Environmental Protection Authority
Te Mana Rauhī Taiao

Staff Advice Report

Application APP201737: to import microorganisms into containment.

June 2013

New Zealand Government

Summary and Recommendations

Application APP201737 seeks approval to import Risk Group 1[1] and 2[2] microorganisms (including bacteria, archaea, protozoa, fungi, bacteriophages, viruses) as cultures or within samples derived from animals, plants and the environment, for laboratory based research.

The organisms included in the scope of the application are broad, but have similar characteristics in relation to the risks they pose and their containment requirements; therefore they can be considered a discrete group for the assessment of the application.

The organisms can be adequately contained, and the risks of having the organisms in containment are negligible, while the benefits are non-negligible.

It is recommended that application APP201737 be approved subject to the controls listed in Appendix 1.

[1] A microorganisms that is unlikely to cause human, plant or animal disease.
[2] A pathogen that can cause human, plant, or animal disease, but is unlikely to be a serious hazard to laboratory workers, the community, livestock, or the environment; laboratory exposures may cause infection, but effective treatment and preventative measures are available, and the risk of spread is limited.

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1. Application process and background information

1.1. Purpose of this document

1.1.1. This document has been prepared by Environmental Protection Authority (EPA) staff, to advise the Hazardous Substances and New Organisms (HSNO) Decision Making Committee (the Committee) on the application, consideration process, and our risk assessment of application APP201737. This document discusses information provided in the application and other readily available sources.

1.2. The applicant

1.2.1. The applicant is AgResearch. AgResearch is a Crown Research Institute whose purpose is to enhance the value, productivity and profitability of New Zealand's pastoral, agri-food and agri-technology sector value-chains to contribute to economic growth and beneficial environmental and social outcomes for New Zealand.

1.3. The application

1.3.1. Application APP201737 seeks approval for the importation into containment of Risk Group 1[3] and 2[4] microorganisms (including bacteria, archaea, protozoa, fungi, bacteriophages, viruses) as cultures or within samples derived from animals, plants and the environment, for laboratory based research.

1.3.2. The application was lodged on 27 May 2013.

Background on why the application is needed

1.3.3. The application is needed to enable researchers to import potentially new organisms (as cultures or within samples derived from animals, plants and the environment) into laboratories for identification and other research purposes, and enable long term storage of the organisms.

1.3.4. There are several existing approvals for the importation of many of the organisms within the scope of this application; however the scope of those approvals is limited to either cultured organisms or specific locations from which samples may be collected.

[3] A microorganisms that is unlikely to cause human, plant or animal disease.
[4] A pathogen that can cause human, plant, or animal disease, but is unlikely to be a serious hazard to laboratory workers, the community, livestock, or the environment; laboratory exposures may cause infection, but effective treatment and preventative measures are available, and the risk of spread is limited.

1.3.5. For example:

- The approval for Application ERMA200432 allows the importation of axenic and defined mixtures of Risk Group 2 microorganisms for research purposes, but does not allow for the importation of samples containing those organisms.
- The approval for Application ERMA200817 allows the importation of aquatic and soil microbes (cultures and samples) for research purposes, but is limited to organisms and samples collected in the Arctic.
- The approval for Application NOC07002 allows the importation into containment of microorganisms and other small (<30mm) marine organisms from marine water and sediment samples; and marine invertebrates (<120mm) from New Zealand's Exclusive Economic Zone, the Southern Ocean and Antarctica waters for scientific research.

1.3.6. Samples that potentially contain the new organisms subject to this application are also imported under the provisions of the Biosecurity Act without HSNO Act approval. This occurs when laboratories (approved containment or transitional facilities) import samples derived from animals, plants, and the environment for destructive analysis. Destructive analysis does not include culturing (growing) the organisms, therefore no HSNO Act approval is required. In addition, the provisions of the Biosecurity Act allow for long term storage. Both culturing and long-term storage of organisms (cultured or within sample substrates) are included in the scope of this application.

1.4. Public notification

1.4.1. Under s 53(2) of the Act the EPA has discretion to publicly notify an application to import into containment any new organism, if it considers that there is likely to be significant public interest in the application. In this case the application was not publicly notified because this application is not expected to be of significant public interest, nor is it likely that public notification would result in additional information relevant to the consideration of this application. This is because the activities being undertaken and the organisms to be imported are not novel.

1.5. Legislative requirements

1.5.1. The application was lodged pursuant to s 40(1) of the Act. The application must be determined in accordance with s 45, taking into account the matters specified in s 44 and 37 and other matters relevant to the purpose of the Act, as specified in Part 2 of the Act, and relevant provisions of the HSNO (Methodology) Order 1998 (the Methodology).

1.5.2. The decision path for the consideration of this application has been provided as a separate document.

1.6. Information for consideration

1.6.1. The information available for the consideration of the application includes the application form (completed by the applicant) and this report (prepared by EPA staff).

1.7. Comments from Department of Conservation and the Ministry for Primary Industries

1.7.1. In accordance with s 58(1)(c) of the Act and clauses 2(2)(e) and 5 of the Methodology, the Department of Conservation (DoC) and the Ministry for Primary Industries (MPI) were notified and provided with the opportunity to comment on this application. Neither DoC nor MPI raised concerns about this application.

2. Purpose of the application

2.1.1. Section 45(1)(a)(i) of the Act requires that the application be for one of the purposes specified in s 39(1) in order to be approved. This application is for the importation of new organisms into containment for research; therefore it fits within s 39(1)(h) *such other purposes as the Authority thinks fit*, being research.

3. The organisms to be considered

3.1. Organisms included in the scope of the application

3.1.1. The organisms to be considered are: Risk Group 1 and 2 microorganisms, derived from animals, plants and the environment, to be imported into containment in cultures or within samples.

3.1.2. This organism description is sufficient for a risk assessment because while it includes a broad group of organisms, the organisms have common risk characteristics (as described below), in particular in relation to containment requirements. In addition, as noted in 1.3.5, risk groups have been used to define organisms for HSNO Act approvals in the past, and those organisms have been effectively contained.

Risk Group 1 and 2 microorganisms

3.1.3. Risk Group 1 and 2 are groupings based on risk characteristics. For this purposes of this application the definition of Risk Group 1 and 2 organisms is taken from the Australia New Zealand Standard (ASNZS) 2243.3 2003:

- Risk Group 1 (low individual and community risk) is defined as a microorganism that is unlikely to cause human, plant or animal disease.
- Risk Group 2 (moderate individual risk, limited community risk) is defined as a pathogen that can cause human, plant, or animal disease, but is unlikely to be a serious hazard to laboratory workers, the community, livestock, or the environment; laboratory exposures may cause infection, but effective treatment and preventative measures are available, and the risk of spread is limited.

3.1.4. Microorganisms are a diverse group of organisms that are microscopic or sub-microscopic, which means they are too small to be seen by the unaided human eye. Microorganisms include, but are not limited to, organisms such as:

- Prokaryotes (organisms lacking a unit membrane-bound (true) nucleus and other organelles, usually having its DNA in a single circular molecule) including bacteria and archaea.
- Eukaryotes (single-celled or multicellular organisms whose cell contains a distinct, membrane-bound nucleus) including:
  - Protozoa (a group characterized for being single-celled and lacking a cell wall, most of them are motile and heterotrophic).
  - Microalgae (phototrophic (use light as energy source) microorganisms that can be unicellular or multicellular).
  - Fungi (Non-phototrophic microorganisms including mushrooms, yeasts, rusts, moulds, smuts, which are characterised by the absence of chlorophyll and by the presence of a rigid cell wall).
- Viruses (organisms containing either DNA or RNA that are able to alternate between intracellular (infectious) and extracellular states, includes bacteriophages (viruses that infect bacteria)).

Cultures

3.1.5. Cultures are pure isolates, mixtures of pure cultures, or mixed cultures in the form of frozen or lyophilised liquid cultures, culture supernatants; bacteria growing on agar slopes, or sterile solid and liquid matrices. Cultures may be axenic[5] or mixed (more than one species), and will not necessarily be identified to species level.

Samples

3.1.6. Samples containing the organism may be collected from animals, plants or the wider environment. This includes, but is not limited to: soil, water, gastro-intestinal tract and contents, dung, saliva, non-viable plant material, and animal feed samples.

Unwanted organisms

3.1.7. The applicant has indicated that they will not collect samples from sick or unhealthy animals or plants, in order to reduce the high likelihood that unwanted organisms[6] will be imported. Working with unwanted organisms is restricted under the Biosecurity Act 1993. Any unwanted organisms that fit within the organism description may be imported under this application, within the bounds of the restrictions of the Biosecurity Act.

Associated organisms

3.1.8. No associated organisms have been identified for this application.

[5] Not contaminated by or associated with any other living organism.
[6] Defined in the Biosecurity Act 1993 as any organism a chief technical officer believes capable of causing unwanted harm to any natural and physical resources or human health, and any new organism the EPA has declined approval to import, or any organism specified in the Second Schedule of the Hazardous Substances and New Organisms Act 1996.

3.2. Organisms excluded from the scope of the application

3.2.1. Human clinical samples, and microorganisms cultured from human clinical samples, are not included in the scope of the application. It is noted that the approval for application NOC07006 allows for the importation of cultures of Risk Group 2 anaerobic commensal microorganisms associated with the human body for research purposes.

3.2.2. Organisms that belong to Risk Group 3 or above are excluded from the scope of the application.

3.2.3. It is recognised that there is potential for organisms that are outside the scope of this application to be present in samples from animals, plants and the environment, for example microorganisms that belong to Risk Group 3.

3.2.4. Any organisms that are outside the scope of the application may not be imported or cultured under the approval for this application. However, it is recommended that the following provisions be included in the decision to address situations where organisms out of scope are inadvertently imported.
If the approval user becomes aware of the presence of any organisms outside the scope of the application they must notify the EPA and the MPI Inspector within five working days and either:

1. *Destroy the organisms.*
2. *Transfer the organisms to an appropriate approval.*
3. *Cease work on the organism and hold it in secure storage for a maximum of 12 months, while applying for a suitable HSNO Act approval to continue working with the organism.*

3.2.5. These provisions have been imposed on EPA approvals where the organism description is bound by Risk Group classifications, and where unidentified organisms can be imported.

4. Adequacy of containment regime

4.1. Proposed containment regime

4.1.1. The organisms are proposed to be imported into containment, which means they will be imported and maintained in a containment facility approved by MPI as meeting the appropriate containment standard. The facility holding the organisms will also be required to meet all the controls imposed on an approval.

4.1.2. A full list of the proposed controls, along with definitions for clarity of interpretation, can be found in Appendix One. The proposed controls are outcome focussed, or results-based, instead of prescriptive. That means instead of prescribing specific measures that must be adhered to, the controls direct that secure containment is required. The onus is then on the organisation to demonstrate that they can meet that outcome. For example proposed **control 1** requires that the organisms must be contained, and proposed **control 6** requires that the containment facility where the microorganisms are held be designed, constructed and maintained to prevent the microorganisms from escaping.

4.1.3. Proposed **control 2** specifies that the organisation, entity or person(s) responsible for the ownership, control and management of the containment facility where the organisms are held must ensure compliance with the controls.

4.1.4. The proposed controls require documentation specifying how the controls will be implemented (proposed **controls 3**), and where and how the organisms will be contained (proposed **controls 5**). Proposed **control 4** requires that the facility operates according to the procedures that they have specified. This means the facility must specify how they will meet the controls and MPI can measure compliance with the controls and audit against the facility documentation. Proposed **control 8** requires that the approved organisms be identifiable as new organisms, and are able to be linked to the HSNO Act approval, meaning that any organism imported under this application can be linked to back this approval for this application.

4.1.5. Proposed **controls 9-11** specify requirements for notifying the EPA and/or MPI about using the approval, modifications to the containment regime and any escapes and/ or breaches of containment.

4.1.6. The HSNO Act (s 45(2)) requires that an approval *must include controls that provide for applicable matters in Schedule 3*; and *may include controls that provide for any other matters in order to give effect to the purpose of the Act* (to protect the environment, and the health and safety of people and communities, by preventing or managing the adverse effects of hazardous substances and new organisms). The controls that provide for matters in Part 2 of Schedule 3 of the Act are set out in Appendix 2. Controls 3, 4, 10 and 11 do not directly address any matters on Part 2 of Schedule 3 of the Act, but are considered necessary for administrative purposes and to enable MPI to measure compliance with an approval.

4.2. Potential pathways of escape

4.2.1. The following pathways of escape have been identified and addressed by the proposed controls:

- transport to/between containment facilities
- unauthorised persons
- waste or contaminated equipment
- undesirable organisms (vermin)
- laboratory personnel
- failure of containment regime through inadequate maintenance/upkeep of regime
- failure of containment regime following fire or natural disaster.

Escape during transport to/between containment facilities

4.2.2. Escape during transport to or between containment facilities has been identified as a potential pathway for escape. Proposed **controls 12-13** address the requirements for moving the approved microorganisms to or between containment facilities, including maintaining containment and accompanying documentation.

Unauthorised persons

4.2.3. Unauthorised persons have been identified as providing a potential pathway of escape, as they may deliberately or accidentally remove organisms from the containment facility. Proposed **controls 14-16** address requirements around access to the facility including the requirements to exclude unauthorised persons, and the identification of entrances (including entrances that are primarily used as exits).

Escape in waste or on contaminated equipment

4.2.4. The removal of waste and contaminated equipment from the facility has been identified as a potential pathway of escape. Proposed **controls 17** and **18** specify requirements for removing equipment (including personal protective equipment) and waste from a containment facility to prevent the escape of approved organisms. It is noted that waste can be treated off-site (to kill any approved organism or heritable material) and the organisms must be contained during transport to the treatment location.

Undesirable organisms in the facility

4.2.5. The presence of undesirable organisms, such as vermin, has been identified as a possible pathway of escape. Proposed **control 19** requires the facility be secured and monitored to ensure the exclusion of undesirable organisms that might compromise the containment of the microorganisms.

Laboratory personnel

4.2.6. Accidental/unintentional removal of organisms by laboratory personnel has been identified as a potential pathway of escape. Proposed **control 7** requires that persons entering and exiting the containment facility do so in a way that does not compromise containment. Proposed **control 20** requires that any person entering the containment facility has sufficient training on the containment regime that they are able to meet their responsibilities – including not accidently removing any new organisms.

Inadequate maintenance or failure of containment measures

4.2.7. Escape as a result of failure of the containment regime through inadequate maintenance of the regime or following fire or natural disaster have also been identified as pathways of escape. Proposed **control 6** requires that the containment facility where the microorganisms are held be designed, constructed and maintained to prevent the microorganisms from escaping. Proposed **control 23** specifies that containment measures must be inspected, monitored and reviewed to ensure that containment is being achieved. **Control 23** also requires that containment measures be inspected as soon as possible after any event that could compromise containment – including fire, Acts of God (such flood, earthquake, tornado), or attempts to break into the facility.

4.3. Conclusion on adequacy of containment

4.3.1. Escape from containment via the pathways identified is **highly improbable** in light of the proposed containment regime. Taking into account the biological characteristics of the organisms, the potential

pathways of escape and the proposed containment regime, it is concluded that the organisms can be adequately contained.

5. Potential for undesirable self-sustaining populations

5.1.1. The microorganisms in the application have the potential to form self-sustaining populations in the New Zealand environment. However, the potential for these organisms to escape from containment and form undesirable self-sustaining populations is limited by the containment regime and adherence with good laboratory practices.

5.1.2. Proposed **controls 21** and **22** specify the requirement for contingency plans to be documented for all approved organisms, and the implementation of those plans.

5.1.3. In the event that a self-sustaining population did establish, it would be difficult to identify such a population because it would be very similar to the existing micro-flora. Consequently it is unlikely that eradication of an undesirable self-sustaining population would be possible.

6. Evaluation of risks and benefits

6.1. Risks of having the organisms in containment

6.1.1. In considering the potential risks (adverse effects) of having the organisms in containment it is noted that the organisms will be imported into and maintained in containment.

Potential adverse effects on the environment

6.1.2. For adverse effects on the environment to occur the organisms would need to escape or be released from containment, and it is highly improbable that this will happen.

6.1.3. The organisms to be imported are Risk Group 1 and 2 microorganisms, Risk Group 2 microorganisms have the potential to cause disease, but are unlikely to be a serious risk to animals, plants or the wider environment under normal conditions. Any disease caused by these organisms would be preventable, treatable, and present a limited risk of spread. Therefore the magnitude of any adverse effects of these organisms on animal and plant health would be **minimal**. In addition it is **highly improbable** that such as adverse effect would eventuate due to the containment regime.

Potential adverse effects on human health

6.1.4. The Risk Group 2 microorganisms have the potential to cause disease, but are unlikely to be a serious risk to laboratory personnel, or the wider community. Any disease caused by these organisms would be preventable, treatable, and present a limited risk of spread. Therefore the magnitude of any adverse effects of these organisms on human health would be **minimal.**

6.1.5. For adverse effects on the health of the public to occur the organisms would need to escape or be released from containment, and it is **highly improbable** that this will happen.

6.1.6. Laboratory personnel working with the organisms have the potential to be exposed to the organisms, however this exposure is voluntary and personnel are trained to safely handle microorganisms, and direct exposure will be limited due to the controls and good laboratory practices. Therefore it is **improbable** that adverse effects on health of laboratory personnel will occur.

Potential adverse effects on Māori and their culture and traditions

6.1.7. Specific engagement with Māori was not required for this application, as it is for importation into containment, and no potentially significant impacts on Māori and their culture and traditions are anticipated. The applicant liaised with Jonathan Proctor from Tanenuiarangi Manawatu Inc as part of their preparation of the application. General concerns about the introduction of environmental samples and new organisms into the environment were raised. It was noted that those concerns were mitigated by importing and maintaining the organisms in containment, thus preventing their release into the environment. Based on the information available, no potentially significant adverse effects on the Māori and their culture and traditions have been identified.

Potential adverse effects on the market economy, society and communities

6.1.8. Based on the information available, no potential significant adverse effects on the market economy, or society or communities have been identified.

Conclusion on potential adverse effects

6.1.9. The potential adverse effects of having the organisms in containment are negligible.

6.2. Benefits of having the organisms in containment

6.2.1. The following potential benefits of having the organisms in containment have been identified:

- On-going gains of scientific knowledge from the study of microorganisms, in particular those of importance in agriculture, food production and greenhouse gas emissions.
- Establishment of a reference collection of bacterial cultures.
- New Zealand scientists can continue to participate in international research programmes.

6.2.2. The on-going gains in scientific knowledge and the ability for New Zealand research institutes to participate in international research programmes will be of **minor** to **moderate** benefit to New Zealand, and it is **highly likely** that these benefits will eventuate if this application is approved. The benefits of having the microorganisms in containment are therefore non-negligible.

6.3. Conclusion on risks and benefits

6.3.1. The potential risks of having the microorganisms in containment have been evaluated as being negligible. The potential benefits of having the microorganisms in containment have been evaluated as being non-negligible.

7. Conclusion and recommendation

7.1.1. AgResearch seeks approval to import Risk Group 1[7] and 2[8] microorganisms, derived from animals, plants and the environment, as cultures or within samples, for laboratory based research.

7.1.2. The organism description is broad, but the organisms included have similar characteristics in relation to the risks they pose and their containment requirements; therefore they can be considered a discrete group for the assessment of the application.

7.1.3. Based on the information available, and taking into account the biological characteristics of the organisms, the potential pathways of escape and the proposed containment regime, it is concluded that the organisms can be adequately contained.

7.1.4. The risks of having the organisms in containment are negligible, while the potential benefits of having the organisms in containment are non-negligible. Therefore the benefits outweigh the risks.

7.1.5. It is recommended that the application be approved subject to the controls listed in Appendix 1.

[7] A microorganisms that is unlikely to cause human, plant or animal disease.
[8] A pathogen that can cause human, plant, or animal disease, but is unlikely to be a serious hazard to laboratory workers, the community, livestock, or the environment; laboratory exposures may cause infection, but effective treatment and preventative measures are available, and the risk of spread is limited.

Appendix One: Proposed controls

Requirement for the containment of approved organisms

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

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.

Requirement to specify how controls will be met

3. Procedures that specify how these controls will be implemented must be documented, and these must be reviewed regularly to ensure they are effective.

4. The containment facility must be operated in compliance with the documentation specified in control 3. (This does not override the imperative to comply with all the controls).

Requirements for the containment regime

5. The containment facility where the approved organisms may be held must be clearly defined, described, and documented, including their location and boundaries.

6. The containment facility must be designed, constructed and maintained to prevent the approved organism from escaping.

7. Persons entering and exiting the containment facility must do so in a way that does not adversely affect containment of the approved organism(s).

8. The approved organism(s) must be identifiable as a new organism and be able to be linked to the relevant HSNO Act approval.

Requirements for notification to the EPA and/or MPI

9. Notification must be given to the MPI Inspector of any proposed modification to the containment regime which may affect the integrity of containment of the approved organism(s), before the modifications are undertaken.

10. The EPA and MPI Inspector must be notified in writing before this HSNO Act approval is used for the first time.

11. The MPI Inspector 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.

Requirements for moving approved organisms

12. The approved organism(s) must be contained during movement within, to, or from the containment facility.

13. When being moved outside of a containment facility, within New Zealand, the approved organism must be 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.

Requirements to limit access to the containment facility

14. Unauthorised persons must be excluded from the containment facility.

15. All containment facility entrances must be clearly identified including specifying who has the right of access.

16. The number and location of entrances to the containment facility where the approved organism(s) are held must be identified and documented.

Requirements for removing equipment and waste from the containment facility

17. 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.

18. 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 facility.

Requirement for dealing with undesirable organisms

19. 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).

Requirement for instruction and training

20. Any person (including contractors, staff, students, visitors, and volunteers) entering the containment facility must have received sufficient instruction on the containment regime to enable the person to meet their responsibilities in relation to containment.

Requirements for contingency plans

21. The containment facility must have a documented contingency plan for each approved organism held in that containment facility.

22. The contingency plan must be implemented immediately if there is any reason to believe that an approved organism has escaped or been released from the containment facility, or any other breach of containment has occurred.

Requirements for internal inspections and monitoring

23. To ensure containment is being achieved, containment measures must be:
    a) Inspected, monitored and reviewed
    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.

24. Any remedial requirements identified under control 23, or by any other means, must be actioned as soon as possible.

Interpretation

In these controls, unless otherwise specified below, a word has the same meaning as it is defined in the Act (if any).

approved organism	New organisms approved under application APP201737 (as described in Section 3 of this report).
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 facility	A place approved by MPI in accordance with section 39 of the Biosecurity Act 1993, for holding approved organisms.
contingency plan	A plan devised for a specific situation where things could go wrong, 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.

maintenance	The process of maintaining (preserving or providing for the preservation of) or continuing a state of good repair.
treat (with reference to waste)	Kill all approved organisms and make heritable material non-viable.
undesirable organism	Organisms such as rodents, insects, and birds within the containment area/facility that could compromise containment (dependent on what organism is being contained).
waste	Unusable or unwanted substances or materials (including water, liquids, solids or air).

Appendix Two: Proposed controls that provide for matters in Part 2 of Schedule 3

Schedule 3 Part 2 Matters to be addressed by containment controls for new organisms (excluding GMOs)		Addressed by control:	
1	To limit the likelihood of any accidental release of any organism or any viable genetic material, the controls imposed by an approval shall specify—		
1(a)	Requirements for treatment and decontamination to prevent escape by way of expelled air, discharge of water or liquid waste, removal of solid waste, or breaches in facility boundary:	6	The containment area(s) must be designed, constructed and maintained to prevent the approved organism from escaping.
		7	Persons entering and exiting the containment facility must do so in a way that does adversely affect containment of the approved organism(s).
		14	Unauthorised persons must be excluded from the containment facility.
		17	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.
		18	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 facility.
1(b)	Equipment and requirements for facility construction to enable the requirements for treatment and decontamination to be readily met:	6	The containment area(s) must be designed, constructed and maintained to prevent the approved organism from escaping.
		17	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.
		18	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 facility.

Schedule 3 Part 2 Matters to be addressed by containment controls for new organisms (excluding GMOs)		Addressed by control:	
1(c)	Requirements to be complied with for the access of persons to the facility:	7	Persons entering and exiting the containment facility must do so in a way that does not adversely affect containment of the approved organism(s).
		14	Unauthorised persons must be excluded from the containment facility.
		20	Any person (including contractors, staff, students, visitors, and volunteers) entering the containment facility must have received sufficient instruction on the containment regime to enable the person to meet their responsibilities in relation to containment.
1(d)	Procedures and requirements for transport, identification, and packaging for all biological material to and from the facility and within the facility:	8	The approved organism(s) must be identifiable as a new organism and able to be linked to the relevant HSNO Act approval.
		12	The approved organism(s) must be contained during movement within, to, or from the containment facility.
		13	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.
1(e)	Requirements for the disposal of any biological material:	17	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.
1(f)	Requirements for facility construction:	1	The approved organism(s) must be contained.
		6	The containment area(s) must be designed, constructed and maintained to prevent the approved organism from escaping.
		9	Notification must be given to the MPI Inspector of any proposed modification to the containment regime which may affect the integrity of containment of the approved organism(s), before the modifications are undertaken.

Schedule 3 Part 2 Matters to be addressed by containment controls for new organisms (excluding GMOs)		Addressed by control:	
		24	Any remedial requirements identified under control 23, or by any other means, must be actioned as soon as possible.
1(g)	Requirements to secure the facility and openings, including securing against failure in the event of foreseeable hazards.	6	The containment area(s) must be designed, constructed and maintained to prevent the approved organism from escaping.
2	To exclude unauthorised people from the facility, the controls imposed by an approval shall specify—		
2(a)	Means of identification of all entrances to the facility:	5	The containment facility where the approved organisms may be held must be clearly defined, described, and documented, including their location and boundaries.
2(b)	The numbers of entrances and access to the facility:	5	The containment facility where the approved organisms may be held must be clearly defined, described, and documented, including their location and boundaries.
2(c)	Security requirements for the entrances and the facility.	14	Unauthorised persons must be excluded from the containment facility.
		15	All containment facility entrances must be clearly identified including specifying who has the right of access.
		16	The number and location of entrances to the containment facility where the approved organisms are held must be identified and documented.
3	To control the effects of any accidental release or escape of an organism—		
3(a)	Controls imposed by an approval shall specify an eradication plan for escaped organisms:	21	The containment facility must have a documented contingency plan for each approved organism held in that containment facility.
3(b)	Controls imposed by an approval may specify requirements to limit the likelihood of an escaped organism spreading, surviving, and breeding, including, but not limited to,—	21	The containment facility must have a documented contingency plan for each approved organism held in that containment facility.
		22	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.

Schedule 3 Part 2 Matters to be addressed by containment controls for new organisms (excluding GMOs)		Addressed by control:	
3(b)(i)	Exclusion zones (spatial or temporal):		n/a
3(b)(ii)	Location of the facility outside the usual habitat range of the organism.		n/a
4	Controls imposed by an approval shall specify inspection and monitoring requirements for containment facilities.	19	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).
		23	To ensure containment is being achieved, containment measures must be: a) inspected, monitored and reviewed 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.
5	Controls imposed by an approval may specify the qualifications required of the person responsible for implementing those 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.
		20	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.