



# Facility Standard

## Standard for Offshore Facilities Holding and Testing Plants for Planting

[Subtitle]

1 September 2019

## **TITLE**

Facility Standard: Standard for Offshore Facilities Holding and Testing Plants for Planting

## **COMMENCEMENT**

This Facility Standard comes into force on 1 September 2019

## **REVOCATION**

This Facility Standard revokes and replaces MAF Biosecurity Authority (Plants) Standard PIT.OS.TRA.ACPQF: Accreditation of Offshore Plant Quarantine Facilities and Operators, dated 8 October 2001.

## **ISSUING AUTHORITY**

This Facility Standard is issued by the Ministry for Primary Industries.

This standard is not issued under the Biosecurity Act.

Dated at Wellington, 1 September 2019

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## Introduction

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

## Purpose

This standard specifies the structural and operational requirements for:

- a) Offshore facilities holding plants for planting from which selected plant(s) or plant material(s) would be exported to New Zealand and, for
- b) Offshore facilities conducting tests on plants for planting prior to export to New Zealand.

## Background

The import of plants for planting is a high risk pathway for the inadvertent introduction of quarantine pests (referred to as 'regulated pests') into New Zealand. This is because pests are often associated with imported plant parts and can survive in living plant material that may not show any signs of infection.

The Import health standard (IHS) for plants for planting allows for plants of certain species to be imported, under predetermined conditions, into a lower level of quarantine or with a shorter period of quarantine in New Zealand, if sourced from an MPI-approved offshore facility where plant material has been tested for, and found free from, specified regulated pests prior to export. This can only occur if the following are in place:

- a current import health standard for the relevant plant species;
- an MPI approval for the offshore facility holding and testing plants for planting; and
- a signed agreement between MPI, the offshore facility and their NPPO on the effective phytosanitary measures to be implemented by the facility including the requirements of this standard.

## Who should read this Facility Standard?

This Facility Standard should be read by any person wishing to have an offshore facility approved for the purpose of importing plants for planting into New Zealand.

## Why is this important?

MPI must have confidence that plant material exported from an offshore facility is free from specified, regulated pests to prevent their introduction into New Zealand.

Non-conformance with this standard or the relevant IHS may result in biosecurity clearance being denied and the imported plant material may be reshipped or destroyed. Non-conformance may also result in suspension or cancellation of the MPI approval for the facility.

## Document History

Refer to Appendix 1 for the amendment record of this standard.

## **Other information**

### **Layout**

The standard has a general requirements section (Part 2) that applies to facilities holding plants for planting and testing these plants. Part 3 has specific requirements for offshore facilities holding plants for planting only and Part 4 is specific requirements for offshore facilities undertaking the testing of plants for planting only.

### **Guidance**

The information contained within a border throughout this document is for guidance and is not part of the statutory requirements.

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## Part 1: Requirements

### 1.1 Application

- (1) This standard applies to offshore facilities approved by MPI for:
- a) holding plants for planting to be exported to New Zealand under the relevant Import health standard (IHS)<sup>1</sup>, for the following types of plants for planting as defined in the relevant IHS<sup>1</sup>:
    - i) dormant cuttings;
    - ii) non-dormant cuttings;
    - iii) rooted cuttings;
    - iv) whole plants; and
    - v) plants in vitro [tissue cultures],
- and
- b) testing of plants for planting for specified regulated pests prior to export to New Zealand according to MPI's pre-export testing agreement between MPI, the facility and their NPPO.

#### Guidance

- The holding and testing of plants for planting is usually done at the same facility. However, MPI will consider approving a different facility to do some or all tests. If so, the separate testing facility will also need to be approved by MPI under this standard.

### 1.2 Incorporation by reference

#### Guidance

- This standard is incorporated by reference in the relevant IHS for plants for planting and thus becomes a mandatory requirement under the IHS for importers wishing to import from an MPI-approved offshore facility.

### 1.3 Definitions

- (1) Abbreviations and definitions of terms used in this standard are set out in Appendix 2.

<sup>1</sup> To date, the MPI Import health standards (IHS) relevant to plants for planting include the IHS 155.02.06: *Importation of Nursery Stock*, and the MPI.IHS.ACTINIDIA.PFP: *Import health standard for Actinidia plants for planting* and can be found at the following link: <https://www.biosecurity.govt.nz/importing/plants/nursery-stock/requirements-documents-for-importing-nursery-stock/>.

## Part 2: General Requirements

### 2.1 Application

- (1) The requirements of this section apply to both offshore facilities holding plants for planting, and to offshore facilities conducting tests on plants for planting (together referred to as 'offshore facility').
- (2) Specific requirements for facilities holding and testing plants for planting are set out in Parts 3 and 4 of this standard, respectively.

### 2.2 Management system

#### 2.2.1 System manual

- (1) The offshore facility must have a system manual, which describes how the facility meets the requirements of this standard. The system manual must include, but is not limited to, the following:
  - a) an overview of the facility's management system including the identification of key personnel with responsibility for:
    - i) the holding and testing of plants destined for export to New Zealand, and
    - ii) communicating with MPI
  - b) documented operating procedures and work instructions for:
    - i) facility access (refer to 2.3.1)
    - ii) staff competence and training (refer to 2.3.2)
    - iii) equipment maintenance (refer to 2.3.3)
    - iv) specific operational requirements for the facility holding plants for planting (refer to 3.2) and for the facility conducting tests on plants for planting (refer to 4.2)
  - c) control and maintenance of records relating to facility activities of plants for planting (refer to 2.4)
  - d) communication with MPI (refer to 2.5)
  - e) internal audit of the system (refer to 2.7).
- (2) The facility must notify any major changes to the management system or the system manual to MPI by emailing to [plantimports@mpi.govt.nz](mailto:plantimports@mpi.govt.nz) within 14 calendar days.

#### Guidance

- The management or corporate entity may be different for the facility holding and testing plants for planting when these facilities are independent to each other.
- Management system: the management system can be based on an international standard such as ISO 9001 or ISO 17025 or equivalent (e.g. good laboratory practice).
- System manual: documented procedures should be detailed enough to allow transparency of actions related to the requirements of this standard and should include what, how, where and when activities are undertaken and who is responsible for completing these activities.
- Major changes to the management system or system manual: examples of major changes include (but not limited to):
  - changes in key staff involved in the work related to the holding and testing of plants for planting destined for export to New Zealand;
  - modification of the procedures related to pest management;
  - a significant modification or change to a diagnostic test

- *Contingency plan*: it is recommended that a contingency plan be put in place by the facility in the event of one or more key staff leaving, to ensure the continuity of the work related to this standard

## 2.3 Resources and infrastructures

### 2.3.1 Facility access

- (1) The offshore facility must have controlled access to:
  - a) the area of the facility holding plants for planting in order to maintain the plant health status and the integrity of traceability systems, and
  - b) the area of the facility undertaking testing of plants for planting in order to ensure the integrity of testing results.
- (2) The MPI auditor(s) must be granted access to the offshore facility for audit purposes and at a suitable time as agreed between the two parties.
- (3) The facility's personnel must provide reasonable assistance to the MPI auditor(s) in carrying out the audit.

### 2.3.2 Personnel

- (1) The offshore facility must have personnel with the technical qualifications, skills and experience appropriate for the holding, inspection, treatment and testing of plants for planting destined for export to New Zealand.
- (2) Personnel must follow all processes and procedures documented in the facility's system manual.

#### Guidance

- *Training*: a training programme defined by the offshore facility should be in place for all new staff, to ensure competency, and there should be appropriate supervision and monitoring of new staff. Ongoing training should be provided for other staff, as required.

### 2.3.3 Equipment

- (1) The offshore facility must ensure that all equipment used to meet the requirements of this standard is maintained, calibrated and appropriately cleaned to ensure it is fit for purpose.

#### Guidance

- *Cleaning products*: should be of known efficacy to effectively kill the pests that may be associated with plants.
- *Calibration of equipment*: the intervals between calibration should be appropriate to the use, type and manufacturer's recommendation.

## 2.4 Facility Hygiene

- (2) The offshore facility must have effective hygiene procedures in place to:
  - a) prevent entry, spread and establishment of pests within the facility;
  - b) monitor, identify and treat pests and potential vectors, and maintain pest absence within the facility;
  - c) ensure that plants that have been tested for, and found free from, any regulated pests specified in the agreement between MPI and the offshore facility are held in a manner to prevent re-infestation with those pests.



### Guidance

- As part of providing effective hygiene practices, all plants that have been tested for regulated pests in accordance with the agreement should be regularly monitored for any signs and symptoms of those pest, or their vectors. This may include regularly inspecting plants for signs of these pests and monitoring for vectors (for example using sticky traps).
- *Methods of monitoring*: these may be different trapping system (e.g. yellow sticky traps), regular examination of plants.
- *Plant protection practice*: these may be pesticide, biological control agents to control insects, mites, nematodes and fungi. Information can be found in the EPPO standard PP 2: *Good plant protection practice*.
- *Facility hygiene*: information on facility hygiene can be found in the IPPC guidelines: *Guide to delivering phytosanitary diagnostic services*, [https://www.ippc.int/static/media/files/publication/en/2018/06/Diagnostics\\_manual\\_English\\_1.1.pdf](https://www.ippc.int/static/media/files/publication/en/2018/06/Diagnostics_manual_English_1.1.pdf).

## 2.5 Records

- (1) Records generated by the offshore facility must be maintained for all activities related to plants for planting destined for export to New Zealand and must include names of the personnel who undertook these tasks and the date of the activity.
- (2) All records must be kept for at least seven years and be made available to MPI within a reasonable time on request.
- (3) In addition to the technical and diagnostic records specified in sections 3.2.9 and 4.2.5, the offshore facility must keep, but are not limited to, the following records:
  - a) competencies, skills and experience, and training for personnel responsible for the holding and testing of plants for planting (refer to section 2.3.2);
  - b) internal and external audit reports, including any corrective actions to correct non-conformances (refer to section 2.6); and
  - c) cleaning, maintenance and calibration of equipment (refer to section 2.3.3).

### Guidance

- Information on the type and content of records can be found in the guidelines of ISPM 36: *Integrated measures for plants for planting*.

## 2.6 Communication

### 2.6.1 Pest reporting

- (1) The offshore facility must notify MPI if a pest regulated by MPI, or a pest of unknown regulatory status, is found in:
  - a) the facility where plants for planting destined for export are being held, or
  - b) the area of the facility where the plants for planting were being held, after the plants were exported to New Zealand.
- (2) Pests to be reported to MPI are those that have unknown regulatory status, or are listed as regulated on:
  - a) the relevant IHS for plants for planting
  - b) the Agreement letter between the facility and MPI;

- c) the MPI Biosecurity organisms register for imported commodities (BORIC) database <https://www.biosecurity.govt.nz/news-and-resources/resources/registers-and-lists/biosecurity-organisms-register-for-imported-commodities/>.
- (3) The facility must send a pest report to MPI via the email address [plantimports@mpi.govt.nz](mailto:plantimports@mpi.govt.nz) within 48 hours of pest identification. When there is a significant delay in confirming the identification of a regulated pest, a preliminary report must immediately be provided.
- (4) The pest report must include:
  - a) the identity of the pest including the scientific name;
  - b) the date of detection;
  - c) the name of the plant species concerned, and
  - d) whether any plants derived from infested mother plants have been previously exported to, or are about to be exported to New Zealand.

#### Guidance

- MPI recommends the reporting of regulated pests to follow the guidelines of ISPM 17: *Pest reporting*.
- If a detected pest is not listed in any of the documents listed in 2.6.1 (1) a)-c), the facility should contact MPI directly to clarify the regulatory status of the pest.

## 2.6.2 Non-conformances

- (1) The offshore facility must clearly document the occurrence of any non-conformances with this standard, and corrective actions taken.
- (2) The facility must notify any critical non-conformances with the system manual or with this standard to MPI by emailing to [plantimports@mpi.govt.nz](mailto:plantimports@mpi.govt.nz) within 48 hours of becoming aware of the non-conformance, and must resolve them before export of plants for planting to New Zealand can commence/continue.

#### Guidance

- Examples of critical non-conformances to communicate include, but are not limited to: failure of the facility to conduct and record required inspections of plants; failure to detect significant and obvious non-compliances; failure to meet the requirements of this standard.

## 2.7 System Conformance

- (1) The offshore facility must conduct an annual internal audit of their activities for conformance with this standard and the system manual. The internal audit is the responsibility of the facility and must be conducted by personnel independent of the audited activities. Any corrective actions must be completed in a timely manner.
- (2) In addition, the following audits of the offshore facility's activities for conformance with this standard and the system manual must be conducted :
  - a) *External audits* (responsibility of the facility) – either by the National Plant Protection Organisation (NPPO) of the exporting country, or their delegated authorities; or an ISO certification body; or a third party approved by MPI to conduct the audit, at a frequency agreed with MPI, and;
  - b) *MPI audits* - the frequency and timing of which will be determined by MPI.
- (3) All internal and external audit reports and corrective actions taken must be provided to MPI within 30 days of completion of the audit report.

**Guidance**

- *Frequency and timing of audits:* MPI recommends annual external audits. The relative timing of external and MPI audits may be alternated or occur simultaneously (for example when the facility is audited for the first time).
- When determining the frequency and timing of MPI audits, MPI will take into account internal and external audits, the scope and outcome of those audits, and whether they meet MPI's auditing expectations. MPI audits may be less frequent if MPI considers that the facility has an appropriate level of oversight by external accreditation bodies, and that have a good history of compliance.

## 2.8 Suspension and termination of MPI's approval

- (1) MPI may suspend or terminate the approval of an offshore facility by written notice to the facility and their NPPO if:
  - a) the facility is not conforming to this standard; or
  - b) the facility is not conforming to any specific conditions included in the agreement with MPI; or
  - c) the phytosanitary status of the plants for planting destined for export to New Zealand may be compromised.
- (2) MPI may reinstate an offshore facility's approval by written notice to the facility and their NPPO only when all conditions prescribed by MPI have been met.

**Guidance**

- MPI will formally advise the offshore facility and their NPPO of the date from which their approval will be suspended/reinstated/terminated.

## Part 3: Specific requirements for offshore facilities holding plants for planting

- (1) The requirements of this section are only applicable to an offshore facility holding plants for planting destined for export to New Zealand and are in addition to the requirements specified in Part 2 of this standard.

### 3.1 Physical requirements

- (1) The offshore facility holding plants for planting must be designed, constructed and maintained to ensure effective prevention of infestation, infection or contamination of pests and their vectors on plants for planting destined for export to New Zealand.

#### Guidance

- Information on facility design can be found in the guidelines of ISPM 34: *Design and operation of post-entry quarantine stations for plants* and ISPM 36: *Integrated measures for plants for planting* for the infrastructure.
- *Contingency plan*: a contingency plan to manage any situation or incident that may compromise the phytosanitary status of plant material held in the facility should be considered by the facility. Examples of incidents are: electrical outages, fires, holes in the facility's structure, decontamination of a facility after detecting a regulated pest.

### 3.2 Operational requirements

#### 3.2.1 Inspection of plants

- (1) Designated personnel at the offshore facility holding plants for planting must inspect all plants in the facility for signs and symptoms of pests during production and propagation. The frequency of inspection must be appropriate to the type of pests that may be associated with the plants.

#### Guidance

- *Frequency of inspection*: frequency of inspection for some plants for planting species are specified in the relevant IHS for plants for planting and must be followed.

#### 3.2.2 Pest identification

- (1) If a suspected pest or pests, are observed during inspection of plants for planting, designated personnel at the offshore facility holding plants for planting must collect a sample as soon as practicable and send to the diagnostic laboratory for identification.
- (2) For **specific pest testing** required prior to export to New Zealand, refer to section 3.2.5 (below).

#### 3.2.3 Specific pest testing

- (1) Specific tests must be conducted on the plants for planting by an MPI-approved facility prior to export to New Zealand as per the relevant IHS for plants for planting and the Agreement between MPI, the facility and their NPPO.
- (2) The offshore facility must make the testing history available to MPI prior to exporting the plants for planting to New Zealand

### **3.2.4 Traceability of plants**

- (1) The offshore facility holding plants for planting must have a system for identification and tracing of plants from arrival at the facility to dispatch for export to New Zealand.

### **3.2.5 Maintenance of the plant's phytosanitary status**

- (1) Designated personnel at the offshore facility holding plants for planting must maintain the phytosanitary status of plants for planting after any inspection and testing is done.
- (2) If the phytosanitary status cannot be maintained, then plant material must not be exported to New Zealand.

### **3.2.6 Technical records**

- (1) In addition to the records described in section 2.5 the offshore facility holding plants for planting must, as a minimum, also keep the following records to ensure the integrity and transparency of the results:
  - a) identity of source of plant material, including country of origin;
  - b) pest management activities;
  - c) plant inspections;
  - d) results of testing carried out as required in the agreement between MPI and the facility;
  - e) pre-export inspection and treatment activities;
  - f) phytosanitary certificates and import permits.
- (2) These records must be kept and be made available to MPI as described in section 2.5.

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## Part 4: Specific requirements for offshore facilities testing plants for planting

- (1) The requirements of this section are only applicable to the offshore facility conducting tests of plants for planting destined for export to New Zealand and are in addition to the requirements specified in Part 2 of this standard.

### 4.1 Physical requirements

- (1) The offshore facility conducting testing of plants for planting (i.e. laboratory) must be designed to prevent contamination of samples from the time of sample receipt to the end of processing.

#### Guidance

- *Design of the facility:* it should take into account at least the key steps of the diagnosis process with consideration of possible source of contaminations and incompatible steps. Key steps of the diagnosis process are reception of samples, preparation of samples, testing of samples and storage of samples and reagents. Information can be found at the IPPC guidelines: *Guide to delivering phytosanitary diagnostic services*, [https://www.ippc.int/static/media/files/publication/en/2018/06/Diagnostics\\_manual\\_English\\_1.1.pdf](https://www.ippc.int/static/media/files/publication/en/2018/06/Diagnostics_manual_English_1.1.pdf).

### 4.2 Operational requirements

- (1) The offshore facility conducting testing of plants for planting must be operated in a manner to:
- a) prevent contamination of samples from the time of sample receipt to the end of processing
  - b) ensure accurate performance of required tests.

#### 4.2.1 Samples and handling

- (1) All practicable steps must be taken to correctly sample plant material to maximise the likelihood of accurately detecting pests, if present, in plant material destined for export to New Zealand.
- (2) All practicable steps must be taken during the handling of samples to prevent contamination and mixing of samples as well as to protect the integrity of the sample.
- (3) The offshore facility undertaking tests of plants for planting must have a procedure for the system used to identify and trace plant samples from the point of sample reception through to documenting test results in laboratory reports.

#### 4.2.2 Diagnostic methods

- (1) Only verified or validated diagnostic methods for pest identification must be used for plant material destined for export to New Zealand.
- (2) The performance of tests of plants for planting must be monitored to ensure the validity of results, and to manage sample contamination, repeat of analysis and change of performance of a test, according to documented procedures.

#### Guidance

- *Diagnostic methods:* diagnostics methods are specified in the relevant IHS for plants for planting and will be incorporated into any agreement between MPI and the facility. These may be biological indexing, plating, serological, and/or molecular testing. Information on diagnostic methods can be found in the guidelines of ISPM 27: *Diagnostic protocols for regulated pests* and

the following EPPO standards: PM7/101: *ELISA tests for plant pathogenic bacteria*, PM7/125: *ELISA tests for viruses*, PM7/101: *Rep-PCR for identification of bacteria*, PM7/129: *DNA barcoding as an identification tool for a number of regulated pests*, and for plating, refer to the EPPO standards diagnostic protocols for specific pests:

[https://www.eppo.int/RESOURCES/eppo\\_standards/pm7\\_diagnostics](https://www.eppo.int/RESOURCES/eppo_standards/pm7_diagnostics).

- *Verification/validation of test*: information can be found in the EPPO standard PM7/98: *Specific requirements for laboratories preparing accreditation for a plant pest diagnostic activity*.
- *Performance of a test*: this may be monitored by using controls, taking part into blind testing and proficiency testing. Information can be found in the EPPO standards PM7/84: *Basic requirements for quality management in plant pest diagnostic laboratories*.

#### 4.2.3 Diagnostic records

- (1) In addition to the records described in section 2.5, the offshore facility conducting tests of plants for planting must, as a minimum, also keep the following records to ensure the integrity and transparency of the results of:
  - a) diagnostic test results;
  - b) test verification and validation results;
  - c) monitoring of the test performance.
- (2) These records must be kept and be made available to MPI as described in section 2.5.

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## Appendix 1: Amendment Record

Amendments to this standard for the Offshore Facilities holding and testing plants for planting is given a consecutive number and is dated.

Version Date	Section Changed	Change(s) Description
8 October 2001		
3 July 2019	All	New format and branding

Draft



## Appendix 2: Definitions

### **Approval**

MPI agreement, following a confirmatory audit, that a facility meets the requirements of this standard. An approval requires continued conformance with the standard.

### **Audit**

An official evaluation to determine the degree of conformity with prescribed criteria in this standard.

### **CAR**

Corrective action request.

### **ELISA**

Enzyme linked immunosorbent assay.

### **EPPO**

European Plant Protection Organisation, an intergovernmental organization responsible for cooperation in plant health within the Euro-Mediterranean region.

### **Equivalence** (of phytosanitary measures)

The situation where, for a specified pest risk, different phytosanitary measures achieve a contracting party's appropriate level of protection [FAO, 1995; revised CEPM, 1999; based on the World Trade Organization Agreement on the Application of Sanitary and Phytosanitary Measures (WTO, 1994); ISPM 24, 2005].

### **Competence**

The ability to do something well and effectively.

### **Import permit**

An official document issued by MPI that specifies the conditions under which a particular commodity may be imported into New Zealand and which may be a requirement of an import health standard.

### **Import health standard (IHS)**

A document issued under section 24A of the Biosecurity Act 1993 that specifies the requirements for the effective management of risks associated with the importation of risk goods into New Zealand.

### **Inspection**

Official visual examination of plants, plant products or other regulated articles to determine if pests are present and/or to determine conformance with phytosanitary regulations [FAO, 1990, revised FAO, 1995; formerly inspect]. For examination of plants for planting, refer to its definition (above).

### **IPPC**

Acronym for International Plant Protection Convention, as deposited in 1951 with FAO in Rome and as subsequently amended [FAO, 1990].

### **ISPM**

International standard for phytosanitary measures developed by the IPPC.

### **MPI**

Acronym for Ministry for Primary Industries. MPI is New Zealand's NPPO as prescribed by the IPPC.

### **National Plant Protection Organisation (NPPO)**

Official service established by a government to discharge the functions specified by the IPPC [FAO, 1990; formerly Plant Protection Organisation (National)].

**Pest**

Any species, strain or biotype of plant, animal, pathogenic agent injurious to plants or plant products [FAO, 1990, revised FAO, 1995, IPPC, 1997].

**Phytosanitary certificate**

Certificate patterned after the model certificates of the IPPC [FAO, 1990].

**Phytosanitary certification**

Use of phytosanitary procedures leading to the issue of a phytosanitary certificate [FAO, 1990].

**Plants for planting**

Plants intended to remain planted, to be planted or replanted [FAO, 1990]. Formerly called nursery stock.

**Plants *in vitro* (as a commodity class)**

Plants growing in an aseptic medium in a closed container [FAO, 1990; revised CEPF, 1999; ICPM, 2002; formerly "plants in tissue culture"]

**Post-entry quarantine (PEQ)**

Quarantine applied to a consignment after entry [FAO, 1995].

**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.

**Propagation material**

Whole plants or parts of plants intended for growing purposes.

**Quarantine pests**

A pest of potential economic importance to the area endangered thereby and not yet present there, or present but not widely distributed and being officially controlled [FAO, 1990, revised FAO, 1995; IPPC 1997].

**Regulated pest**

Pests for which phytosanitary actions would be undertaken if they were intercepted/detected.

**Standard**

Document established by consensus and approved by a recognised body, that provides, for common and repeated use, rules, guidelines or characteristics for activities or their results, aimed at the achievement of the optimum degree of order in a given context [FAO, 1995; ISO/IEC Guide 2:1992 definition].

**Testing**

Official examination, other than visual, to determine if pests are present or to identify the pests [FAO, 1990].

**Treatment**

Officially authorised procedure for the killing, removal or rendering infertile of pests [FAO, 1990, revised FAO, 1995].