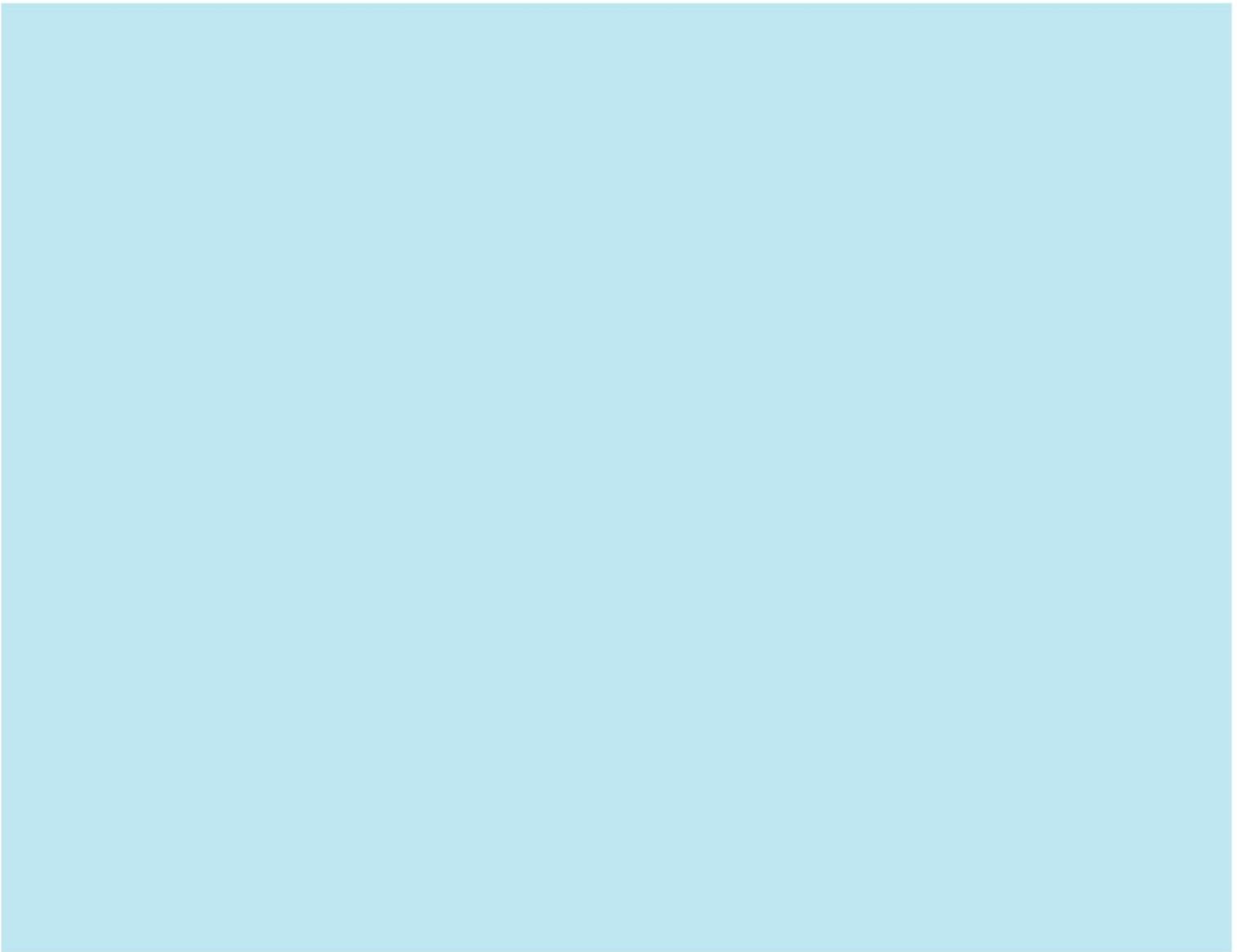
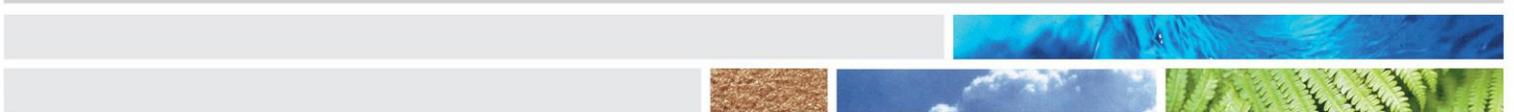




Environmental
Protection Authority
Te Mana Rauhi Taiao

Explanation and Guidance for Controls on Application APP201517

July 2018



Review and amendment

This guidance document is subject to on-going review and amendment. All stakeholders are responsible for ensuring that the most recent version of this guidance document is used.

Version, Amendments/ Updates	Date
Version 1	December 2013
Version 2	July 2018

Disclaimer

This document provides guidance only. It does not constitute, and should not be regarded as legal advice. While every effort has been made to ensure the information in this guidance is accurate, the Environmental Protection Authority does not accept any responsibility or liability whatsoever if the document has been relied on. Specific advice from a qualified professional advisor should be sought before undertaking any action based on this guidance document

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Introduction

The purpose of this document

This document supports the decision for the application APP201517 under the Hazardous Substances and New Organisms (HSNO) Act 1996, by providing explanatory information and guidance about the controls specified in the approval.

The APP201517 decision was notified on 31 July 2013, and came into effect on 1 August 2014, at which time all containment facilities holding the zoo animals listed on the approval were required to be operating in compliance with the controls. The approval can be found on the EPA website:

www.epa.govt.nz

Scope and layout of this document

This document lists the controls imposed through the approval, provides an explanation of the controls and guidance about how to comply with those controls.

The controls are numbered according to the decision, and are enclosed in a border. The accompanying text describes why the requirements are in place, and gives (non-mandatory) guidance about how the requirements can be achieved.

Any guidance on how to comply with the controls may not be the only way to achieve compliance. Approval users are encouraged to discuss how they intend to comply with the controls with MPI to avoid expending resources on alternative approaches that may not be acceptable.

This document does not replace the APP201517 decision.

This document deals only with matters relevant to the HSNO Act addressed in the APP201517 decision.

Agencies involved with this guidance document

Environmental Protection Authority (EPA)

The EPA is responsible for making decisions under the HSNO Act on applications to import, develop, field test, or release new organisms (including genetically modified organisms) in New Zealand. For all containment and certain release applications, the EPA imposes controls (requirements) that must be met.

The EPA has prepared this document to support compliance with, and enforcement of, the controls imposed under the APP201517 approval, in consultation with the Ministry for Primary Industries (MPI).

Ministry for Primary Industries (MPI)

MPI is responsible for:

- regulating and enforcing the provisions of the Biosecurity Act 1993, including the approval of containment and transitional facilities and the approval of operators of those facilities
- enforcing the new organism provisions of the HSNO Act, including HSNO Act approvals and associated controls (as per section 97A(5) of the HSNO Act).

MPI conducts verification (audits and inspections) of containment facilities and their operators to ensure the provisions of the HSNO approval are complied with.

MPI will use this document to:

- assist facilities holding zoo animals under the approval to develop and implement adequate and appropriate measures to meet the desired outcomes
- assist with measuring the level of compliance against the requirements of the approval
- assist with reporting and advising the EPA on the level of compliance and the adequacy of control setting of the approval.

New organisms must be contained

Requirement for the containment of approved organisms

1. The approved organism(s) must be contained.

The overarching purpose of the controls is to prevent the release of the approved organisms into the New Zealand environment. Containment means restricting an organism to a designated secure location or facility to prevent escape and ensuring that it is not released into the New Zealand environment when it is moved between such locations or facilities.

This means that all new organisms approved for importation or development in containment need to be contained at all times, either in a containment facility or during movement to, from or between containment facilities.

Consequently, this control fully captures the desired outcome of the approval. While it may seem absolute, its intent is to signal that provided an approval user does everything that can reasonably be expected to maintain containment, they should not expect enforcement action as a result.

The control allows MPI to take enforcement action should it be required but this is highly dependent on the expectations of containment being agreed to and whether those expectations have been met in practice.

Under the Biosecurity Act, new organisms can only be given direction to a containment facility approved under that Act. For more information about becoming a containment facility please contact MPI.

Accountability for compliance with HSNO controls

Requirement for accountability for compliance with controls

2. The organisation, entity or person(s) responsible for the ownership, control and management of the containment facility where the approved organisms are held (including Board members and/or directors) must ensure compliance with the controls of this approval.

The entity or person(s) responsible for the ownership and control of the containment facility includes natural persons, organisations (corporate and non-corporate), Board members, and/or directors, and the person(s) involved in the management of the containment facility, can be held accountable for compliance with the controls.

These people are ultimately responsible for ensuring that the controls in the approval are complied with and that the containment facility has the resources and mechanisms in place to contain any approved organisms held within the containment facility. They will be held accountable for any non-compliance with the controls specified in the approval.

Demonstrating compliance with HSNO controls

Requirement to specify how controls will be met

- 3. Procedures that specify how all the controls will be implemented and complied with must be documented, and these procedures must be reviewed at least annually to ensure they:
 - a) are effective in maintaining containment and achieving their purpose,
 - b) reflect any relevant changes in the facility and its operation, and
 - c) incorporate any improvements to best practice.**
- 4. The containment facility must be operated in compliance with the documentation specified in control 3.**

These controls require documented measures to be in place to meet all the controls that will be reviewed to assess their effectiveness, and updated accordingly. Documentation is important for both the operation and approval of a facility, as it will be used for day-to-day operations, training and auditing.

Any facility holding, or intending to hold, the approved organism(s) will need to document and implement a quality management system (QMS) that describes the systems, policies and procedures, in sufficient operational detail, to:

- clearly demonstrate how the requirements of the approval are to be met
- measure and monitor the effectiveness of the measures (systems and procedures)
- demonstrate how measurement and monitoring is used to continually improve: how containment is achieved, the controls are effectively met, and the adequacy of the quality management system.

The procedures specifying how the controls will be met need to be identified and documented in relation to each approved organism held. In general, the expectation is that this applies to species rather than individual organisms of a species; however, systems and procedures may vary for different individuals of the same species depending upon factors such as size, gender, character, behaviour, health, temperament, and any special needs or requirements.

The documentation may be in the form of a quality management system, risk management plan, 'containment manual', or any other format that enables ready access for practical use and inspection.

The operation of the facility where the approved organism(s) are held must be in compliance with the documented procedures. MPI will audit to this documentation as the means by which it assesses whether the controls have been complied with.

It is important to note that complying with the documented procedures does not remove the need to comply with the other controls imposed under application APP201517, and any other conditions imposed on the containment facility.

The documentation should be 'dynamic', meaning that it is a living document and is expected to be reviewed annually at a minimum, and updated as needed to reflect international best practice, what is actually done in the facility, and, where necessary, after specific events, such as:

- a breach, or potential breach of containment or escape
- finding of any non-compliance
- changes in containment regime (structural or operational)
- relevant changes in best practice.

Controls 3 and 4 link all the other controls with the verification and enforcement of those controls, and require that the operation of the facility be consistent with the documented risk management plan.

Continuity of containment and planning

Requirement for continuity of containment

5. The person(s) responsible for compliance with the HSNO Act controls must demonstrate that the containment facility has access to on-going financial resources and the management expertise necessary to ensure that the containment of all approved organisms held within the facility can be adequately maintained in the long term.

This control addresses the continuity of containment of the approved organism(s), referring to the need to ensure that the necessary resources to maintain containment (meeting all controls) are available and accessible on a long-term basis. This recognises that considerable resources will be required to maintain containment of most of the approved organisms for their lifetime, and there can be significant costs and limitations involved with relocation of zoo animals in the event of a zoo closing.

The expectation is that, when choosing to import an approved organism into containment, the approval user will consider not only the initial cost of importing and creating appropriate containment areas for that organism, but also the on-going resources (financial, structural, managerial and technical) needed to maintain the containment regime for the life of the organism, and any off-spring. To provide assurance that adequate containment can be maintained long term the containment facility is required to demonstrate that the containment facility has access to on-going financial resources and the management expertise necessary to ensure that the containment of all approved organisms held within the facility can be adequately maintained in the long term.

While it is accepted that it is difficult to predict what resources may be required in the future, this control is focused around providing sufficient evidence that there is a sound business model in place, contingency plans are in place and can be implemented, contingency funds are available and able to be accessed and that there is a sufficient level of management and financial acumen to manage and plan the resourcing of containment in the long term.

Ways of meeting the requirements of this control include, but are not restricted to, the following:

- Evidence of contingency resourcing, such as business insurance, private or public backer, or dedicated investment monies.
- A sound and robust business plan that describes the business model, future plans (and how these will be resourced), and allocated resourcing for specific areas and tasks.
- Contingency plans in the likely event of closure, including events which may trigger closure and disposal of approved organisms.
- Steps that will be taken to manage resources more effectively if on-going business viability is at risk such as disposal of approved organisms or a decrease in staff.
- Organisational and management structure showing roles and responsibilities, reporting lines and how and where necessary technical resourcing will be accessed.
- Risk management strategy, including identification of risks and how these will be managed and resourced

Appreciating that business circumstances change over time, it would be expected that such provisions will change over time and therefore the supporting documentation will be updated on a regular basis, particularly for audit purposes.

Containment regime for different approved organisms

Requirements for the containment regime

- 6. The containment facility and all containment area(s) where the approved organisms may be held must be clearly defined, described, and documented, including their location and boundaries.**
- 7. The containment area(s) must be designed, constructed, managed, and maintained to prevent the approved organism from escaping, taking into account the physical, health and behavioural needs of the approved organism(s).**
- 8. Persons entering and exiting the containment facility and/or any containment areas must do so in a way that does not adversely affect containment of the approved organism(s).**
- 9. The approved organism(s) must be identifiable as a new organism and able to be linked to the relevant HSNO Act approval.**

Defining the containment facility

The containment facility and containment area(s) where the approved organism(s) will be held and managed needs to be clearly defined because it is within this defined space or operational regime that approved organisms must be contained. For both operational and compliance reasons, it is important that the containment facility is clearly identified so that the approval user, any person involved in managing containment of the approved organism(s), and MPI, as the enforcement agency, understand where the legal boundaries of the facility are.

The documented description of the containment facility should, at minimum, include a map clearly defining the physical area that is the containment facility, and proximity to any notable structures (such as roads, buildings etc). In addition, it may be useful to describe the facility and its boundaries

in words, and identify key structures, buildings, entry or exit points, and any other information that may be useful in managing containment.

Defining containment areas

A facility will often house a range of different approved organisms with different containment needs. The conditions appropriate for holding organisms within a facility will vary depending on the specific facility and the approved organisms involved, and the activities being undertaken involving those organisms.

The term **containment area** means the specified place(s) and operations within the containment facility designated and delimited for a specified approved organism.

A **containment area** may be:

- the entire containment facility (where the perimeter is suitable to contain the organism)
- one or more specified areas (such as exhibition areas, enclosures, veterinary treatment areas) within the containment facility
- specified conditions, operations or equipment for the routine exercise, display, movement, or handling of approved organisms (such as cages, tanks, aquariums, leads for walking animals).

A specified containment area may include areas used for a particular purpose, such as public display, feeding, sleeping or veterinary treatment of approved animals. The containment area for individuals of the same species may vary. For example, some individuals may be suitable for free-ranging exhibition or walk-about in the containment facility, while others may not. There may also need to be specified areas for males and females of a species, particularly in times of oestrus or to manage aggressive behaviour.

The containment facility is required to define the containment area(s) for each approved organism held in the containment facility in the containment facility documentation. Maps and descriptions of containment measures and activities may be useful in defining a containment area. Design and construction of containment facilities and containment areas

When planning, designing, constructing or modifying a containment facility or containment area, considerations that should be taken into account include, but are not restricted to:

- preventing the escape of approved organisms
- preventing the entry of unauthorised persons
- keeping undesirable organisms out of the containment areas or facility
- preventing waste (including waste water) carrying approved organisms from being released
- ensuring that access (entry and exit) to containment areas for feeding, cleaning, training, or veterinary care can be effectively achieved without compromising containment
- ensuring that aggressive, injured or sick animals can be safely isolated and managed
- ensuring that the specific containment needs of each approved organism can be effectively managed, taking into account such factors as gender, temperament, individual behaviour, past history and intelligence
- deterring unsupervised contact between the public (visitors to the containment facility) and the approved organisms
- exclusion of furnishing and enrichment that could compromise the containment of a new organism
- alternative methods of opening or closing electronically operated gates and doors.

It is expected that the facility will have an adequate number of suitable containment areas available to house each of the specimens in appropriate social groupings to prevent containment breaches due to behavioural issues (for example, aggression).

Where appropriate, walk-through containment areas should have clearly marked areas distinguishing public access areas from animal-only areas.

Drive-through containment areas should have appropriate mechanisms for entry and exit to manage potential risks of escape, such as a system using interlocked double gates.

Containment facilities holding animals for public exhibition, conservation, education or research should refer to *Zoo Aquarium Association New Zealand Guidelines for Containing Zoo Animals in New Zealand* when designing and constructing containment areas.

Note: If other guidelines are to be used as a basis for structural design, a case-by-case assessment must be carried out to ensure that the structural design is necessary and sufficient for the containment of the approved organisms that will be kept within the facility.

Taking into account physical, health and behavioural needs

Containment of new organisms is more easily achieved and less problematic if the physical, health, and behavioural needs of those organisms are being met. Healthy, content, and well-fed animals will be less aggressive, more easily managed and less inclined to satisfy needs outside their immediate containment areas. Such needs include taking account of numbers in enclosures, gender and age balance and using appropriate population control measures to prevent overcrowding, maintaining appropriate social group dynamics and interactions (or lack thereof), and providing suitable enrichment that does not compromise the containment of the organism.

When physical, health and behavioural needs of the approved organisms are not met, they are more likely to become stressed, anxious and difficult to manage as they search for ways to meet those needs. Consequently, the likelihood of breaching containment is higher.

It is also important to note that the social dynamics of animals is important and is a necessary consideration of any containment regime. Some animal species are more socially or solitary inclined than others, as are some individuals of a species, especially specific genders at certain times of their lives (eg, oestrus, dominance rituals). Therefore the following matters should be taken into consideration: group dynamics, hierarchy, leaders, family units, dominance challenges, aging, encounter logistics and feasibility, enrichment strategies, consequences of drug therapies, injury, hormonal influences and contraception controls. All of these are likely to impact in some way, either individually or in combination, on the physical, health and behavioural needs of individuals and animal groups as a whole.

It will be important to show how the physical, health and behavioural needs of the organisms have been taken into account in the planning, design, construction, and management of containment areas. This may include advice and guidance from appropriate and qualified technical expert, external audit (for example as part of industry body membership). In this respect, ready access to experts with working knowledge of specific animal species and their behavioural, health and welfare needs is very important.

Note: Approval users should note that they are legally required to comply with the provisions of the Animal Welfare Act with respect to all animals under their care. Meeting the requirements of the HSNO Act controls must not be interpreted as meeting the requirements of that Act. Consequently, approval holders are strongly recommended to ensure they are familiar with the requirements of the Animal Welfare Act.

Maintenance of containment areas

Containment areas that rely on physical barriers or equipment to contain an approved organism need to be maintained so that the containment of the approved organism is not compromised. In addition, containment areas that encompass activities involving approved organisms (such as encounters) need to be regularly reviewed to ensure that the scope, operation, and boundaries of those activities are effective in managing containment. Such review would include, for example, the routes taken within a containment facility during dingo walkabouts to ensure that the dingo behaviour is not adversely affected by proximity to any other animals.

Maintenance is the process of maintaining or continuing a state of good repair and includes repair activities where materials are replaced with identical or similar materials. The frequency of maintenance work will depend on the specifics of the containment area (such as materials, age of fixture, exposure to elements, damage caused by organisms); however, containment areas should be checked regularly to ensure additional maintenance or repair work is not required.

Maintenance and repair to existing physical barriers or equipment does not require notification to the MPI Inspector. Maintenance and repair work to containment areas should be planned and undertaken in ways that do not compromise the containment of any approved organism. This may require

approved organisms being moved to alternative containment areas which, because of their purpose, must also be suitable for containment.

Significant modifications to the containment regime

Significant modifications to the construction or the operation of containment areas, such as changing conditions under which an approved organism is held, or altering structures that restrict the approved organism, may affect the integrity or adequacy of the containment of the approved organism.

Therefore modifications to containment areas need to be planned and considered carefully, and should be discussed with your MPI Inspector before they are undertaken, especially if the changes could adversely affect the containment.

Entering and exiting the containment facility

This control focuses on operational procedures rather than the adequacy of physical or structural provisions. While physical structures must be designed and constructed to prevent the escape of approved organisms, these are only as effective as the operational measures employed when using them. Therefore operational procedures specifying how people enter and exit the containment facility and containment areas must take into account the organisms being contained. Procedures may include checking the location of the contained animal, locking the animal(s) in a separate area, the use of double doors, the use of personal protective equipment, or requiring multiple staff to be present. In addition, it is necessary to take into account the intelligence and behaviours of the animals being contained.

Interactions with approved organisms

Interactions with approved organisms, such as feeding, watering, cleaning, training, and conducting health checks will occur routinely in containment facilities. The way these interactions are managed and undertaken should not compromise the containment of the approved organism in any way. It is expected that approval holders will ensure that there are documented operational procedures or protocols for those interactions describing the measures that will be employed to ensure the containment of the approved organisms is not compromised.

Interactions with approved organisms may also involve public encounters. Such interactions are not prohibited under the HSNO Act provided the containment of the approved organism is maintained. However encounters may be restricted under other legislation, such as the Animal Welfare Act and the Health and Safety at Work (HSW) Act.

Public encounters include (but are not limited to):

- feeding (where visitors feed an approved organism, either within or from outside the containment area)
- direct contact (where one or more visitors is able to physically interact with an approved organism)
- walk-about and demonstrations (where an approved organism is removed from its normal housing under direct supervision and control of a trained staff member to interact with the public)
- behind the scenes visits (where visitors enter restricted (normally staff only) areas, but do not enter the containment area where an approved organism is present).

Approval users should refer to *Zoo Aquarium Association New Zealand Guidelines for Containing Zoo Animals in New Zealand* when planning public encounters.

Note: If other guidelines are used as a basis for operational procedures, a case-by-case assessment must be carried out to ensure that the containment regime is sufficient for the containment of the approved organisms in that facility.

Approval users should refer to the Animal Welfare (Zoos) Code of Welfare 2005 (or the most current document) when designing public encounters to ensure that the physical and behavioural needs of the animals are being met in relation to their containment.

Identification of approved organisms

Identification of approved organisms within the facility is important to ensure that they are handled and disposed of correctly, and to verify that the required containment has been achieved. Each approved organism should be able to be linked to the approval and the containment provisions that specifically relate to it, both within the approval and through the prescriptive measures applied through the containment manual to meet the approval.

The level of identification must be appropriate for that organism and is generally related to the potential risks and size of that organism. For example, a group of very small organisms of the same species might be identified as a group with x individuals, while larger animals such as giraffes will be identified as individual specimens.

Part of this identification process involves informing MPI of all HSNO Act approvals used within the facility, and being able to identify which organisms relate to the approval.

Practices may include:

- Clearly labelling organisms as approved/new or 'not new' organisms.
- Segregating approved/new and 'not new' organisms from each other.
- Maintaining a genealogical history of organism parentage and breeding.
- Maintaining a log of all approved organisms within the facility including the HSNO approval numbers.

Notification about new organisms

Requirements for notification to the EPA and/or MPI

- 10. Notification must be given to MPI of any movement of approved organisms outside of the facility, or any proposed modification to the containment regime which may affect the integrity of containment of the approved organism(s), before the modifications are undertaken.**
- 11. The EPA and MPI must be notified in writing before this HSNO Act approval is used for the first time.**
- 12. MPI must be notified as soon as possible, and within 24 hours, of any escape and/or breach of containment and the actions taken in response to that incident.**

An essential part of any notification is ensuring that the recipient has received it and any requested action has been understood and undertaken. This is particularly important with urgent issues, issues involving a critical non-compliance and issues that may immediately lead to action from MPI. Do not assume notification has been received if it has not been acknowledged.

Notification can generally be done through email, however urgent notifications should be by phone if possible.

Notification about first use of HSNO Act approvals

All facilities need to notify both the EPA and the relevant MPI Inspector in writing (letter or email) that they intend to use the approval prior to using that approval for the first time. This ensures that the EPA and MPI know which facilities are using approvals.

Notification of movement outside the facility

Movement of new organisms outside of containment facilities, including to other containment facilities, requires permission under the Biosecurity Act. Therefore it is necessary to notify MPI, and obtain the relevant approvals prior to moving the organism(s).

Notification of intention to modify the containment regime

Modifications to containment areas, such as changing conditions under which an approved organism is held, or altering structures that physically contain the approved organism, may affect the integrity or adequacy of containment of the approved organism. Therefore modifications to containment areas need to be planned and considered carefully, and should be discussed with your MPI Inspector before they are undertaken, especially if the changes could adversely affect containment. This applies to operational matters as well as structural matters because changes in operations have the potential to adversely impact the ability to maintain containment.

While approval users may have varying views on whether a particular modification is likely to adversely affect containment, it is recommended that MPI be contacted if there is any doubt about whether a proposed change will continue to meet requirements.

Facilities are required to notify a MPI Inspector before the modified containment area can be used for containment of a new organism. This may involve approval of plans before work is carried out, and an inspection of the completed modification before use. This is to ensure that appropriate consideration has been given to planning, especially the technical and logistics aspects; compliance with the controls is maintained before, during, and after the modification; and the completed modifications are compliant with the controls.

Notification of escape or breach of containment

Facilities are required to notify MPI of any escape of an approved organism or breach of containment, as soon as possible, and within 24 hours of the event being identified. If there is any doubt whether a breach has occurred, it is strongly advised that MPI be contacted, especially if there is a possibility of unauthorised access (eg, after hours break-in).

In such cases initial notification by phone may be most appropriate, followed up by emails outlining more details of the incident and the actions taken in response.

Moving approved organisms

Requirements for moving approved organisms

- 13. The approved organism(s) must be contained during movement within, to, or from the containment facility.**
- 14. When being moved outside of a containment facility, within New Zealand, the approved organism must accompanied by documentation stating the:**
 - a) identity of the approved organism**
 - b) containment requirements**
 - c) details of the sender**
 - d) details of the receiving facility.**

Approved organisms may need to be moved for routine and non-routine purposes.

Movement within the containment facility may include:

- for exercise, public encounters, or display in a different containment area within the facility
- for a health checks or veterinary treatment
- for non-routine purposes, such as in response to an emergency.

Movements from one containment area to another containment area within the containment facility do not require MPI approval, provided the containment areas have been specified in the facility documentation. However, the organism must be contained during the move.

Approved organisms may also need to be moved outside of the containment facility, for example:

- moving to other containment facilities
- for export (to another country)
- for veterinary treatment (where necessary treatment cannot be undertaken within the containment facility).

The organisms need to be contained during all movement outside the containment facility.

Note: MPI approval is required for all movements outside of the containment facility. Please contact your MPI Inspector, who will advise you of the specific requirements under the Biosecurity Act.

Other regulations relating to moving approved organisms

There are a range of laws beyond the HSNO Act that are relevant when moving approved organisms, both within New Zealand and outside of New Zealand. These include the Animal Welfare Act, the HSW Act, and the Biosecurity Act.

Approval users may also need to comply with the requirements of the Convention on International Trade in Endangered Species (CITES) when acquiring or transferring approved organisms (if relevant). International transport of approved organisms will generally need to meet the Guidelines on Transport and the Regulations of the International Air Transport Association (IATA), and other relevant regulations.

Restricting access to the containment facility

Requirements to limit access to the containment facility

- 15. Unauthorised persons must be excluded from the containment facility.**
- 16. All containment facility entrances must be clearly identified including specifying who has the right of access.**
- 17. The number and location of entrances to the containment facility where the approved organism(s) are held must be identified and documented.**

Access to the containment facility and to approved organisms needs to be controlled to ensure that the integrity of the containment is maintained.

Authorised persons are those persons identified in the containment facility documentation as being allowed to be in the containment facility or any part thereof. Entrances include all recognised and intended entry points including those that are primarily used as exits (such as fire escapes) and those that are not in active use on a regular basis.

Containment facilities may be open to the public (visitors), or require tradesmen, contractors, or other people to access the facility at various times. Such visitors are generally considered to be 'authorised persons' who are permitted to enter the facility and access certain areas within the facility, subject to specified rules. However, the presence of members of the public poses a risk to the integrity of the containment of approved organisms within the containment facility. Therefore it is important that members of the public (visitors or intruders) are deterred from entering containment areas or liberating approved organisms from their containment area or the containment facility and interacting with approved organisms in such a way that presents a risk to themselves and containment.

Entrances in active use should be kept to a minimum and all entrances (including those that are primarily used as exits) need to be listed in the containment facility documentation. Facilities also need to consider mechanisms to minimise the risks of theft, malicious damage or release of approved organisms by intruders entering the grounds out of visiting hours.

Measures that may be taken to prevent unauthorised access to the containment facility or specific areas of the containment facility include physical and operational measures such as:

- physical barriers (gates, fences, walls, windows, doors, locks)
- signs (for example 'Authorised Personnel Only')
- a perimeter structure (designed, constructed and maintained) to prevent (as far as is reasonably practical) the entry of unauthorised people
- supervision of entrances
- security personnel after hours.

Controlling access to the containment facility, and limiting access to approved organisms, may also be required under other laws such as the Biosecurity Act, the Animal Welfare Act, and the HSW Act.

Disposal of waste and removal of equipment

Requirements for removing equipment and waste from the containment facility

- 18. Any waste (including biological material) that may harbour the approved organism(s), or heritable material from the approved organism, must be treated to ensure that the approved organism or any heritable material is killed prior to discarding.**
- 19. Any equipment, that may harbour the approved organism(s) or heritable material from the approved organism, must be treated to ensure that the approved organism or any heritable material is killed prior to the equipment being used for another purpose or being removed from the containment area/facility.**

For the purposes of this section:

- 'Waste' refers to unusable or unwanted substances or material (including solids, liquids and air) that may contain an approved organism or heritable material from an approved organism.
- 'Biological material' refers to material that may contain an approved organism or heritable material from an approved organism which is wanted for other purposes (e.g. invertebrate for display purposes).
- 'Equipment' refers to items or materials (includes protective clothing or machinery or devices) that may be contaminated with an approved organism or heritable material from an approved organism.

The removal of waste (including water from aquariums and water from cleaning contaminated equipment), biological material or equipment from the containment facility is a potential pathway for small approved organisms or heritable material to escape from containment.

Equipment, waste and biological material that may carry or contain approved organisms or heritable material must be treated or decontaminated **prior** to being discarded (for example in general rubbish collection, water treatment, or storm water). Decontamination or treatment should remove all approved organisms and heritable material.

If treatment or decontamination is being contracted out to a commercial waste contractor, that contractor must be approved by MPI to undertake that treatment or decontamination through approval as a transitional facility to the MPI Standard: *Requirements for Suppliers of Official Treatments*.

In regards to machinery, only the parts that could potentially be contaminated with the approved organisms need to be decontaminated.

In most instances it is expected that decontamination or treatment will occur prior to the waste leaving the facility. However if decontamination or treatment will occur outside of the containment facility, the waste needs to be treated prior to being discarded.

Deceased animals

As deceased animals are not regulated under the HSNO Act, as they are not organisms for the purpose of the HSNO Act. The following information is provided for clarity.

Carcasses and organs of deceased animals should be disposed of swiftly. The preferred methods of disposal are deep burial or incineration within the containment facility. If deep burial or incineration is to occur outside of the containment facility, this will need to be approved by the MPI Inspector to ensure there is no biosecurity risk.

There will be times when animal carcasses or part(s) thereof, may be of interest to scientific institutions or desired for display purposes (taxidermy or mounting of invertebrates). This is not prohibited under the HSNO Act. However, it may be limited by the requirements of the Biosecurity Act; therefore MPI approval may be needed if the deceased animal is to be removed from the containment facility.

Undesirable organisms

Requirement for dealing with undesirable organisms

20. The containment facility must be secured and monitored to ensure the exclusion of undesirable organisms that might compromise the containment of the approved organism(s).

The presence of 'undesirable' organisms such as rodents or insects within the containment area or facility could compromise containment. To avoid this, undesirable organisms should be, where possible, prevented from gaining access to the facility. However should undesirable organisms gain access, measures must be taken so that such organisms are captured or killed.

What constitutes an undesirable organism will depend upon the type of approved organisms contained within the containment facility, and will be defined by the containment facility and listed in the containment facility documentation.

How a containment facility or area is secured against the entry of undesirable organisms will depend on the nature of the organism(s) that are to be excluded, and why. For example a reptile enclosure might need to be secured against rats, to prevent rats taking live eggs or young reptiles out of the cage, tank, or enclosure and thus breach containment.

Measures that may be taken to exclude undesirable organisms include physical and operational measures such as:

- Fully enclosed facilities (e.g. no gaps in walls).
- Self-closing outer doors.
- Windows are either sealed closed or screened with mesh that will exclude undesirable organisms.
- Ventilation inlets and outlets, and drains are screened with mesh that will exclude undesirable organisms.
- Insect control measures (such as sticky strips).
- Vermin control measures (such as a rodent control programme which involves mouse traps placed at strategic locations which are checked weekly).

Instruction and training

Requirement for instruction and training

- 21. Any person (including contractors, staff, students, visitors, and volunteers) entering the containment facility and/or containment areas must have received sufficient instruction on the containment regime to enable the person to meet their responsibilities in relation to containment.**
- 22. The containment facility must have sufficient staff with the appropriate qualifications, training, and experience in the care and behaviour of the approved organism(s) to ensure containment is effectively maintained.**

Training is an essential part of the operation of a containment facility. Training ensures that those people with responsibilities understand what those responsibilities are and how their duties should be carried out in order to prevent the containment of approved organisms being compromised.

Training needs to be targeted so that the right behaviours are being exercised by the right people and those not required to know some information are not unnecessarily informed of it. For example visitors to the zoo may be instructed through signs (such as 'keeper only area', 'no entry'), or verbal instructions and supervision by zoo staff (such as before and during an encounter). A zoo keeper would have detailed training on the general containment requirements and contingency plans for the facility, and specific training about the containment regime, physical abilities and characteristics of the approved organism(s) that they will be working with.

Training needs to encompass day-to-day operations, irregular or one-off events, contingency plans and emergency situations in relation to containment of approved organisms.

All persons need relevant information, instruction and training appropriate for their responsibilities and duties. This will include an understanding of the purpose of the containment facility and how that is reflected in their actions and work.

Documentation regarding instruction and training should include:

- Records of training (who, when, what, pass/fail)
- Refresher training schedules
- Measures determining the adequacy and level of understanding of training
- A list of which keepers are trained to work with which approved organisms.

Staff must be able to demonstrate that they have the expertise, technical knowledge and understanding of the approved organism(s) being held in the facility to be able to manage and maintain containment of the organism(s). In addition there must be sufficient staff available to carry out the required operations to maintain and care for the animals held in the facility. This includes succession planning, and allowing for staff absence (illness and holidays).

Contingency plans

Requirements for contingency plans

- 23. The containment facility must have a documented contingency plan for each approved organism held in that containment facility.**
- 24. The contingency plan must be implemented immediately if there is any reason to believe that an approved organism has escaped or been released from a containment area or the containment facility, or any other breach of containment has occurred.**

What is a contingency plan?

A contingency plan is a plan devised for a specific situation where things have gone wrong. For example a breach of containment or escape of an approved organism. It contains information, tasks and procedures that are necessary for timely decision-making and response to an unexpected event, or situation where the preferred plan fails.

What contingencies does a containment facility need to plan for?

A containment facility will need a contingency plan covering any reasonably foreseeable event that may compromise containment of any approved organism housed by the containment facility, and cover the actions to be taken in the event that escape or breach of containment occurs. In particular, the actions to be taken to recapture or eradicate the escaped approved organism.

This means facilities must plan for:

- any reasonably foreseeable emergency (e.g. fire, earthquake, flooding, power outages, freezer or other equipment failure, communication failures, off-site emergency veterinary treatment)
- approved organism escapes from containment (including escape from the specified containment area or the containment facility) through accidental or deliberate actions of personnel or visitors
- unauthorised entry into the containment facility
- unexpected facility closure
- the structural integrity of the containment facility being compromised.

If the MPI Inspector has concerns about other scenarios, they may require additional plans to be put in place prior to a containment facility being approved.

In developing contingency plans, facilities need to consider all possible or likely escape routes from containment areas and the containment facility, and what events might lead to the escape or release of an approved organism.

What does the contingency plan need to include?

The contingency plans need to layout the actions to be taken in the event of an escape or breach of containment, with particular emphasis on recapture or eradication of the escaped approved organism.

A contingency plan may include the following information:

- the nature of the contingency event
- the chain of command for decision-making
- the risks to containment associated with the event
- the actions that will be immediately taken to manage those risks should the event occur, including recapture or eradication measures
- the equipment and measures that will be required to implement those actions, including the location and accessibility of that equipment and the authorisation (eg, firearms) to use it and names and contact numbers of emergency, regulatory and technical personnel
- communications - who, what, when, and how) (internal and external)
- training, practice drills and tests.

The contingency plans may also address other issues under other laws, such as the Animal Welfare Act, or the HSW Act where safety of the public and personnel will be the focus. A separate contingency plan for each law is not necessary.

Internal inspection and monitoring

Requirements for internal inspections and monitoring

- 25. To ensure containment is being achieved, containment measures must be:**
- a) inspected, monitored and reviewed as appropriate**
 - b) inspected as soon as possible after any event that could compromise the containment regime such as an Act of God (such as flood, earthquake) or any unauthorised attempt to enter the containment facility.**
- 26. Any remedial requirements identified under control 25, or by any other means, must be actioned as soon as possible.**

Inspection and monitoring of containment measures

Facilities need to undertake monitoring and maintenance of containment measures (structural and operational) on a regular basis to ensure that containment of approved organisms is maintained.

The frequency and extent of monitoring of containment measures will depend on the type of barriers in place, and the approved organisms within the containment area. For example, some containment measures may require a daily visual check, with monthly physical integrity checks; while other containment measures may need to be checked more or less frequently. Additional inspections also need to be undertaken following any event, such as flooding or earthquake, which may have resulted in damage.

Inspectors will be seeking verifiable evidence that inspection and monitoring measures are adequate and appropriate. Consequently, planning and thought must be put into determining what these are, whether they are fit-for-purpose and what technical expertise and competency is required to use and evaluate them.

Where the integrity of a structural containment measure is found to be lacking; through damage, wear and tear, or any other cause; remedial measures need to be undertaken immediately. This may include moving an approved organism to a different containment area while remedial work is undertaken.

Where compliance with an operational measure is found to be lacking; through personnel not following standard operating procedures or any other cause; remedial measures need to be undertaken immediately.

Terms and Definitions

• approved organism	New organisms approved under application APP201517.
• audit	A systematic documented review or examination and evaluation of evidence to determine the extent to which specific criteria are fulfilled.
• authorised person	Authorised persons are those identified in the containment facility documentation as being allowed to be in the containment facility or any part thereof.
• breach	Escape of organism(s), unauthorised entry to the facility or containment area, and/or the structural integrity of the facility being compromised.
• containment	Restricting an organism to a secure location or facility to prevent escape (section 2 of the HSNO Act).
• containment area	The specified place and/or conditions within the containment facility designated for a specified approved organism.
• containment facility	A place approved by MPI in accordance with section 39 of the Biosecurity Act 1993, for holding approved organisms.
• containment measures	The systems and processes that comprise the containment regime
• contingency plan	A plan devised to respond to a specific situation where things could go wrong, affecting containment for example escape of an approved organism. It contains information, tasks and procedures that are necessary for timely decision-making and response to an unexpected event, or situation where the preferred plan fails.
• controls	Any obligations or restrictions imposed on any approved organism, or on any person in relation to any approved organism, by the HSNO Act, or any regulations, rules, codes, or other documents made in accordance with the provisions of this or any other Act for the purposes of controlling the adverse effects of that organism on people or the environment (section 2 of the HSNO Act).
• disposal	(In relation to an approved organism) rendering the organism biologically inactive in such a manner as to prevent the occurrence of any future biological activity, or exporting the organism from New Zealand (section 2 of the HSNO Act).
• decontaminate	Kill or remove all approved organisms and heritable material.
• documentation	Written or electronic records (including manuals, lists, diagrams, maps, policies, procedures, plans and protocols, records of training, access).
• EPA	The Environmental Protection Authority.
• heritable material	(In relation to an approved organism) viable biological material, including gametes and spores, arising from that organism that can, without human intervention, regenerate the organism or reproduce a new generation of the same species of the organism (section 2, HSNO Act).
• HSNO Act	Hazardous Substances and New Organisms Act 1996.
• MPI	Ministry for Primary Industries.
• MPI Inspector	A person appointed under the Biosecurity Act to undertake administering and enforcing the provisions of the Biosecurity Act and who may also be appointed as an enforcement officer for the purpose of enforcing the provisions of the HSNO Act relating to new organisms.
• maintenance	The process of maintaining (preserving or providing for the preservation of) or continuing a state of good repair.

<ul style="list-style-type: none"> • new organism 	<p>Defined by section 2A of the HSNO Act</p> <ul style="list-style-type: none"> (a) an organisms belonging to a species that was not present in New Zealand immediately before 29 July 1998 (b) an organism belonging to a species, subspecies, infra-subspecies, 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 (ca) an organism for which a conditional release approval has been given under the HSNO Act (cb) a qualifying organism approved for release with controls (d) a genetically modified organism (e) an organism that belongs to a species, subspecies, infra-subspecies, variety, strain, or cultivar that has been eradicated from New Zealand.
<ul style="list-style-type: none"> • organism 	<p>Defined in section 2 of the HSNO Act:</p> <ul style="list-style-type: none"> (a) Does not include a human being (ab) Includes a human cell (b) Includes a micro-organism (c) 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 (d) Includes an entity (other than a human being) declare to be an organism for the purposes of the Biosecurity Act 1993 (e) Includes a reproductive cell or developmental stage of an organism.
<ul style="list-style-type: none"> • treat (with reference to waste) 	<p>Kill all approved organisms and make heritable material non-viable.</p>
<ul style="list-style-type: none"> • undesirable organism 	<p>Organisms such as rodents, insects, and birds within the containment area/facility that could compromise containment (dependent on what organism is being contained).</p>
<ul style="list-style-type: none"> • waste 	<p>Unusable or unwanted substances or materials (including water, liquids, solids or air).</p>