas within the building which are designated as a transitional facility under the Act. Signs must warn that entry is restricted to persons permitted by the operator.

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 transitional facility will 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:
 - a) Describe as to how the following standards and requirements will be met in relation to the uncleared animals;
 - i) This standard.
 - ii) Any relevant import health standard (IHS).
 - iii) Any permit to import.
 - iv) Any measures approved in a Chief Technical Officer (CTO) direction under section 27(1)(d)(iii) of the Act.
 - b) Describe how the efficacy of the systems and procedures will be measured and monitored and determined to be continually effective.
- (3) The operating manual, which 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 operating manual 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 animals held in the facility.
 - iii) A site plan of the transitional facility.
 - iv) A description of the design and construction of the facility.
 - c) A site plan and description of the design and construction of the facility.
 - d) The management structure and staff responsible for managing the uncleared animals which 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 or accredited persons (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 import health standard, the import permit 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 that they 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.

- iv) Other key staff.
- v) The operating manual must set out the following contact details:
 - The MPI Inspector with primary responsibility for supervision of the transitional facility.
 - Phone numbers for reporting contamination, and email addresses for requesting transfers, etc.
- e) Activities undertaken:
 - i) *Access and security*: A description of the access and security procedures (see clause 3.2).
 - ii) *Segregation of animals and shared quarantine* (see clause 3.3.1):
 - A description of how the animals will be separated from other animals not of an equivalent biosecurity status, including during movement (if applicable).
 - A description of how these measures and procedures will be monitored, maintained and determined to be effective.
 - iii) *Procedures for identification of ornamental fish*: (see clause 3.3.2).
 - iv) *Waste disposal*: A description of how the disposal procedures for liquid and solid waste will be met. For *water treatment and disposal*: (see clause 3.4).
 - v) *Record keeping*: A description of the types of records kept (see clause 3.5).
 - vi) *Transfers or movement*: A description of how the animals are received from another facility.
 - vii) *Procedures for disease surveillance and reporting* (see clause 3.6).
 - viii) *Training*: A description of staff and visitor training (see clause 3.7).
 - ix) *Repairs and maintenance*: A description of the repairs and maintenance procedures of the facility.
 - x) *Cleaning and hygiene*: A description of the facility's cleaning and personal hygiene regime and how it mitigates risks associated with the animals (see clause 3.8).
 - xi) *Pest control*: A description of the pest control regime (see clause 3.9).
 - xii) *Internal audit and quality assurance systems review*:
 - A description of the scope and the process undertaken for internal audits and quality assurance system review.
 - A description of the procedures for addressing non-compliances (see clause 3.12).
 - xiii) *Document control*:
 - A description of the process for making changes to the operating manual and how the operating manual will be monitored and checked for relevance.
 - Identification of the person(s) responsible for ensuring the operating manual is up to date.
 - A history of the changes to the operating manual.
 - xiv) *Contingency plan*: An outline of potential risks, procedures to be followed in the event of an adverse incident and identification of available resources for the contingency (see clause 3.10).
- (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 reports.
 - 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

The approval of the facility will be limited to the purpose and scope of activities listed in the operating manual.

3.2 Transitional facility access and security

- (1) A transitional facility must have access procedures to ensure the security of fish and marine invertebrates. The access and security procedures must be outlined in the operating manual.
- (2) Only persons (i.e. other than staff members) 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.
- (5) Animals must not be moved from the facility prior to inspection and must remain secure unless biosecurity clearance is obtained from the MPI Inspector.
- (6) During quarantine, access to the facility must only be via the personnel entrance. This entrance should contain an outer changing room that provides for the storage of street clothes and footwear.
- (7) The operator must provide protective clothing and footwear for staff and visitors to use in the facility, to prevent contamination of street clothes and footwear. This must remain in the facility, and always be kept separate from street clothes. Disposable overshoes may be used provided they are destroyed after use.
- (8) The operator must develop procedures for the movement of people to and from the facility that prevent the potential transfer of pathogenic agents from quarantined fish to non-quarantined fish. These procedures must address the risk of transfer via the hands, arms, footwear and clothing. Procedures must include the requirement for people who make contact with fish or water to wash their hands and forearms with soap and water before exit from the facility.
- (9) Procedures for access and exit must be displayed at the entrance.

3.3 Receipt and movement of animals

3.3.1 Shared quarantine

- (1) Each import shipment of ornamental fish and marine invertebrates must be physically isolated from any other shipment, preferably in separate rooms. This isolation includes all equipment associated with the feeding and handling of fish and the water supply. Procedures must address the risk of transfer of pathogenic agents from one shipment to another via agents such as water, equipment, people, their footwear and clothing.
- (2) Alternatively, successive shipments of ornamental fish and marine invertebrates may share the same quarantine period and therefore the same equipment and water circulation. In this event the clearance of all fish in the facility or the room must be delayed until the last shipment is approved for release.

- (3) If ornamental fish and marine invertebrates are to be considered as not in the same direct water system for the purposes of clearance or disease investigation, the following requirements (the related details of which must be approved by the Inspector) must be met:
 - a) Water is not able to be transferred between tanks by splashing or dripping. If the tanks are in close proximity, this may include the need for tank lids.
 - b) Equipment such as nets, gloves (or arms if gloves are not used), feeding equipment, and thermometers must not be used between the tanks, or must be cleaned and disinfected between the tanks.
 - c) Where water flow is between tanks, there must be a system for water sterilisation between tanks e.g. UV irradiation.
 - d) Each group of tanks must be clearly marked to show the date of arrival of the fish.

3.3.2 Identification of ornamental fish

- (1) The operator must be responsible for the identification of the imported ornamental fish and marine invertebrates. In cases where identification of fish or marine invertebrates is in doubt the Inspector may seek advice from MPI, and the operator of the transitional facility must provide proof of identity.
- (2) If an imported ornamental fish or marine invertebrate is not on the approved species list set out in Appendix 2 of the current *IHS: Ornamental Fish and Marine Invertebrates from All Countries* then the operator must notify the Inspector within 7 days of importation. The operator must re-export the fish or have them destroyed under the supervision of the Inspector.

3.3.3 Progeny of imported fish and marine invertebrates

- (1) The progeny of any ornamental fish or marine invertebrates which breed during the quarantine period may be shifted to another tank in the facility but are subject to all quarantine conditions that apply to the parent fish

3.3.4 Removal of material from the facility

- (1) Nothing may be removed from the facility without the approval of the Inspector. The conditions of removal must address the risk of removing pathogens and ornamental fish and marine invertebrates from the facility.
- (2) Equipment taken into the quarantine room must not be removed unless cleaned and disinfected as described in section 3.8.
- (3) Quarantine clothes may be taken away from the facility for laundering at the end of a quarantine period. If an exotic disease has been identified or an investigation is underway, or the operator has chosen euthanasia of fish rather than disease investigation, the clothes must be destroyed in a MPI-approved manner, or soaked in an MPI-approved solution such as 5 % volume/volume dishwashing detergent, nappy cleaner antiseptic, hand cleaner (chlorhexidine or chloroxylonol based) or salt (NaCl).

3.4 Water treatment and disposal

3.4.1 Water disposal treatment

- (1) Provision must be made so the accidental spillage of water from at least two of the largest fish tanks would be directed automatically to an approved disposal system or is contained for treatment.
- (2) All wastewater, when discharged from the quarantine facility, must enter directly into an approved municipal sewerage system, approved septic tank, or other approved disposal system.
- (3) Alternatively, wastewater must be treated by chlorination or with ultraviolet light irradiation (see clause 3.4.3). Chlorinated water must not be discharged directly into adjacent waterways.

3.4.2 Chlorination of waste water

- (1) All water to be treated must pass through a filter capable of removing suspended organic material prior to chlorination.
- (2) An amount of chlorine compound must be added to the effluent in order to achieve a minimum concentration of free residual chlorine of 200 ppm (200 mg per litre) at 1 hour post treatment.
- (3) Before the treatment period commences, the chlorinated effluent must be brought to a pH between 5.0 and 7.0.
- (4) Sodium hypochlorite (bleach) may be used at 1.6 millilitres of hypochlorite solution (12.5% available chlorine) per litre of water, while calcium hypochlorite powder (eg Pool Chlor, 65-70% available chlorine) may be used at 0.3 gram of powder per litre of water.
- (5) The tank must be agitated for a period of not less than 10 minutes to ensure thorough mixing of hypochlorite, and the hypochlorite retained for a period of not less than 1 hour.
- (6) Tanks not achieving the free residual chlorine level required at the specified time in sub clause (2) must be re-treated until the requirement is met.
- (7) The chlorine in the wastewater may be neutralised by adding sodium thiosulphate at a rate of 1.25 grams (2.5 ml of 50% sodium thiosulphate solution) per litre of treated wastewater, then agitated for not less than 10 minutes before discharge.
- (8) Chlorination records must be maintained noting:
 - a) Amount of compound added.
 - b) Volume of effluent.
 - c) Time that treatment period commenced.
 - d) pH at commencement of the treatment period.

3.4.3 Ultraviolet (UV) light irradiation

- (1) All water to be treated must pass through a filter capable of removing suspended organic material and, where necessary, other filtration to ensure that the UV transmittance of the water is within manufacturer's specifications prior to irradiation.
- (2) Commercial UV water treatment units operating in the spectral range of 190-280 nm (254 nm recommended) delivering doses of at least 130 mWs/cm² must be used. The dose is calculated as the product of the intensity (mW/cm²) and the exposure time in seconds (s). Servicing and maintenance must be done at least as frequently as required by the manufacturer of the UV sterilisation system. The bulbs must be monitored regularly to ensure they are delivering the appropriate intensity. Filters need to be checked to make sure they are functioning.

3.5 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, for auditing purposes, maintain for at least three years the following records filed with each shipment:
 - a) Overseas supplier, country of origin, dates of arrival and release date.
 - b) Number of each ornamental fish and marine invertebrate species, in total, and by tank.
 - c) Details of clinical signs of disease, number affected in a tank and treatment.
 - d) Details of ornamental fish and marine invertebrate mortality by tank.
 - e) Details of water quality parameters.
 - f) Details of laboratory test results.
 - g) Details of destruction of packaging where MPI-approved methods are required.

- h) Details of significant management changes, such as food changes, and power and aeration failures.
 - i) Biosecurity clearances.
 - j) Internal audits and corrective actions.
 - k) External audits and corrective actions.
- (3) The Inspector must make an inspection record in the appropriate MPI database for each import of ornamental fish and marine invertebrates showing:
 - a) The date of arrival.
 - b) The country of origin.
 - c) The number of fish on arrival.
 - d) Date of biosecurity clearance.
 - e) The number of fish released.
 - f) A summary report providing:
 - i) Details of significant sickness, mortalities, treatments and laboratory findings.
 - ii) The corrective action request (CAR) issued and progress toward compliance.
- (4) The Inspector is required to keep records of inspections and audits of the operation of quarantine. These records which are to be archived must include:
 - a) Audit findings.
 - b) Reports of critical situation reports, CARs and the results of follow-up visits.
 - c) Reports of major disease incidents and outcomes.

3.6 Disease surveillance

- (1) If the Inspector decides a disease investigation is warranted based on clinical signs of illness or death of ornamental fish or marine invertebrates, and gives the importer the option to test the fish (at the importer's expense) or destroy/reship the affected fish, and the operator chooses not to have fish tested, all other fish in the batch must be reshipped or euthanized and double-bagged before destruction by a MPI-approved method.
- (2) The consequences of testing or the decision not to test (see clause 3.6(1)), must be completed before other fish in the batch are given biosecurity clearance. Other fish in the batch may be given biosecurity clearance one week after being in a clean direct water system or on successful completion of quarantine as determined by the Inspector, whichever is the longer.
- (3) Dead fish must be removed from tanks as soon as possible and kept in a freezer (or otherwise as directed) until released, directed for MPI-approved destruction, or taken for testing by the Inspector. The operator must have a system in place to identify dead fish by consignment. If the information is to be used as information for disease investigation, high risk species must be identifiable by species, tank, week of death, and low risk species by week of death.
- (4) All disease testing must be conducted at the Investigation and Diagnostic Centre of Biosecurity New Zealand, Upper Hutt, Wellington.
- (5) The following are permitted for routine prophylactic use:
 - a) Salt
 - b) Formalin
 - c) Methylene blue
 - d) Malachite green
 - e) Copper sulfate
 - f) Chloramine-T
 - g) Benzalkonium chloride
 - h) Acriflavine
 - i) Quinine sulphate

- j) Hydrogen peroxide
 - k) Bay oil (*Pimenta racemosa*)
 - l) Tea tree oil (*melaleuca*)
- (6) No other medication of chemicals or drugs is to be administered to ornamental fish or marine invertebrates without prior written approval from the Inspector.
- (7) Anthelmintic treatment protocols used in risk mitigation (see Appendix 1 of the *IHS: Ornamental Fish and Marine Invertebrates from All Countries*) must be approved by the Inspector before use.
- (8) Treatments or prophylactic measures must not interfere with disease surveillance and must be recorded.
- (9) The Inspector may take water or other samples for testing at any time.

3.6.1 Occurrence of an exotic disease

- (1) The operator must observe ornamental fish and marine invertebrates for signs of illness and abnormal behaviour periodically throughout the day. Daily records must be kept by tank and species including, as a minimum, the number of fish dead and a brief description of any abnormalities on the cadavers.
- (2) Ornamental fish and marine invertebrates must be available for inspection by the Inspector who must be allowed to take specimens at any time for disease testing. The operator must provide the Inspector with packaging for the fish as required.
- (3) For species that are not high risk species, the operator must maintain records as detailed in section 3.5 and provide them to the Inspector as requested.
- (4) For high risk species, the operator must maintain records as detailed in section 3.5 and provide them to the Inspector as requested.
- (5) The operator must notify the Inspector if fish display clinical signs of infection with pathogens listed in Appendix 1 of the *MPI Import Health Standard for Ornamental Fish and Marine Invertebrates from All Countries* or increased/significant mortality.
- (6) Where the operator claims that mortalities are linked to non-listed pathogens, or to environmental causes, evidence must be presented to the Inspector. Evidence may include records regarding fish health on arrival, microscopy results, regular water quality parameter records, and other environmental or operational records.
- (7) If an exotic disease is diagnosed, the operator must notify the chief technical officer within 24 hours.
- (8) In the event of a positive test result for an exotic disease all fish in the batch must be tested and shown to be free of the relevant disease organism/s, or euthanased (in which case testing is not mandatory).
- (9) In the event of a positive test result for an exotic disease, or when the operator chooses not to have fish tested:
- a) All ornamental fish and marine invertebrates directed by the Inspector must be destroyed.
 - b) All dead ornamental fish or marine invertebrates must be double bagged and removed from the facility by the Inspector for disposal.
 - c) The protective clothing, packaging, tanks and equipment from the direct water system and any parts of the facility that are potentially contaminated must be thoroughly cleaned and disinfected (section 3.8) or destroyed.
 - d) All fish testing and destruction, and cleaning must be under direction of the Inspector.

Guidance 3.6.1

- (1) When exotic disease is suspected, the Inspector may order any tests deemed necessary to be able to give biosecurity clearance to ornamental fish and marine invertebrates in the shipment that test negative or are not part of the disease investigation.

- (2) The chief technical officer may order further tests, and/or the destruction of fish, treatment of tank water, the cleaning and decontamination of equipment and facilities.
- (3) Diseased fish may only be treated with approval from the Inspector.
- (4) The Inspector may direct the management of disease control and extend the period of quarantine or contact the chief technical officer to recommend the destruction of the ornamental fish or marine invertebrates. If the chief technical officer orders destruction of a shipment, all shipments in the facility may be destroyed if there is doubt about the isolation of shipments.
- (5) Other fish in the direct water system may be cleared one week after being moved to a clean direct water system or on successful completion of quarantine as determined by the Inspector, whichever is the longer.

3.7 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 the animals, and for visitors to the facility. The programme must describe how the training is to be implemented, how the effectiveness of training is assessed, and the time scales for implementation and refresher courses. The training programme must be described in the operating manual.
- (3) The operator must ensure that persons likely to be handling animals are aware of and understand the following:
 - a) The requirements of this standard.
 - b) The documentation related to the management of the animals.
 - c) Their responsibilities and obligations while in the transitional facility in relation to the management of the animals.

Guidance 3.8

Visitors to the transitional facility might include contractors undertaking repairs and maintenance work, persons transporting animals, 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 animals they may come in contact with.

3.8 Cleaning and hygiene

- (1) Facilities must be available for adequate cleaning and disinfection:
 - After exotic disease is diagnosed, or the operator chooses not to have fish tested when the exotic disease is suspected (see clause 3.6.1).
 - When using equipment between water systems (see clause 3.3.1).

This includes all equipment such as filters and tanks that come in contact with water or fish in quarantine.

- (2) Equipment and fish tanks must be thoroughly cleaned before disinfection:
 - a) Hypochlorite solution at 200 ppm for 5 minutes, or
 - b) An approved iodophore solution containing 0.5% available iodine for 5 minutes, or
 - c) Other approved disinfection methods.

3.9 Pest control

- (1) Surveillance must be maintained for the presence of vermin and control activities undertaken if they are detected.

3.10 Contingency plan

- (1) Contingency plans must be in place to take account of a vehicle breakdown or accident during transport of ornamental fish, and fire, flooding or any other emergency. Resources must be identified and accessible for the contingency. The Inspector must be advised of the emergency as soon as is possible.

3.11 Biosecurity clearance

- (1) At the end of the quarantine period the Inspector must consider if the following conditions have been met:
 - a) The conditions of the import health standard have been met and the documentation certification is in order.
 - b) The transitional facility has been operating according to this standard.
 - c) The ornamental fish and marine invertebrate species are approved for importation.
 - d) The ornamental fish and marine invertebrates are in good health and there is no evidence of exotic disease.
- (2) The Inspector's consideration must include, but is not limited to:
 - a) Type (freshwater or marine) and country of origin of ornamental fish and marine invertebrates.
 - b) Date of arrival and proposed date of release.
 - c) Probable cause of disease, mortality and morbidity.
 - d) Laboratory findings.

Guidance 3.11

Once satisfied that the conditions of this standard have been met, the Inspector may issue a biosecurity clearance in writing to the operator.

3.11.1.1 Minimum requirements for inspection

- (1) The Inspector shall have a schedule for regular inspection of the facility and audit of operator's procedures. The Inspector shall make as many visits as considered necessary but the minimum number of visits is:
 - a) For high risk fresh water fish, three times during the quarantine period:
 - i) On arrival (immediately or within 48 hours on a percentage of shipments basis);

- ii) At 13-16 days;
 - iii) Prior to release.
- b) For low risk freshwater fish and all marine fish and invertebrates, two visits:
 - i) On arrival (immediately or within 48 hours on a percentage of shipments basis);
 - ii) Prior to release.
- (2) Prior to the last Inspector visit, the operator must forward records of fish mortality and any necessary evidence (see 3.6.1.4) required by the Inspector to make a decision on whether the fish may be released.
- (3) Arrival inspections must include:
 - a) Collect CITES documentation.
 - b) Check the shipment for plants. Supervise their destruction by treatment with steam treatment, incineration or another MPI-approved method.
 - c) Correlate the commercial fish list documents with the number (as close as possible) and species of ornamental fish and marine invertebrates.
 - d) Check for the presence of non-approved ornamental fish and marine invertebrate species.
 - e) Verify the number of fish remaining from previous shipments if in direct water systems with the new shipment.
- (4) At every visit the Inspector shall:
 - a) Be satisfied that the operator and the facility continue to meet the requirements of this standard.
 - b) Inspect the ornamental fish and marine invertebrates for any signs of disease.
 - c) Check for the presence of non-approved ornamental fish and marine invertebrate species.
 - d) Inspect quarantine records.
- (5) After release visit:
 - a) Make arrangements for biosecurity clearance for ornamental fish when requirements of 3.11 are met.

3.11.1.2 Submission of specimens to the laboratory

- (1) Specimens must be submitted to the laboratory at the discretion of the Inspector.
- (2) All disease testing must be conducted at the Investigation and Diagnostic Centre of Biosecurity New Zealand, Upper Hutt, Wellington.
- (3) The Inspector must phone the laboratory before submitting samples, to advise the laboratory and receive direction on the type of samples to send. Packaging of specimens of potentially infectious material must be in accordance with instructions from the laboratory.
- (4) The operator must provide packing materials for specimens to be sent to the laboratory as required. Samples are to be dispatched in a clearly addressed sealed box by the fastest secure method. Samples must be accompanied by a biosecurity authorisation clearance certificate (BACC) for transfer to the laboratory (a transitional facility).

3.12 Internal audit and quality assurance system 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 kept as a record.
- (2) The internal audit is an assessment of the facility activities to verify that activities continue to follow the procedures outlined in the operating manual and meet the requirements of this standard and the ornamental fish and marine invertebrates import health standard. 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) Specifications and requirements in the operating manual.
- (3) A review of the quality assurance systems includes reviewing the operating manual to ensure its continuing suitability and effectiveness and to introduce any necessary changes or improvements. The review 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 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.

3.13 External MPI audit

- (1) The MPI inspection reports must be kept as a record.
- (2) The operator of the transitional facility must ensure that the facility is assessed by an MPI Inspector to ensure the requirements specified in this standard are met.
- (3) The operator must provide the MPI Inspector, or any other representative of the chief technical officer, access to the facility, records and documents for inspection and audit. The operator must be available to assist and ensure that all relevant procedures and records are made available to the Inspector.

Guidance 3.13

The Inspector will conduct inspections and on-site audits as specified in section 3.14. Additional audits will be conducted as required, and are based on the performance of the operator, especially if non-compliance is found.

Transitional facilities are assessed by the MPI Inspector to ensure the transitional facility's approval and operator's approval, and any other regulatory requirements in relation to the animals 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.

Should the operator display a lack of sufficient knowledge leading to failure of an inspection, the MPI Inspector may require the operator to re-take the relevant training course or recommend suspension or cancellation of the operator approval.

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 CAR. The CAR details the non-compliance, lists the corrective action(s) and the timeframe that these actions must be completed or resolved.

Draft for Consultation

Schedule 1 – Document History

Date First Issued	Title	Shortcode
20 April 2011	Standard for Transitional Facilities for Ornamental Fish and Marine Invertebrates	154.02.06
Date of Issued Amendments	Title	Shortcode
	Facility Standard: Ornamental Fish and Marine Invertebrates	ORNAFISH.TF

Draft for Consultation

Schedule 2 – Definitions

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.

Batch

All ornamental fish or marine invertebrates in the same direct water system that share susceptibility to any pathogens from Appendix 1 of MPI *Import Health Standard: Ornamental Fish and Marine Invertebrates from All Countries*.

Biosecurity Clearance

A clearance under section 26 of the Biosecurity Act 1993, for the entry of goods into New Zealand.

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.

Direct Water System

Water system with flow or operating practices (eg use of the same nets and gloves without sterilisation, splash from lidless tanks) between tanks that allow potential pathogen transfer.

Water treatments between tanks (eg UV filters) and operating practices must be approved by MPI for tanks to be considered as not in the same direct water system.

Director-General

The chief executive of the Ministry for Primary Industries or his/her delegate.

High Risk Fish Species

Species of ornamental fish and marine invertebrates with approval to be imported to New Zealand that are susceptible to one or more diseases listed in Appendix 1 of MPI *Import Health Standard: Ornamental Fish and Marine Invertebrates from All Countries*. These fish are listed in Appendix 1 of the HIS.

Import permit

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

Inspector

A person appointed as an Inspector under the Biosecurity Act, 1993.

Laboratory

MPI approved veterinary diagnostic laboratory that is also a transitional facility.

Low risk fish species

Species of ornamental fish and marine invertebrates listed in Appendix 2 and not specifically listed in Appendix 1 of the MPI *Import Health Standard: Ornamental Fish and Marine Invertebrates from All Countries*.

MPI

Ministry for Primary Industries.

Ornamental Fish

Approved species of fresh water fish, marine fish and marine invertebrates. The approved species are listed in Appendix 2 of the MPI *Import Health Standard: Ornamental Fish and Marine Invertebrates from All Countries* the import health standard.

Operator

The person who has overall responsibility for the facility, its maintenance and operation in terms of section 40 of the Biosecurity Act, 1993.

Pest

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

Procedure

A document that specifies, as applicable, the purpose and scope of an activity; what shall be done and by whom; when, where, and how it shall be done; what materials, equipment, and documentation shall be used; and how it shall be controlled.

Quarantine

Confinement of organisms or organic material that may be harbouring pests or unwanted organisms. Section 2, Biosecurity Act, 1993.

Quarantine period

A minimum period of quarantine as specified in the *IHS: Ornamental Fish and Marine Invertebrates from All Countries*.

Risk goods

Any organism, organic material, or other thing or substance, that (by reason of its nature, origin, or other relevant factors) it is reasonable to suspect constitutes, harbours, or contains an organism that may:

- a) Cause unwanted harm to natural and physical resources or human health in New Zealand; or
- b) Interfere with the diagnosis, management, or treatment, in New Zealand, of pests or unwanted organisms: Section 2, Biosecurity Act, 1993.

Test (when used in relation to testing of batches)

A representative number of fish (as determined by the Inspector and MPI) tested to show that the batch of fish is free from a specified disease of concern.

Note: The number of fish required for a batch test will vary with such factors as the species of fish, number of fish in the batch and the disease agent being investigated, and will be determined by MPI on a case basis.

Uncleared Goods

Imported goods for which no biosecurity clearance has been given. Section 2, Biosecurity Act 1993.

Unwanted Organisms

Any organism that a chief technical officer believes is capable or potentially capable of causing unwanted harm to any natural and physical resources or human health: Section 2, Biosecurity Act 1993.

Draft for Consultation