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Ministry for Primary Industries – Manatū Ahu Matua

Containment Facilities

A Regulatory System Review

December 2024

Te Kāwanatanga o Aotearoa
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Purpose of the Review

This review considers how the Ministry for Primary Industries meets its regulatory responsibilities for containment facilities.

Containment facilities are physical structures containing micro-organisms, vertebrates, invertebrates, and plant matter not already established in New Zealand which are termed "new organisms", and unwanted organisms already present in New Zealand. These can be held in containment for use in research, testing, entertainment or education. Containment facilities can also hold new organisms approved by the Environmental Protection Agency and Biosecurity New Zealand for use in the event of a full-scale incursion of a threatening species of animal, plant or another organism.

Containment facilities include research institutions, laboratories, universities, zoos, open fields used for trials, and herbariums. The purpose of containment facilities is to hold organisms that should not become established in New Zealand. They are designed to prevent the risk of contamination, exposure or release of organisms that could pose serious threats to public health, the environment, and agricultural productivity into the environment.

Research and testing of new organisms allows organisations to develop new products, biochemicals and technologies, and to study organisms for scientific purposes. These activities are crucial for New Zealand's future growth, prosperity and sustainability.

At its worst, potential consequences of containment breaches could include catastrophic and irreversible loss of biodiversity and native taonga, and ecosystem disruption could be significant leading to costs for pest control and eradication. Thus, the regulatory system governing containment facilities provides important safeguards for biosecurity in New Zealand.

MPI has the statutory role to enforce regulations for new organisms in containment. This supports the continued protection of New Zealand's unique natural environment and primary industries.

MPI's enforcement responsibilities for transitional facilities were not considered in this review.

This review reflects the system as we found it. As with all systems, changes occur on an ongoing basis to continually improve efficiency and effectiveness and so this report provides a snapshot in time view of how the system regulating containment facilities is operating at this time.

Executive Summary

Regulatory framework

Containment facilities are designed to contain organisms including micro-organisms, vertebrates, invertebrates and plants. Some containment facilities are required to meet the Australian/New Zealand Standards (AS/NZ2243.3) for safety and containment, as part of meeting containment standards set by the Environmental Protection Authority (EPA) for containment of distinct types of organisms.

The legal framework governing containment facilities in New Zealand is a complex mix of primarily two Acts:

1. the Hazardous Substances and New Organisms Act 1996 (HSNO Act) administered by Ministry for Environment (MfE), regulated by the Environmental Protection Authority (EPA), and enforced by Ministry for Primary Industries (MPI); and
2. the Biosecurity Act 1993 administered, regulated, and enforced by MPI.

Roles and Responsibilities

EPA

The EPA sets containment standards for containment facilities. These standards are tailored to the different types of organisms and specify protocols that facility operators must comply with.

Under the HSNO Act, operators of containment facilities are required to implement strict measures to prevent escape or release of new and unwanted organisms into New Zealand's environment. The EPA is responsible for approving new organisms for release, or containment with controls or conditions.

WorkSafe New Zealand

WorkSafe New Zealand has responsibility for influencing businesses and workers to ensure work is healthy and safe within containment facilities.

MPI

MPI is responsible for regulatory oversight and enforcement of containment of new and unwanted organisms through:

- approving containment facilities and their operators;
- verifying that facilities are following management plans and containment standards; and
- taking enforcement action to uphold the integrity of the containment operations and to enforce standards and controls.

Verifiers from within the New Zealand Food Safety business unit conduct verification of containment facilities.

Staff within the Biosecurity New Zealand business unit manage other aspects of regulatory activity for containment, like:

- application screening for new containment facilities;
- contribution to the development of containment standards;
- provision of technical advice;
- supporting work on import health standards; and
- surveillance and incursion response.

Other MPI teams provide assistance with various aspects of the regulatory services.

MPI also operates containment facilities including:

1. the Animal Health containment facility; and
2. the Plant Health containment facility.

These two facilities operate up to a physical containment 3 (PC3) level, the highest level of containment available in New Zealand. They are subject to the same regulatory framework as all other containment facilities, and that includes being verified by MPI.

Key Findings

MPI is effective in approving containment facilities and operators, and verifying that operators are working within the regulations. A small team of five dedicated, well qualified, highly capable individuals carry out the majority of containment verification and enforcement work despite facing long held resourcing challenges, the loss of expertise in the HSNO Act, and the repetitive nature of the work. This team are supported by a further eight or so verifiers who report outside the team to other regionally based managers within the wider directorate. These additional verifiers are located around New Zealand and attend to containment verification in addition to their food safety verification responsibilities under the Animal Products Act 1999.

While well managed, there are some opportunities for strengthening the overall regulatory system, as set out below.

Verifier Capability and Capacity:

The main containment facilities verification team is small. While currently fully staffed, until recently it had been operating with a vacancy for two years. Holding vacancies in a small team has meant extended hours for staff, and more travel. The acting team manager had less time to devote to ongoing team training, function development, and to provide support to the staff given he performed an operational role also during this time. This can all impact overall efficiency. More specifically, keeping containment verifiers up to date with training on HSNO regulations has not been able to be prioritised. Regular training would be expected for warrant holders under the relevant legislation.

Having resources available to have a different verifier do every fourth site visit as a mitigation against capture or complacency would also be beneficial.

Placement of Containment Facility Verification:

Locating the containment facility verification function in the Verification Services directorate within New Zealand Food Safety was intended to consolidate all verification functions in one place within MPI. However, there are operational differences between the two different teams. Containment facility verification work is driven by biosecurity requirements, while other verification is food safety related. They have different purposes and legislation, different approaches, work with different systems, and have different charge out rates.

Containment facility verification is aligned to transitional facility verification. In fact, the biosecurity verifiers work at many sites which are registered as both containment and transitional facilities. Inspection and verification of transitional facilities is largely the responsibility of Biosecurity New Zealand; however, the Biosecurity verifiers verify a significant number of transitional facilities in certain sectors including quarantine sites for plants, pets and horses, cold stores and animal products processing plants.

MPI might consider whether aligning the Biosecurity Verifier functions more closely with Biosecurity New Zealand could bring benefits. While this would have some complexity because of the potential conflict between roles where the Biosecurity business unit would be regulators, enforcers and operators of facilities, it would bring greater consistency to verification of the different types of facilities, and would have efficiencies through utilising similar information technology systems.

There would be better system alignment with the Biosecurity activities that support the verification of containment facilities.

Given MPI might be the designated enforcer for the incoming genetic technology legislation, MPI has an opportunity to look at whether the Biosecurity verifier team would have involvement in that activity or with that function. If so, the team may then be more appropriately located within Biosecurity New Zealand. The enforcement of genetic technology legislation will involve determining the regulatory status of organisms developed in New Zealand as well as imported genetically modified organisms which brings a consistent approach to border activity as well as to New Zealand based containment.

Containment Facility Standards:

The HSNO act provides powers for the EPA to approve standards specifying requirements for containment of new and unwanted organisms. Five of the six current containment facility standards were developed between 1999 and 2007. Operators experience difficulties interpreting these out-of-date standards as they don't align with current scientific knowledge and technological advancements.

The EPA has been reluctant to update the existing rules-based standards as it sees more benefit in outcome-based standards and favours developing one universal outcome-based standard incorporating five of the six standards. The 2018 Zoo standard is an outcome-based standard; however, it took over a decade for MPI and EPA to agree that final standard because it required significant cross-agency input to develop, and substantial resources to implement. MPI ceased activity on a universal outcome-based standard due to resourcing constraints and misalignment with standards for transitional facilities. Restarting this development work would bring efficiencies for the operators of containment facilities, notwithstanding the increase in workload to implement such a standard. Outcome-based standards do however place pressure on MPI verifiers to interpret and decide on what measures containment facilities must meet to comply with them.

Regulatory Collaboration:

Effective outcomes for the containment regulatory system depends on effective collaboration between MPI, EPA, and WorkSafe New Zealand (WorkSafe). Collaboration between MPI and both EPA and WorkSafe on containment and new organism regulation has diminished over time. A revised

Memorandum of Understanding (MOU) between MPI and EPA was finalised in early 2024 providing a foundation for renewed collaborative efforts which will hopefully clarify operational roles, responsibilities, and enforcement expectations for containment facilities and new organisms. Work is now needed to operationalise the undertakings.

The incoming gene technology legislation may require new and updated MoUs for the relevant regulatory parties to ensure roles and responsibilities are clear and well-articulated for containment.

Verification and Enforcement Challenges:

Successful enforcement action under the HSNO Act or the Biosecurity Act can be difficult due to being unable to prove either how an organism arrived in New Zealand, or that its introduction was intentional. For similar reasons there have been very few enforcement actions against containment facilities or any other parties for new organism breaches.

The facilities owned and run by MPI are verified by MPI's Containment Facility verifiers (biosecurity verifiers). While the biosecurity verifiers are independent of the facilities, and there are mechanisms in place to ensure that verifiers undertake their work with these facilities with appropriate separation, as these facilities operate at the highest levels of containment in New Zealand it may be prudent to consider whether MPI facilities should be verified by an independently contracted party (potentially from overseas), at least on a biennial basis. At the very least, verification report summaries should be provided to the Deputy Director General of Biosecurity and Director General for additional assurance oversight.

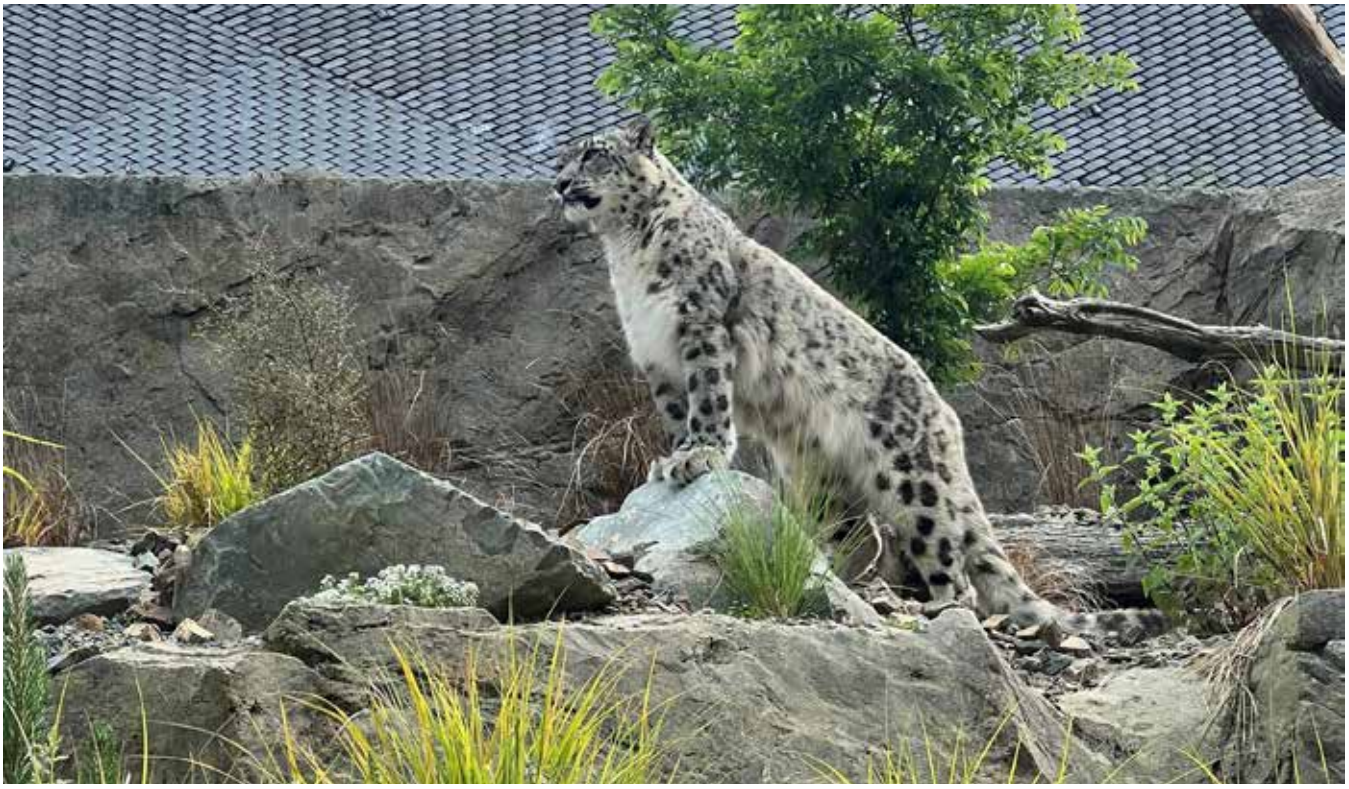
Funding and Resource Allocation:

Verification is a cost recovered service; however, current biosecurity verifier charge-out rates do not recover the full costs of the containment verification team. There is no funding available to meet demands for specialist technical advice, and to better support facility operators.

MPI is also therefore constrained in commencing further regulatory work to improve the system. Notably, biosecurity verifier charge-out rates are lower than for the verifiers of food safety operators.

Conclusion

By committing to updating containment standards, addressing training requirements, strengthening assurance processes, and re-evaluating funding, New Zealand's biosecurity defences and regulatory effectiveness will be well placed to continue safeguarding New Zealand's unique biodiversity and agricultural interests from the risks posed by new or unwanted organisms and biotechnological advancements. Reconsidering placement of the verifier team into Biosecurity New Zealand would also bring efficiencies.



Background

The regulatory framework

"Containment" is defined in the HSNO Act as 'restricting an organism to a secure location or facility to prevent escape'; and includes, in respect of genetically modified organisms, field testing and large-scale fermentation. Containment can be described as the physical structures and operational procedures designed to reduce or prevent the release of a "new organism" into New Zealand's environment. Examples of containment facilities are zoos, laboratories, research institutes, and herbariums (plant libraries of preserved plants).

Containment measures differ depending on; the nature of the organisms to be contained, the risks organisms present, and the mechanisms of potential escape. For example, the design of an animal enclosure depends on the physical nature, health, and behavioural needs of the animals intended to be held in containment.

Containment is regulated primarily by the Hazardous Substances and New Organisms Act 1996 (HSNO Act).

For the most part, 'new organism' is the term used to refer to any organism not legally present in New Zealand before 29 July 1998 (the date the new organism provisions of the HSNO Act took effect). However, a new organism also includes genetically modified organisms regardless of the date of presence, and any organism declared as eradicated from New Zealand. Organisms can include micro-organisms, vertebrates, plants, and developmental stages of these (e.g. eggs, sperm, pollen, pupae etc).

The purpose of the HSNO Act is to protect the environment and the health and safety of communities by preventing or managing the adverse effects of hazardous substances and new organisms. The HSNO Act:

- regulates containment of new organisms;
- interfaces with the Biosecurity Act 1993 (Biosecurity Act) which regulates the risks of unwanted organisms;
- enables inspectors warranted under the Biosecurity Act to use the powers from that Act for new organism enforcement.

New organisms and containment facilities may also be regulated under other Acts like the Agricultural Compounds and Veterinary Medicines Act 1997, the Animal Welfare Act 1999, and the Health and Safety at Work Act 2015, dependent on the organisms' legal status and intended use.

Containment facility standards

The HSNO Act provides powers for the EPA to approve standards specifying requirements for containment of new and unwanted organisms. The EPA has approved six containment facility standards:

1. micro-organisms
2. zoos
3. plants
4. vertebrates
5. invertebrates
6. field testing of farm animals

MPI's Verification Services directorate estimates that New Zealand has approximately 140 containment facilities registered against the micro-organism standard and one or more of the other five containment facility standards.

Regulatory roles and responsibilities

The following agencies have regulatory responsibilities under the HSNO Act:

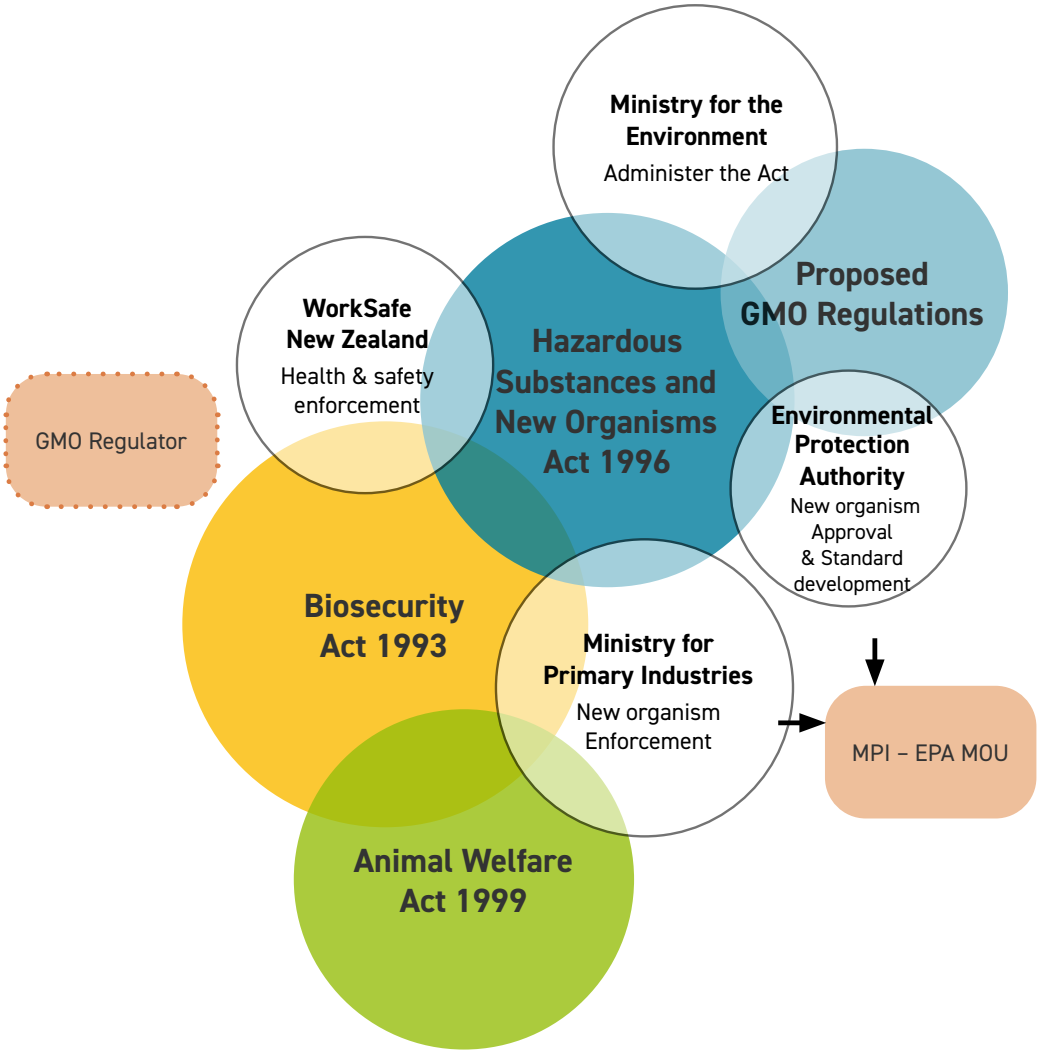
Agency	Responsibility
Ministry for the Environment (MfE)	• Has responsibility for the HSNO Act
Environmental Protection Authority (EPA)	• Determines an organism as "new" • Sets controls on new organism use • Regulates the introduction and use of new organisms in New Zealand
Ministry for Primary Industries (MPI)	• Approves containment facilities and the operators of containment facilities • Enforces regulations for new organisms including for containment facilities
WorkSafe New Zealand (WorkSafe)	• Enforces regulations relating to the health and safety of workers at containment facilities.

MPI responsibilities

Containment facility approval, verification, and compliance activities are conducted by about 12 New Zealand Food Safety verifiers from different teams within the Verification Services Directorate:

1. A Biosecurity Verification Team of five: a Team Manager Biosecurity, three biosecurity verifiers who verify most of the containment facilities in the Auckland region, and a Specialist Adviser Biosecurity based in Wellington.
2. Six regionally located circuit verifiers from Verification Services, primarily verifying food safety premises but also verifying containment facilities in the mid and lower North Island and the South Island.
3. A veterinarian in the Live Animals Verification Services team who verifies zoos in the upper North Island.

Figure 1 Agency relationships and relevant legislation



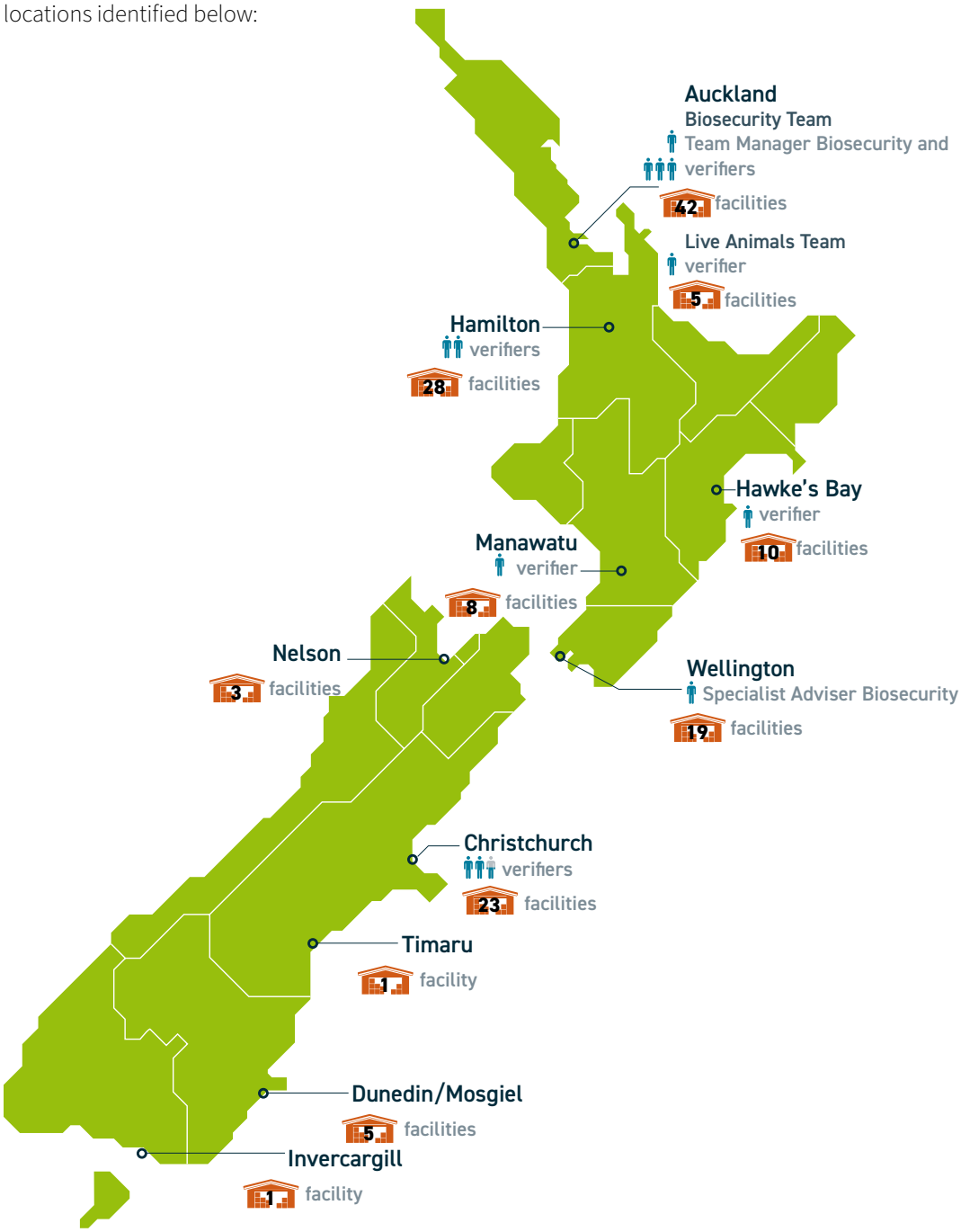
The 2013 decision to locate biosecurity verifiers in what would eventually become New Zealand Food Safety had been intended in part to reduce duplicate verification for food and biosecurity purposes for the same client, but also to group more complex verification activities together.

The regional circuit verifiers report to regionally based managers who are potentially less familiar with the rules and requirements for containment facilities and previous MPI decision-making in this area. Containment facility verification can be a complex technical area where knowledge of historical decisions about ambiguous matters is important for ongoing consistency and expertise.

Of the approximately 140 containment facilities within Verification Services' remit, 35 percent are located around the Auckland region. All but five of these facilities operate as dual containment/transitional facilities. The geographical dispersion of containment facility verifiers and facilities across New Zealand is illustrated in Diagram 1 below.

Diagram 1: Distribution of containment facilities and biosecurity verifiers across New Zealand

Note: the facilities are spread around New Zealand – the number of facilities shown are managed from offices in the locations identified below:



Biosecurity New Zealand supports the regulation of containment facilities through:

- administratively processing all containment facility applications (The Biosecurity Support Team);
- contributing to the development of containment facility standards, new organism applications, and technical clarifications including Chief Technical Officer (CTO) decisions (the Biosecurity Import and Export Standards directorate); and
- investigating and identifying suspected exotic pests and diseases which may include suspected new organisms (Biosecurity Animal and Plant Health Surveillance & Incursion Teams).

Two of New Zealand's highest category physical containment level 3 (PC3) containment facilities[1], the Animal Health Laboratory based at Wallaceville, Upper Hutt, and the Plant Health Laboratory in Auckland, are operated by MPI staff from the Diagnostic & Surveillance Services directorate within Biosecurity New Zealand. MPI verifies these containment facilities in the same way they verify all other containment facilities, by the biosecurity verification team within New Zealand Food Safety.

MPI's legal team gives advice to MPI staff involved in new organism enforcement and on the containment standard. This has become important since EPA initiated a policy of only providing advice where it was statutorily required (e.g. to determine new organisms and set standards only). MPI's separate prosecutions legal team also advises on, and conducts related prosecutions under the Biosecurity and HSNO Acts.

MPI's Compliance Investigations and Support team investigates alleged critical non-compliances and refers files to the prosecutions team for prosecution decisions.

1 AS/NZS 2243.3:2022 Standards New Zealand

Findings and Observations

Verifier resourcing

Biosecurity verification requires a range of capabilities including good judgement, research skills, and relationship management. However, it can also involve repetitive activities. There can be limited potential for career progression. Ensuring these verifiers have the required knowledge, expertise and competency requires effort and ongoing investment.

Individual verifiers can often work with the same containment facility operators year-on-year. This can assist with developing good relationships with the operators. However, operator capture, or complacency could be a potential risk. Verifiers could give leeway for minor non-compliances in support of retaining a good relationship with the operators, unless mitigating measures are put in place. The Team Manager Biosecurity holds fortnightly meetings with containment facility verifiers to test issues or concerns, to help mitigate the risk of capture or complacency.

The approval of a containment facility/operator and the ongoing verification has often been undertaken by the same verifier. Ideally these activities would be conducted by different verifiers to preserve impartiality.

Until very recently, the team of four Biosecurity Verifiers was one person short for about two years. Managing this staffing shortfall required curtailment of some activities that add rigour to the verification framework. It was more challenging to regularly rotate verifiers across the premises or conduct unannounced audits. Opportunities to further develop intelligence-led targeted verifications have not been taken forward. Recent organisational changes have led to the team of Biosecurity Verifiers being reinstated to five, potentially providing an opportunity to allow the higher-level containment facilities to have one in four visits undertaken by a different verifier. However, recently the circuit verifiers from the Food Safety directorate have handed back some of the Biosecurity work to focus on delivering for the Animal Product Act. This has added further workload pressure on the Biosecurity verifiers.

Containment facility verifiers are well trained in verification responsibilities. They are provided with a good understanding of the Biosecurity Act. However, until recently, for several years there was no formal HSNO Act training. This training had been run by a Specialist Adviser HSNO, a now disestablished role. Some of this training is highly technical. Responsibility for delivering this training cannot easily be delegated to another staff member or contracted to third party provider, resulting in a gap in capability. There is also an opportunity to provide ongoing training on animal welfare responsibilities for verifiers of zoos and animal related facilities.

While transitional facilities fall outside the scope of this review, it is relevant to mention that most of the 140 containment facilities also have transitional facilities attached. The containment facility verification teams across the country are also responsible for verifying nearly 300 of the nearly 4,000 other Biosecurity Transitional Facilities. These are transitional facilities that hold certain types of high-risk products e.g. Biologicals, high value crops, plant material, live animals.

The containment facility verification team also conduct specialist inspections, for example pork inspection under the “consumer ready cuts of pork” pathway, post entry quarantine plant inspections, and mills under the Ruminant Control Protein Plan.

Resources have been stretched, particularly during the short-staffed years, however the backlog of verification is starting to reduce now the team is at full strength.

Verification of MPI-run facilities

Given MPI’s role as enforcer of the HSNO Act as relates to containment facilities, and its role as an operator of PC3 level containment facilities, it may be appropriate to identify a suitable independent verifier to review those facilities operated by MPI periodically as an additional level of assurance. This may mean commissioning an offshore organisation, but this would provide additional independent assurance that the highest-level containment facilities in New Zealand are functioning as they should be. In any case, summaries of reports from the verification of MPI facilities should periodically be provided to the Director General

of MPI, and the Deputy Director General of Biosecurity New Zealand for transparency.

Enforcing complex rules governing new organisms

Determining new organism status and illegal importation

Under the HSNO Act it is not an offence to simply possess a new organism. It is only an offence if the new organism is imported, manufactured, developed, or released in New Zealand without an approval by EPA and an individual possesses it knowingly, recklessly, or negligently. It can be difficult for MPI to gather sufficient evidence to prove that an organism is in fact a new organism and has been illegally imported, especially if the species has been present in New Zealand for some time.

EPA has made a policy of only making a determination when they receive a formal application under relevant statutory provisions. They no longer provide non-binding decisions, or provide informal guidance, either to MPI as the enforcement agency, or to other operators and stakeholders. In these situations MPI must form a view on whether an organism is "new" or "not new" to support enforcement decision-making. Amid this uncertainty, where an organism presents significant risks MPI can use CTO decision-making powers under the Biosecurity Act to classify the organism as an unwanted organism and use the full extent of Biosecurity Act powers to manage the risk. Over the last few years, MPI has received requests to investigate plants that are suspected to be new organisms. To ensure a manageable investigative workload, MPI has established an internal process to stand down further investigation of suspected new organisms (particularly plants) if:

a. due diligence has established no evidence of illegal activity; or
b. a prior investigation of the organism has established that the organism presents negligible biosecurity risk.

The Plant Biosecurity Index is a register of plants that MPI uses to discern what species of plant are eligible to be imported into New Zealand and the relevant import conditions that must be met. It has also been used by MPI to assist decision-making on what organisms are not new. However it is not a complete list and nor is it intended solely for this purpose.

Separate risk assessments and approvals under the Biosecurity Act and HSNO Act

The importation of new organisms into New Zealand requires risk assessments and approvals under both the HSNO Act and the Biosecurity Act. The HSNO Act assessment primarily focuses on the risks of the new organism, while the Biosecurity Act assessment focuses primarily on the risks associated with the new organism (e.g. unwanted organisms attached to the new organism). There is often overlap in these assessments which can then result in a lengthy and complex process for importers to navigate. This can lead to frustration for importers and containment facility operators. Collaboration between EPA and MPI on streamlining the process or harmonising these requirements would be beneficial for facility operators.

Changes in the name or class of an organism can create confusion

The scientific name of an organism can change over time which can create confusion for MPI and importers about which organisms can be legally imported, adding delays with importing. Organisms may also be approved using different names under the Biosecurity Act and HSNO Act creating further confusion for biosecurity staff (quarantine officers etc) as to which organisms can be legally imported. The EPA has no work planned to bring clarity to these taxonomy challenges.

Compliance Tools

Verifiers report that there are sufficient compliance tools available to support compliance of containment facilities. Compliance Orders allow verifiers to apply a graduated compliance response, from voluntary, to assisted, directed, or enforced, as widely used by MPI. This graduated response model helps ameliorate risks where immediate enforced compliance could result in abandonment of the facility and escape of contained organisms that pose a risk to the New Zealand public.

Containment facility verifications in recent years have not identified many instances of critical non-compliance with containment facility standards. The Biosecurity Verification team has not referred facilities or instances of illegal importations of unwanted or new organisms to the Investigations & Compliance Support directorate for breaches of HSNO or Biosecurity Act requirements for many years. Our review of instances of non-compliance identified positive and proactive interventions, with records of operators mostly responding promptly.

Zoo animals held in containment

Non-compliance at zoo animal containment facilities presents unique challenges for MPI to enforce. MPI must balance its responsibility for verifying compliance with containment standards while ensuring animal welfare requirements are also upheld. Veterinarians have been utilised in the approval of zoo containment facilities, helping to ensure that animal welfare requirements are met. In the event large-scale disposal of zoo animals is required, MPI could be asked to euthanise animals as a last resort.

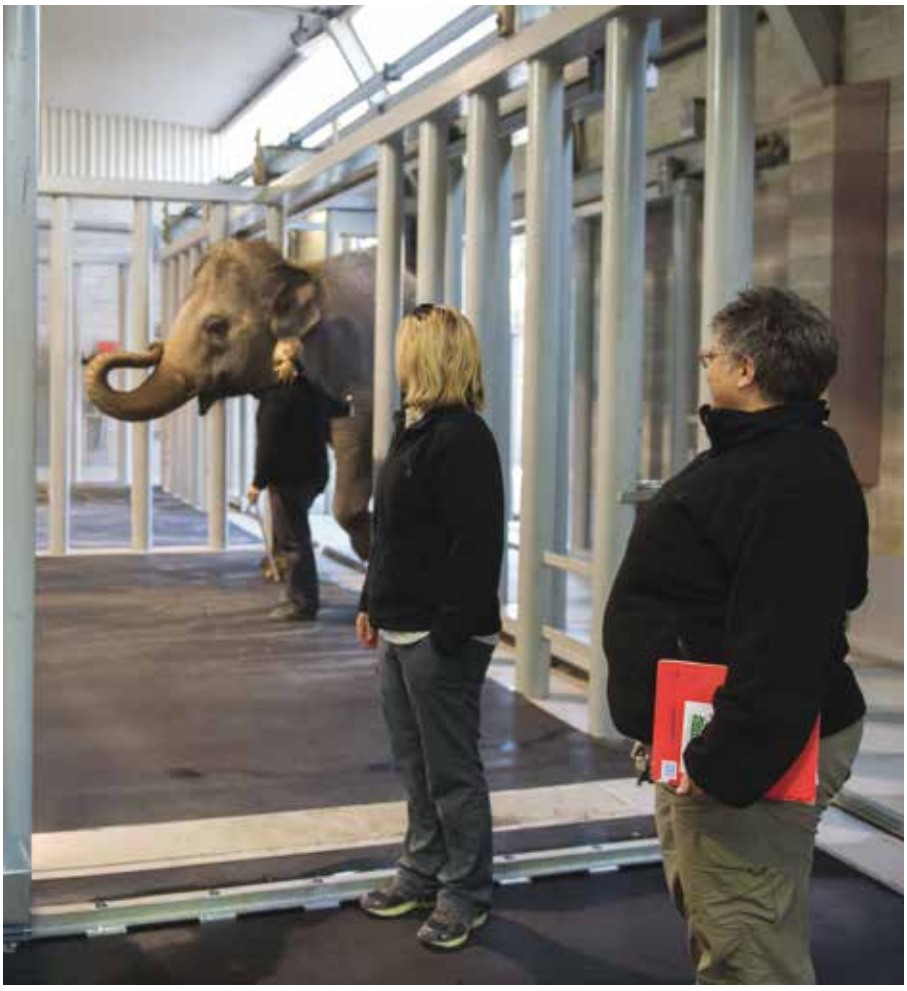
Containment facility standards

Overview

All containment facility standards were developed between 1999 and 2007. However the Zoo Standard has subsequently been updated to an outcomes-based standard. All other standards are heavily prescriptive. Given changes to technology, scientific advances, and developments in scientific thinking since their creation, some rules and requirements are no longer fit for purpose. They pose challenges for operators to comply with, and for verifiers to interpret or work with.

For example, the 2007 microorganism containment standard specifies that facility operators must comply with the AS/NZS 2243.3 Safety in Laboratories Standard 2002. The latest version of AS/NZS 2243.3 was issued in 2022. The 2007 microorganism standard, and the 2002 version of the AS/NZS standard, are also applied by the Hazardous Substances and New Organisms (Low-Risk Genetic Modification) Regulations 2003 and in the conditions of some EPA approvals. While the 2007 microorganism standard does say that "the latest version of [the AS/NZS standard] applies", meaning the intent was that the newest standard (2022) would be applied, there are further legal requirements to implement this intent and so the 2002 version is the current standard. Operators find that this results in a lack of certainty as to which standards they are required to meet in which circumstances.

Facility operators also find some of the rules within standards lack currency with scientific advances which can potentially result in overregulation. For example, the HSNO Act imposes the same requirements on safe control cell lines that cannot survive in the environment as with infectious bacterial cells that can.



In the past, MPI granted dispensations from specific rules in containment facility standards when these rules were not practical or sensible to apply. Verifiers have been advised they have no legal discretion to waive requirements and so this practice has rightly ceased. But this has become a hindrance to facility operators who wish to work to modern standards.

For some time, the EPA has sought the development of more outcome-based standards that allow flexibility in the way containment facilities are operated. Providing input into developing outcome-based standards takes significant MPI time and effort as a framework must be developed to train verifiers how to interpret whether facilities are complying with the standards. In addition, MPI must commit to updating some transitional facility standards for alignment as, under the Biosecurity Act, these hold a different legal status to containment facility standards under the HSNO Act.

Zoo containment facilities standard

The EPA published the first New Zealand outcome-based containment facility standard: the Zoo Containment Facilities Standard in 2018. This standard review took over a decade to complete, at a time when EPA and MPI were working very collaboratively.

The outcomes-based standard provides flexibility to operators but requires both facility operators and MPI verifiers to exercise a greater level of judgement in their decision-making. The pathway to the new standard was aided by verifiers having a thorough technical understanding of the previous rules which could provide a useful foundation for verification.

The introduction of this standard has been successful, partly because of expertise in the zoo sector, particularly at those larger zoos that have in-depth knowledge and experience which has allowed them to develop the detailed procedures that underpin outcome-based rules. Although no new zoos have been opened since prior to this in order to test the efficacy of it.

Smaller zoos can lack the resources and expertise to demonstrate how their activities meet outcome-based standards, and fall back on the older prescriptive zoo standard and ongoing feedback from the verifiers to guide their activity.

This standard was, however, difficult to implement due to the need to upskill the technical expertise of verifiers, the additional costs associated with obtaining expert advice and the inconsistencies in that expert advice, and the potential for over or under regulating without clear rules.

Instances of non-compliance at zoo animal containment facilities present unique challenges for MPI to enforce. MPI must meet its responsibility for enforcing containment while ensuring animal welfare requirements are upheld. MPI can utilise the skills of veterinarians who are food safety verifiers, in the approval of zoo containment facilities. This helps ensure MPI covers its broader responsibility for enforcement of the animal welfare requirements on zoo operators.

Proposed universal standard

The EPA has proposed a single universal containment facility standard to streamline requirements for facility operators of all containment facilities. We heard of reluctance to embrace further outcome-based standards given MPI's past experience of the significant resource required to support implementation of the zoo standard, particularly in light of the ongoing absence of guidance from EPA. Converting five different facilities standards to a single universal standard will take considerable time and will further impact already constrained policy staff. Then there is the work required to amend the transitional facilities standards to ensure alignment. However there would be benefits and efficiencies for operators of containment facilities once implemented.

Working with co-regulatory agencies

The operation of the containment system is dependent on effective working relationships between the regulatory agencies that govern and manage the system.

An MOU between EPA and MPI was first agreed in 2006, supported by an Operational Agreement that included detailed procedures on how the agencies would work together operationally. A revised MPI-EPA MOU was signed in May 2024 focusing on the high-level regulatory responsibilities of both agencies including in the regulation of new organisms. Work is still required to operationalise the revised MOU.

For many years, MPI and EPA had a collaborative working relationship, working together on matters of mutual interest like the development of containment facility standards.

Increasingly EPA has taken a narrower view of what it considers are its regulatory responsibilities, and no longer provides advice on facilities, standards and new organisms, either to MPI or facility operators. EPA has subsequently been reluctant to provide interpretation of the new Zoo standard. MPI has therefore developed its own guidance material for verifiers.

While MPI has the legislative right under S12 of the HSNO Act to give advice and information on the provisions of the Act, it does not regulate the Act. There are risks in providing advice in the event that an investigation relies on information provided by enforcers which may potentially be unsupported by the intention of the Act. This lack of EPA support has left MPI open to challenge from those it regulates where the EPA may not back MPI's enforcement decisions.

It is not clear that the EPA routinely monitors the work MPI conducts as the enforcement agency as part of its responsibilities. MPI, EPA and MfE senior leaders meet periodically to discuss matters of joint interest, but there has been no cross-agency governance to support this work. There had been a multiagency Zoo Technical Advisory Group (ZTAG) comprising subject matter experts from MPI, EPA, WorkSafe, and Department of Conservation (DoC) post a Coroner's investigation into a zookeeper death years ago. ZTAG has since been dissolved, but re-establishing a

multi-agency governance group could help align regulatory systems to achieve better outcomes and begin to give effect to the new MoU. This may be particularly beneficial if MPI is assigned the enforcement responsibilities in the new Genetic Technology legislation.

WorkSafe is the lead government agency responsible for influencing businesses and workers to ensure work is healthy and safe within containment facilities. However, its containment facility activity is largely reactive. WorkSafe are not required to approve containment facilities for health and safety compliance prior to their opening, and so MPI verifiers can find themselves having to make judgements on health and safety at facilities as part of their HSNO Act approval process. It adds to the time and complexity of the process. Importantly, MPI is not empowered to undertake this function under any Act.

MPI has sought engagement with WorkSafe to progress a potential MOU and clarify co-regulatory enforcement expectations at containment facilities, however, this has not progressed, and no agreement has been reached.

Funding of containment facility enforcement

Verification of containment facilities operates as a cost recovered activity. However we were advised that the full cost of the Team Manager, and approximately 50 percent of the work conducted by the Specialist Adviser Biosecurity is technical and advisory are not directly cost recovered and nor are they allocated for in the annual vote allocation. The full cost of the team must therefore be supplemented by other means.

Biosecurity verifier charge-out rates are lower than for the verifiers of food safety operators. For example Food Safety verifiers charge $206 per hour as of 1 July 2024 (previously $230 prior to July) for verifying under the Animal Product Act for New Zealand Food Safety. In contrast, biosecurity verifiers charge $155 for non-veterinarian technical supervisor and $186 for veterinarian supervisor. Reconsideration of the charge out rates and overall funding is overdue.

Up until 2009, MPI received crown funding to develop its policy and enforcement roles for new organism aspects of the HSNO Act. This crown funding recognised that the implementation and development activities undertaken by MPI for new organism enforcement provided a wider benefit to the public and that only some of these services would be cost recovered.

While the number of containment facilities has remained relatively static since 2010, the technical expertise required to interpret approvals and standards has risen over time, and with the potential for standards changing to outcomes basis, the work to meet these is expected to grow.

The team is not funded to absorb these challenges. It would be timely to reconsider the current funding model and whether it is commensurate with the level of service, and the public versus private good of its activities.

Placement of verification of containment facilities

In 2023, the New Zealand Government proposed changes to modernise the rules for genetic technology to enable greater use of biotechnology while still ensuring strong protections for human health and the environment. The proposal includes the establishment of a dedicated biotech regulator to oversee and streamline the approval process for the safe and ethical use of genetic technologies in New Zealand. The proposal suggests that enforcement of the new Act could sit with MPI.

The proposal has potential implications for both the Biosecurity Act and HSNO Act. Ongoing MPI technical expertise is required to understand the proposed changes, coordinate an MPI-wide response, and operationalise enforcement of the new regulations.

If the Biosecurity Verifiers were called upon to undertake the new enforcement responsibilities, MPI would need to consider staffing requirements and funding for those also.

Given the linkages with the Biosecurity Act and HSNO, the gene tech legislation would likely fit best within Biosecurity New Zealand, suggesting that a move of the Biosecurity Verifiers back into Biosecurity New Zealand would be logical.

Verification activity should ideally maintain connections to the verification community of practice. Placement of the Biosecurity Verification team into Biosecurity New Zealand need not impact this critical connection.

Conclusion

By committing to updating containment standards, addressing training requirements, strengthening assurance processes, considering placement of the team, and re-evaluating funding, New Zealand's biosecurity defences and regulatory effectiveness will be better placed to continue safeguarding New Zealand's unique biodiversity and agricultural interests from the risks posed by new organisms and biotechnological advancements.

Inspector General Regulatory Systems – Kaitirotiro Matua Pūnaha Waeture

Ministry for Primary Industries – Manatū Ahu Matua

Te Kāwanatanga o Aotearoa
New Zealand Government