

**BIOSECURITY NEW ZEALAND
STANDARD 154.03.01**

**Supervision of
Containment Facilities**

**Biosecurity New Zealand
Ministry of Agriculture and Forestry
P O Box 2526
Wellington
New Zealand**

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ENDORSEMENT

This Biosecurity New Zealand standard is hereby approved.

Veronica Herrera
Biosecurity Standards Manager
Date:

REVIEW

This Biosecurity New Zealand standard is subject to review and amendment at any time, to ensure that it continues to meet current needs. Amendments will be made to the signed original as required.

AMENDMENT RECORD

Amendments to this standard will be given a consecutive number and will be dated.

Please ensure that all amendments are inserted, obsolete pages removed and the record below is completed.

Amendment No:	Entered by:	Details:	Date:
1			
2			
3			
4			
5			

This standard can be found at the following URLs:

<http://www.biosecurity.govt.nz/border/transitional-facilities/animals/index.htm>

<http://www.biosecurity.govt.nz/border/transitional-facilities/plants/>

SIGNED ORIGINAL

Name

Operational Standards Team

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CONTACT PERSONS

The contact persons to deal with matters relating to this standard:

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SCOPE

This Biosecurity New Zealand standard specifies the requirements for the supplier of supervision, ensuring that operators are in compliance with HSNO approvals made under the Hazardous Substances and New Organisms (HSNO) Act 1996 (and subsequent amendments), for the following categories of new organisms to be held in containment:

- Microorganisms
- Invertebrates (includes requirements for quarantine)
- Vertebrate laboratory animals
- Field testing of farm animals
- Zoo animals
- Field testing of genetically modified (GM) plants in containment
- New organisms of plant species (including GM) in plant-houses and laboratories

For each category of organism there is a corresponding Biosecurity New Zealand standard for the operator and these are cited in the references.

This standard does not include registration or supervision of transitional facilities or diagnostic laboratories.

SERVICE OUTLINE

The supplier shall provide the chief technical officers with a service to supervise the activities of operators who are required to hold new organisms in containment, including HSNO approvals.

REFERENCES

The following containment standards and publications are referred to in this standard:

- Biosecurity New Zealand standard 154.03.02: Containment facilities for microorganisms.
- Biosecurity New Zealand standard 154.02.08: Transitional and containment facilities for invertebrates.
- Biosecurity New Zealand standard 154.03.03: Containment facilities for vertebrate laboratory animals.

- Biosecurity New Zealand standard 154.03.04: Containment facilities for zoo animals.
- Biosecurity New Zealand standard 154.03.06: Field testing of farm animals.
- Biosecurity New Zealand/ERMA standard 155.04.09: Containment facilities for new organisms (including genetically modified organisms) of plant species.
- Australian/New Zealand Standard ISO 9001:2000 Quality management systems – requirements.
- ISO/IEC 17020: General criteria for the operation of various types of bodies performing audit.
- Biosecurity Act 1993.
- Hazardous Substances and New Organisms (HSNO) Act 1996.
- Hazardous Substances and New Organisms (Low-Risk Genetic Modification) Regulations 2003.
- Australian/New Zealand Standard 2243.3:2002 Safety in laboratories: Microbiological aspects and containment facilities.

1. DEFINITIONS

For the purposes of this standard and the above containment standards the following definitions apply:

Additional controls

Controls which are additional to the routine requirements of the relevant containment standard for a facility. These are listed in the ERMA New Zealand decision document, which gives HSNO approval to the containment of that organism under the HSNO Act.

Approval of a facility and an operator

Approved by the Director-General, MAF, or his/her delegate. The chief technical officers (pre-clearance); with delegated authority to the Operational Standards group, Biosecurity New Zealand. The contact people are listed on page 5.

Associated organism

Organisms imported unintentionally with another organism. They include unwanted organisms and detectable pests and pathogens.

Audit

An official evaluation to determine the degree of conformity with criteria prescribed in a Biosecurity New Zealand standard.

Authorised movement (biosecurity direction)

Authority from an inspector, given under section 25 of the Biosecurity Act, to move uncleared goods to a transitional facility, containment facility, or biosecurity control area or to be exported from New Zealand.

Biosecurity clearance

A clearance under section 26 of the Biosecurity Act given by an inspector for the entry of goods into New Zealand.

Biosecurity New Zealand

The section within MAF responsible for regulatory biosecurity functions.

Chief technical officer

A person appointed by the Director-General as a chief technical officer within MAF under section 101 of the New Zealand Biosecurity Act. Where reference is made to the chief technical officer in this standard the person to contact is the contact person.

Containment facility

A place approved in accordance with section 39 of the Biosecurity Act, for holding organisms that should not, whether for the time being or ever, become established in New Zealand.

Containment operator

A person or organisation approved in accordance with section 39 of the Biosecurity Act, to operate a containment facility.

Corrective Action Request

A report prepared by the facility supervisor detailing any non-compliances found during a facility audit.

Critical Situation Report

A report prepared by the facility supervisor detailing any major non-compliances found during a facility audit.

Culture

The propagation of microorganisms or of living cells in special media conducive to their growth.

Culture collection

One or more cultures of microorganisms held in storage.

Development (of a new organism)

In relation to organisms in the HSNO Act, includes (i) genetic modification, (ii) regeneration of a new organism from biological material of the organism that cannot, without human intervention, be used to reproduce the organism, (iii) fermentation of a microorganism that is a new organism. It does not include field testing.

Director-General

The chief executive of the Ministry of Agriculture and Forestry.

Enforcement officer

An enforcement officer appointed under section 98 or section 99(3) of the HSNO Act.

ERMA New Zealand

Is made up of the following three components:

- the Environmental Risk Management Authority (the Authority) - a quasi-judicial decision-making body (and also the Governing Board of ERMA New Zealand), accountable to the Minister and Parliament for the environment. The Authority makes decisions on applications to import hazardous substances and new organisms (including genetically modified organisms) into New Zealand, as well as their creation and particular use in New Zealand, under the Hazardous Substances and New Organisms (HSNO) Act 1996.
- Ngā Kaihautū Tikanga Taiao - a committee to advise and assist the Authority from a Māori perspective;
- the Agency - the administrative support organisation for the Authority. The Agency's role includes advising applicants and evaluating and reviewing applications to assist the Authority.

Farm animal

A farm animal, being a new organism, which has not been given HSNO approval for release in New Zealand. Examples include genetically modified farm animals such as cattle and other bovine species, sheep, goats, deer, pigs, horses, llamas and alpacas. It also includes the genetic material from these species.

Field test

In relation to a new organism, the carrying out of trials on the effects of that organism under conditions similar to those of the environment into which the organism is likely to be released, but from which the organism, or any heritable material arising from it, could be retrieved or destroyed at the end of the trials.

Genetically modified organism (GMO)

Unless expressly provided otherwise by regulations, any organism in which any of the genes or other genetic material –

- (a) Have been modified by *in vitro* techniques; or
- (b) Are inherited or otherwise derived, through any number of replications, from any genes or other genetic material which has been modified by *in vitro* techniques.

Section 2, HSNO Act.

HSNO Controls

Containment conditions, obligations or restrictions, imposed on a new organism by ERMA New Zealand as per section 45 (2) of the HSNO Act. These may include controls that are additional to those required in the various containment facility standards and include assignation of the physical containment level.

HSNO approval

An approval made by ERMA New Zealand or an Institutional Biological Safety Committee (IBSC) under the under the HSNO Act.

IMPACT

A MAF database for recording operational information relating to imports of risk goods.

Import health standard

A document issued under section 22 of the Biosecurity Act by the Director-General on the recommendation of a chief technical officer, specifying the requirements to be met for the effective management of risks associated with the importation of risk goods.

Inspector

A person appointed under section 103 of the Biosecurity Act to undertake administering and enforcing the provisions of the Biosecurity Act.

Institutional Biological Safety Committee (IBSC)

Committees with delegated authority from ERMA New Zealand to assess applications for the:

- (a) development of low-risk genetically modified organisms in containment and
- (b) importation of low-risk genetically modified organisms into containment, under sections 19 and 42 of the HSNO Act,

IBSC's also assign containment levels for organisms as prescribed in the HSNO (Low-Risk Genetic Modification) Regulations 2003.

Internal audit

An audit carried out by a representative of the registered containment facility to evaluate its own performance in relation to the standard or prescribed criteria.

Low-Risk Genetic Modification

Refers to modifications as defined in the HSNO (Low-Risk Genetic Modification) Regulations 2003.

Microorganism

A tissue culture, moss, lichen, protozoan, fungus, bacterium, virus or other microscopic self-replicating biotic entity. Naked DNA is excluded from the definition. HSNO approval must be given for development or importation of a new microorganism.

New organism

A new organism is defined in the HSNO Act as:

- (1) A new organism is-
 - (a) An organism belonging to a species that was not present in New Zealand immediately before 29 July 1998:
 - (b) An organism belonging to a species, subspecies, infrasubspecies, variety, strain, or cultivar prescribed as a risk species, where that organism was not present in New Zealand at the time of promulgation of the relevant regulation:

- (c) An organism for which a containment approval has been given under this Act:
 - (ca) An organism for which a conditional release approval has been given:
 - (cb) A qualifying organism approved for release with controls:
 - (d) A genetically modified organism:
 - (e) An organism that belongs to a species, subspecies, infrasubspecies, variety, strain, or cultivar that has been eradicated from New Zealand.
- (2) An organism is not a new organism if-
- (a) the organism is not a genetically modified organism and-
 - (i) an approval is granted under section 38 to release an organism of the same taxonomic classification; or
 - (ii) the organism is a qualifying organism and an approval has been granted under section 38I to release an organism of the same taxonomic classification without controls; or
 - (iii) an organism of the same taxonomic classification has been prescribed as not a new organism; or
 - (b) the organism is a genetically modified organism and-
 - (i) an approval is granted under section 38 to release an organism of the same taxonomic classification with the same genetic modification; or
 - (ii) the organism is a qualifying organism and an approval has been granted under section 38I to release an organism of the same taxonomic classification with the same genetic modification without controls; or
 - (iii) an organism of the same taxonomic classification with the same genetic modification has been prescribed as not a new organism; or
 - (c) the new organism was deemed to be a new organism under section 255 and other organisms of the same taxonomic classification were lawfully present in New Zealand before the commencement of that section and in a place that was not registered as a circus or zoo under the Zoological Gardens Regulations 1977.
- (2A) A new organism does not cease to be a new organism because-
- (a) it is subject to a conditional release approval; or
 - (b) it is a qualifying organism approved for release with controls.
- (3) Despite the provisions of this section, an organism present in New Zealand before 29 July 1998 in contravention of the Animals Act 1967 or the Plants Act 1970 is a new organism.
- (4) Subsection (3) does not apply to the organism known as rabbit haemorrhagic disease virus, or rabbit calicivirus.

Operator

Person or organisation approved by the Director-General to operate a containment facility under section 40 of the Biosecurity Act.

Organism

Defined in section 2 of the HSNO Act:

- Does not include a human being,

- Includes a human cell,
- Includes a micro-organism,
- Includes a genetic structure (other than a human cell) that is capable of replicating itself, whether that structure comprises all or only part of an entity, and whether it comprises all or only part of the total genetic structure of an entity,
- Includes an entity (other than a human being) declared by the Governor-General by Order in Council to be an organism for the purposes of the Biosecurity Act,
- Includes a reproductive cell or developmental stage of an organism.

Permit to import

A numbered document issued as a requirement of the import health standard.

Procedure

Describes 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.

Project

Development of genetically modified organisms within a containment facility approved in accordance with section 42A of the HSNO Act.

Release

In relation to new organisms, means to allow the organism to move within New Zealand free of any restrictions other than those imposed in accordance with the Biosecurity Act or the Conservation Act 1987. Section 2, HSNO Act.

Supervisor

An inspector appointed under the Biosecurity Act. This person, employed by the supplier, inspects containment facilities and audits the operation of containment.

Supplier

The party responsible for the performance of audits under a contract with Biosecurity New Zealand. MAF Quarantine Service (MQS) is the present supplier.

The Authority (of ERMA New Zealand)

Environmental Risk Management Authority (refer also to definition of ERMA New Zealand).

Tissue culture

The growth of cells, including tissues and organs, outside the organism in an artificial media of salts and nutrients. This standard applies only to tissue cultures that are determined by the Authority to be a new organism.

Transitional facility

An approved facility for the purpose of inspection, testing, storage, treatment, holding or destruction of uncleared goods, which may be harbouring pests or unwanted organisms, until a biosecurity clearance is given by an inspector.

Unwanted organism

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; and

(a) Includes-

(i) Any new organism if ERMA New Zealand has declined approval to import that organism; and

(ii) Any organism specified in the Second Schedule of the HSNO Act 1996;

(b) Does not include any organism approved for importation under the HSNO Act, unless-

(i) The organism is an organism which has escaped from a containment facility; or

(ii) A chief technical officer, after consulting ERMA NZ and taking into account any comments made by ERMA NZ concerning the organism, believes that the organism is capable or potentially capable of causing unwanted harm to any natural and physical resources or human health:

Zoo

A containment facility approved to the zoo containment standard where live zoo animals are kept for the purposes of public exhibition, conservation or entertainment and includes, for example, a circus, butterfly house, aquarium or an oceanarium. A zoo may also hold indigenous animals that are not new organisms but these animals are not covered by this Standard.

Zoo animal

A new organism with containment HSNO approval to be held in a zoo. The organism is both a new organism under the HSNO Act and a restricted organism under the Biosecurity Act.

2. SERVICE REQUIREMENTS

2.1. General Requirements

Supervision shall be provided in accordance with this standard and ISO/IEC 17020: General criteria for the operation of various types of bodies performing audit.

The supplier shall provide a report to the appropriate chief technical officer giving an update on the supplier's management structure and key personnel (refer section 3.2 below) when there are changes to structure/staff and when major issues are raised at audits.

The supplier and employees should declare any financial interest in a containment facility or any other affiliations that could be construed as a conflict of interest. In such cases, this will be discussed with the contact person and managed in the most appropriate way.

A chief technical officer, or delegated representative, may audit the supervisor at one or more facilities.

2.2. Key Supplier Personnel

2.2.1. Management Representative

The management representative (reporting to senior management) shall have defined authority and responsibility for ensuring that there are systems in place to meet the requirements of this standard and that these systems are implemented and maintained.

2.2.2. Supervisors

The supervisor shall be an inspector as defined by the Biosecurity Act who has a relevant science degree, or relevant science training and associated experience. The supervisor shall have satisfactorily completed lead-auditor training or training to an equivalent standard and shall be able to demonstrate that s/he has an understanding of the principles of containment and quarantine, the relevant legislation and some appreciation of the business and objectives of the operator.

The supervisor shall be familiar with the relevant import health standards and the requirements of the relevant containment/transitional standards outlined in the scope.

2.2.2.1. Communication:

The supplier shall ensure that a supervisor is able to communicate the following information in a way that can be clearly understood by the operator of these facilities:

- (a) the commonly used means for meeting the requirements of the standards including the HSNO controls specified by the Authority for the containment of the new organism(s), and
- (b) the circumstances in which such means can fail to comply, and the steps that should be taken to re-establish compliance.

2.2.2.2. Training:

The supplier shall be responsible for the ongoing training of supervisors, so that they know their responsibilities under this standard.

Refresher audit training, and training in technical issues under the Biosecurity and HSNO Acts, should be conducted annually. This will help to ensure that audits are carried out effectively and to ensure that supervisors are aware of the relevance and importance of their audits.

Supervision shall be provided for new staff undergoing training. The supplier will maintain appropriate records of education, training, skills and experience for supervisors.

3. TECHNICAL REQUIREMENTS

3.1. Approval of a Facility

The supervisor may consider applications before construction of a facility to provide advice on whether the proposed facility is likely to comply with the standard.

The requirements for approval are described in the appropriate operator standard and the supervisor shall inspect the facility before making a recommendation on approval.

Where the facility is leased, the supervisor shall seek confirmation from the operator that the contract does not conflict with the requirements of the standard.

If the quality system is accredited by an external agency as described in section 3 of the operator standard the supervisor shall satisfy him/herself that the requirements of the standard are addressed in that quality system.

The facility must have appropriate financial resources to ensure that the containment facility can be maintained. Evidence may include a letter from the Chief Executive/ Registrar guaranteeing financial viability.

If the facility is modified, the supervisor shall verify that the completed modifications meet the correct standard. The contact person shall be advised if there is a change in the containment level of the facility.

3.2. Approval of an Operator

The supervisor will be satisfied that the applicant is a “fit and proper” person, appropriately trained, qualified and experienced., and is able to comply with the operating standards for that facility (section 40 (3) (a & b) Biosecurity Act). The operator must be aware of the relevant parts of the Biosecurity Act and HSNO Acts, and should be asked questions on this by the supervisor.

NOTE: Appropriate training may include biological containment, quality systems and auditing. Qualifications may include degrees, certificates, and awards. Appropriate experience would likely include laboratory experience, and quality systems experience.

If the applicant is a company or organisation, the representative in matters relating to the resourcing and day to day operation of the facility will need to fill out the application and consent to disclosure forms. This person will be the named facility manager, and will be the main contact person for the supervisor. The supervisor must be able to clearly identify the

chain of command and the roles and responsibilities of the facility operator and the facility manager. Evidence may include an organisational chart, or a position description (which shows accountability for the laboratory).

The supervisor must be confident that the principles and procedures of containment are supported by management. Evidence may include a training package/programme, or containment being addressed by the quality system.

The supervisor shall send the relevant application forms to the appropriate contact person of this standard, along with a written recommendation for approval of the operator and the facility.

3.3. Cancellation of Approval

Expiry of a facility approval may occur at a time or event specified in the approval. If the supervisor is satisfied that the containment facility:

- no longer complies with the HSNO approvals or requirements of the standard, or
- is no longer being used for the purpose(s) specified in the facility's approval,

s/he shall discuss the issue with the operator. Then, if necessary, and after informing the operator of his/her intention in writing, the supervisor shall make a recommendation to the contact person that approval of the facility should be cancelled.

If the supervisor is satisfied that the operator:

- is not operating the facility according to the HSNO approval, or
- is not operating the facility according to the standard, or
- is no longer a fit and proper person, or
- ceases to act as the operator, or
- requests cancellation as the operator.

s/he shall discuss the issue with the operator. Then, if necessary, and after informing the operator of his/her intention in writing, the supervisor shall make a recommendation to the contact person that approval of the operator should be cancelled (section 40 (4) Biosecurity Act). If an alternative operator cannot be approved then approval of the facility shall also be cancelled.

Whenever a facility it is to be closed down or an approval is to be cancelled the supervisor shall be satisfied that the all new organisms have been removed to another approved facility or destroyed as per the HSNO controls of the relevant approval.

3.4. Audit of a Facility

3.4.1. Frequency of Audits

The supervisor shall make as many visits as s/he considers necessary to have confidence that the facility is operating according to the Standard. The minimum number of visits shall be as follows:

MAF Standard	Minimum Audit Frequency
Microorganism – Std 154.03.02	Six monthly
Invertebrate – Std 154.02.08	Six monthly
Vertebrate laboratory animals – Std 154.03.03	Six monthly
Field testing of farm animals – Std 154.03.06	Three monthly
Zoo animals – Std 154.03.04	Annually
Laboratory and plant houses - Std 155.04.09	Annually
Field tests for plants - Std 155.04.09	Case by case basis (for details see Plant field tests below).

Additional audits shall be required in the following circumstances:

- newly approved facilities shall be re-inspected within three months of the first use of the facility to ensure that the requirements of the standard are being met;
- invertebrate transitional facilities shall be examined prior to the arrival of and/or within three weeks of the arrival of an imported invertebrate into the facility;
- a breach of containment, or other major non-compliance.

Where the supervisor is confident that a microorganism, invertebrate or vertebrate laboratory animal facility is operating according to the relevant standard and there have been no major or minor non-compliances (see section 4.4.4) in the previous four consecutive audits, the supervisor may make a recommendation to the contact person for extension to annual audits. Six monthly audits will resume if non-compliance is subsequently found.

3.4.2. Plant Field Tests

Separate audit regimes need to be considered for annual and perennial plants. Specific audit requirements will be developed on a case by case basis between ERMA New Zealand and Biosecurity New Zealand, as the audit regime will depend on the nature of the test and the biology of the species.

3.4.2.1. Annual Plants

On-site audits shall occur at a minimum frequency of three times within a 12 month period of the crop being planted in the field unless otherwise agreed with ERMA New Zealand and directed by Biosecurity New Zealand. Audits shall occur at an exact time of choosing by the inspector, during each of the following periods:

- Planting/sowing/germination in the field;
- Flowering (or as agreed with ERMA New Zealand where reproductive structures are removed in advance);
- Harvest, final removal and destruction of reproductive plant material from the field test area

In addition, other audits may be required:

- Post-harvest audits (at least one audit annually) at a duration specified by ERMA New Zealand, and directed by Biosecurity New Zealand.
- At any report of a breach of HSNO controls or suggestion of a major non-compliance.

3.4.2.2. Perennial Plants (including trees)

On-site audits shall occur at a minimum frequency of twice per year unless otherwise agreed with ERMA New Zealand, and directed by Biosecurity New Zealand. Audits shall occur at an exact time of choosing by the inspector, during the following periods:

- Planting/sowing/germination in the field,
- Flowering (or as agreed with ERMA New Zealand where reproductive structures are removed or bagged in advance),
- Ripening of reproductive structures,
- Final removal and destruction of plant material from the field test area.

In addition, audits shall occur:

- Post-harvest audits (at least one audit annually) for a duration of three years, unless otherwise agreed with ERMA New Zealand and directed by Biosecurity New Zealand.
- At any report of breach of HSNO controls or suggestion of a major non-compliance.

In the first few years the audits for perennial plants will focus primarily on the facility set up, management procedures, reporting requirements, numbers of plants, and security etc.

3.4.3. Requirements for Audit

The supervisor shall prepare and use an audit checklist relevant to the level of containment and associated standard. This checklist shall also address any additional controls attached to a specific HSNO approval. The checklist will be used as the basis for a written audit report, a summary of which will be entered into IMPACT.

In general, auditing ensures that the facility is in compliance with Biosecurity New Zealand containment standards, and all HSNO approvals. A risk-based approach shall be adopted, which will determine which HSNO approvals are audited.

Higher physical containment levels indicate the organism may pose higher levels of risk to the environment and/or human health and safety. Therefore, all approvals requiring organisms to be held at physical containment level 3 (PC3) and above shall be audited each time the supervisor audits the facility, as shall all field tests and outdoor developments.

For the remaining approvals, (i.e. PC1 and PC2), a proportion of each shall be audited with priority being given to approvals with additional controls and the least priority placed on approvals for organisms that are considered to be low-risk according to HSNO (Low-Risk genetic Modification) Regulations 2003.

The contact person should be contacted for technical aspects relating to the particular containment standard.

3.4.3.1. *Microorganisms*

During audits the supervisor shall assess that:

- the containment manual procedures are practised,
- the structural and operational requirements of the standard are being maintained,
- any previous corrective action requests have been actioned,
- HSNO approvals are in compliance with the HSNO controls,
- the register of projects for new organisms is maintained,
- the register of culture collections is maintained including records of the movement of microorganisms into and out of the facility.

3.4.3.2. *Invertebrates*

During audits the supervisor shall assess that:

- the quarantine and containment manual procedures are practised,
- the structural and operational requirements of the standard are being maintained,
- any previous corrective action requests have been actioned,
- the identity of the imported invertebrates correlates with the species specified on the permit to import and approved by the Authority (if new organisms).
- HSNO approvals are in compliance with the HSNO controls,

- every approval that has additional controls must be audited for compliance at each visit,
- for imported invertebrates, the import health certification is in order and the requirements of the import health standard are being met,
- all imported or transferred invertebrates (both into and out of the facility) are recorded on the project register,
- cultures of invertebrates held in the facility correlate with the register.

3.4.3.3. Vertebrate Laboratory Animals

During audits the supervisor shall assess that:

- the containment manual procedures are practised,
- the structural and operational requirements of the standard are being maintained,
- any previous corrective action requests have been actioned,
- the identity of the imported vertebrates correlates with the species specified on the permit to import and approved by the Authority (if new organisms),
- the import health certification is in order and the requirements of the import health standard are being met,
- approval of the animal ethics committee has been obtained where required,
- HSNO approvals are in compliance with the HSNO controls,
- every approval that has additional controls must be audited for compliance at each visit.
- all imported or transferred vertebrate laboratory animals (both into and out of the facility) are recorded on the register,
- the number and type of laboratory animals in the facility correlate with the register.

3.4.3.4. Field Testing of Farm Animals

During audits the supervisor shall assess that:

- the containment manual procedures are practised,
- the structural and operational requirements of the standard, especially the fencing requirements, are being maintained.
- any previous corrective action requests have been actioned,

- the number of farm animals present correlates with the register,
- HSNO approvals are in compliance with the HSNO controls,
- farm animals are identified as required in the standard,
- all transferred farm animals (both into and out of the facility) are recorded on the register,

The supervisor shall be present when all the farm animals are counted at the six monthly tally.

3.4.3.5. Zoo Animals

During audits the supervisor shall assess that:

- any previous corrective action requests have been actioned,
- all additional controls specified by the Authority in a HSNO approval are being met,
- all transferred zoo animals (both into and out of the facility) are recorded on the register,
- the zoo manual procedures are practised,
- the structural and operational requirements of the standard are being met,
- the number and species of zoo animals correlates with the register.

3.4.3.6. Plant Houses and Laboratories

During audits the supervisor shall assess that:

- the structural and operational requirements of the standard are being maintained,
- the containment manual procedures are being practiced,
- any previous corrective action requests have been actioned,
- the identity of the plants correlates with the species specified on the permit to import and/or any relevant HSNO approval issued, the export certification is in order and any post-arrival requirements of the import health standard or import health permit have been, or are being complied with,
- the plants in containment correlate with the register and the numbers of plants match up with the documentation (where possible to determine),
- HSNO approvals are in compliance.

3.4.3.7. Field Testing of Plants

During audits the supervisor shall assess that:

- the containment manual procedures are practiced,
- the structural and operational requirements of the standard are being maintained,
- any previous corrective action requests have been actioned,
- the plants in containment correlate with the register,
- the security requirements are being met, and in particular, field test containment facilities are secure (locked gates, fences intact and monitoring in place etc.),
- HSNO approvals are in compliance,
- all additional controls specified by the HSNO approval are being met.

3.5. Non-compliance

Non-compliance may be found at a routine audit or after a special investigation following a report from the operator. There are two types of non-compliance:

3.5.1. Major non-compliance

Defined as a breach in containment, or a situation that may present a serious risk to biosecurity, the environment, or to the health and safety of people and communities, or result in a decrease in confidence to prevent the occurrence of a serious risk.

- (a) The supervisor shall require immediate corrective action to be taken by the operator in order to restore confidence in containment.
- (b) The major non-compliance shall be investigated and reported via a Critical Situation Report to the contact person named in this standard and also to ERMA within 24 hours. The supervisor must ensure that the contact person receives the report. This report shall describe the non-compliance, the actions that have been taken and recommended course of action. The supervisor shall discuss the non-compliance with the contact person so that a corrective action request can be written by the supervisor. ERMA New Zealand shall be kept informed by Biosecurity New Zealand.
- (c) If a chief technical officer, or delegated representative, considers it necessary s/he may intervene in the management and operation of the facility to ensure compliance with the standards for that facility; or terms upon which the organism is confined in the facility. Any action taken may be in accordance with section 126 of the Biosecurity Act or under section 104 or 136 of the HSNO Act.
- (d) A chief technical officer, or delegated representative, may direct that all work using new organisms is to cease immediately and may not be permitted to recommence until the

non-conformance is rectified. For example, a zoo may be required to close immediately until it is compliant.

- (e) At least one revisit audit is required to determine that the major non-compliance has been effectively resolved and normal activities may resume under an audit regime with increased frequency of supervision by the supervisor.
- (f) When the non-compliance has been remedied the supervisor shall provide to the contact person with a report summarising the events and determining the reasons for the non-compliance, the appropriateness of the response and lessons for the future. ERMA New Zealand will receive a copy of this report included as part of the ERMA Quarterly Report.
- (g) A corrective action request will be issued to the facility.
- (h) The supervisor must ensure that the facility has a programme in place to ensure that the non-compliance does not happen again.

3.5.2. Minor Non-compliance

Defined as an incident that results in the decrease in confidence in the quality management processes but may not immediately cause or lead to a biosecurity risk.

A corrective action request will be issued to the facility.

3.5.3. Corrective Action Request (CAR)

For a minor non-compliance, the cause of the non-compliance must be determined. A corrective action request, comprising a corrective action and a time frame for its implementation (determined between the supervisor and the operator), must be presented in writing outlining:

- (a) what corrective action must be done,
- (b) the time frame for completion of the corrective action,
- (c) the verification activities to be undertaken to ensure that the corrective action has been successfully implemented.

The supervisor must verify that the corrective action has been implemented and the facility is operating effectively within the agreed time frame. This may require a visit to the facility. The facility must also prepare preventative actions, to ensure that the non-compliance does not happen again.

3.5.4. Recommendations

In addition to major and minor non-compliances, supervisor's may find reason to make recommendations to assist a facility with compliance to a standard. These are not non-

compliances, however if attention is not given to these items they may become future non-compliances. These recommendations are not subject to corrective action requests.

3.6 Transfer of Organisms between Facilities or for Export

A new organism shall remain in containment and is not eligible for a biosecurity clearance without a specific HSNO approval (e.g. release from containment, or conditional release), and a biosecurity clearance (BACC) from the supervisor.

The supervisor may authorise the transfer of a new organism between containment facilities of equivalent physical containment level, or the transfer of organisms in a transitional facility to another transitional or containment facility. Approval from the supervisor **MUST** be obtained before the movement between facilities can occur.

NOTE: The development of a GM organism is applicant and site-specific. The organism may be transferred to another facility but further development cannot be undertaken without first obtaining a further HSNO approval.

NOTE: An ERMA approval to import a new organism is valid nationally. However, an IBSC approval can only be used by the applicant granted the approval unless another applicant was specifically named as a co-applicant on the application, or they were included in the HSNO controls as a facility to which a new organism may be transferred.

The supervisor may authorise transfer when satisfied that:

- (a) the HSNO approval permits transfers,
- (b) the method of transfer ensures that new organisms cannot escape and shall meet the requirements of the relevant containment standard and HSNO controls as specified in the relevant approval. Extreme care must be undertaken in transporting unwanted organisms or suspected unwanted organisms (section 52 & 53, Biosecurity Act).
- (c) the receiving facility is an approved facility that meets the containment requirements for the new organism, or in the case of zoo animals meets the enclosure specifications for the species,
- (d) the supervisor of the receiving facility confirms that the receiving facility can accommodate the new organisms and approves the transfer,

The contact person named in this standard must approve the transfer of:

- invertebrates,
- farm animals in a field test,
- zoo animals,
- microorganisms having a requirement of PC3 or more,
- plants having a requirement of PC3 or more.

When making a written application to the supervisor for transfer, the operator should provide the additional controls specified by the HSNO approval. The written authority may be for single or multiple transfers within a specified time.

When transferring new organisms the supervisors of the involved facilities shall be satisfied that:

- (a) the transfer can be monitored so that they know when the transfer is to occur and when it has occurred,
- (b) the number of animals, plants or cultures sent and the number received can be verified,
- (c) a record of the transfer is noted in the relevant registers of the sending and receiving facilities.

The export of any new organism from New Zealand shall be authorised in writing before it leaves the containment facility.

3.7. Quarantine Provisions of the Invertebrate Standard

3.7.1. Associated Organisms

If an associated organism is found the supervisor shall notify the contact person as soon as is practicable. (NB. Some material, such as galls, may be authorised to accompany imported invertebrates.)

The chief technical officer, or delegated representative shall, as appropriate, approve control procedures, and may for example order further tests, extend the period of quarantine (if appropriate) or order the destruction of the invertebrates and associated organisms. In the latter event, the facility and equipment shall be thoroughly cleaned and disinfected, or fumigated as appropriate.

3.7.2. When Quarantine Requirements have been met

When an invertebrate has met the quarantine requirements of the import health standard it may be eligible either for:

- transfer to a containment facility, or
- biosecurity clearance.

3.7.2.1. Transfer to a Containment Facility – New Organisms

The supervisor may authorise the transfer to move an invertebrate from a transitional facility to a containment facility when:

- it is a new organism, and
- the quarantine conditions of the import health standard have been met, and
- the taxonomic identity of the species has been confirmed to correspond to that named in the permit to import, and

- there is no evidence of non-approved associated organisms

The importer shall be advised in writing that the invertebrate has met the quarantine requirements of the import health standard.

Dead specimens of invertebrates, after appropriate treatment to render associated organisms non-viable, may be transferred out of the facility without written authority from the supervisor.

3.7.2.2. *Biosecurity Clearance*

The import health standard must be consulted, or the contact person, for direction as to whether the invertebrate is eligible for biosecurity clearance.

As a general rule, at the end of the quarantine period invertebrates that are not new organisms or unwanted organisms shall be eligible for biosecurity clearance. The exception relates to invertebrates given HSNO approval for conditional release.

The supervisor shall make a recommendation to the contact person that the invertebrates are eligible for biosecurity clearance when satisfied that:

- it is not a new organism (except for new organisms given HSNO approval for conditional release), and
- the conditions of the import health standard have been met, and
- the taxonomic identity of the species has been confirmed to correspond to that named in the permit to import, and
- there is no evidence of non-approved associated organisms.

The supervisor shall include a letter of application for biosecurity clearance from the operator with the recommendation.

When the contact person is satisfied that all of the conditions for biosecurity clearance have been met this will be confirmed by an e-mail from the contact person and the supervisor shall issue a biosecurity clearance in writing.

3.8. Cost Recovery

The supervisor shall recover the costs associated with supervision in accordance with the Biosecurity Act and its Regulations.

3.9. Reporting Requirements

Reports of breaches in containment, or other incidents that have a bearing on the risk of escape of a new organism shall be reported to the contact person and also to ERMA New

Zealand within 24 hours. If there is a major non-compliance, the requirements detailed in section 4.4.4.1 shall be followed.

Uncertainties in interpreting HSNO controls shall be discussed with the contact person.

Within 5 working days of audit completion, the supervisor shall record an audit report in IMPACT (the MAF facility database). The report shall include notes on any incidents of non-compliance encountered. At a later date the outcome of the associated CARs shall also be entered.

3.10. Records

The supervisor is required to keep records of audits. These shall include:

- audit findings,
- Critical Situation Reports, Corrective Action Requests and Recommendations, including the results of follow-up visits,
- reports to the chief technical officer,
- copies of authorisations for movement of organisms,
- relevant HSNO approvals issued under the HSNO Act,
- transfer approvals for new organisms,
- MAF permits.

Records must be legible, readily identifiable and retrievable.