Environmental Protection Authority
Te Mana Rauhī Taiao

DECISION

Date	5 November 2018
Application code	APP203324
Application type	To develop in containment any new organism under section 40(1) of the Hazardous Substances and New Organisms Act 1996
Applicant	University of Auckland
Date application received	24 September 2018
Consideration date	5 November 2018
Considered by	A decision-making committee of the Environmental Protection Authority (the Committee)[1]: • Dr Ngaire Phillips (Chair) • Dr Louise Malone • Dr Sharon Lehany
Purpose of the application	To develop cell line models (including immortalised cell lines) for biomedical research including the study of oncogenesis and the function of tumour suppressor genes using replication-defective retroviral-based gene delivery systems.

1. Summary of decision

1.1 Application APP203324, to develop cell line models (including immortalised cell lines) for biomedical research including the study of oncogenesis and the function of tumour suppressor genes using replication-defective retroviral-based gene delivery systems, was considered in accordance with the relevant provisions of the Hazardous Substances and New Organisms Act 1996 (the HSNO Act) and of the Hazardous Substances and New Organisms (Methodology) Order 1998 (the Methodology).

1.2 The Committee has **approved** application APP203324 in accordance with section 45(1)(a) of the HSNO Act, subject to the controls set out in Appendix 2.

[1] The Committee referred to in this decision is the subcommittee that has made the decision on this application under delegated authority in accordance with section 18A of the HSNO Act.

2. Application process

Application Receipt

2.1 The application was formally received for evaluation and consideration on 24 September 2018 under section 40(1) of the HSNO Act.

Public Notification

2.2 Section 53(2) of the HSNO Act provides that an application under section 40 of the HSNO Act may be publicly notified by the Environmental Protection Authority (EPA) if it considers that there is likely to be significant public interest.

2.3 The General Manager Hazardous Substances and New Organisms has delegation to decide whether to publicly notify an application to develop in containment any new organism under section 19(1) of the HSNO Act. The application was not publicly notified because all research involving the new organisms will be conducted within containment facilities, and significant public interest in this application was not anticipated.

Comments from Department of Conservation and Ministry for Primary Industries

2.4 In accordance with section 58(1)(c) of the HSNO Act, EPA staff advised the Department of Conservation (DOC) and the Ministry for Primary Industries (MPI) of the application, and invited them to provide information and/or comment on the application.

2.5 DOC noted that the application did not appear to have any biodiversity implications and had no comments. MPI did not comment on the application.

2.6 The Committee is satisfied that the DOC comment has been taken into account in making this decision.

Information available for the consideration

2.7 The information available for the consideration comprised: the application form and the EPA staff advice memorandum.

2.8 The Committee considered that it had sufficient information to assess the application. To the extent the application may not meet any legislative information requirements, the Committee waives these requirements.

Consideration period

2.9 The application was considered by the Committee on 5 November 2018.

Legislative criteria for the application

2.10 The application was determined in accordance with section 45 of the HSNO Act, taking into account the matters specified in sections 39, 43 and 45, Schedule 3 (Part 1), relevant matters in Part 2 of the HSNO Act, and the Methodology.

3. Purpose of the application

3.1 Section 45(1)(a)(i) of the Act requires that the application be for one of the purposes specified in section 39(1) of the Act. The purpose of the application is a factor in the Committee's decision on the application.

3.2 The applicant seeks approval to develop the human and rodent cell lines described in Appendix 1 as a genetically modified organism (GMO), to enable the study of genes that may be involved in the progression of a cell to a cancerous state (oncogenesis).

3.3 The Committee was satisfied the application is for a valid purpose: such other purposes as the Authority thinks fit (that being research) as provided for in section 39(1)(h) of the Act.

4. Adequacy of the containment regime

4.1 Section 45(1)(a)(iii) of the HSNO Act requires that the Committee be satisfied that the organisms (as described in Appendix 1) can be adequately contained.

4.2 The Committee noted that the applicant has considerable experience in working with and maintaining containment of genetically modified mammalian cell ines and the use of replication-defective viral packaging systems, evinced by the existing approvals and tissue culture and containment facilities that are used by researchers at the University of Auckland.

4.3 To evaluate the adequacy of containment, the Committee assessed the ability of the organisms to escape from containment by taking into account:

- the biological characteristics of the organism that relate to containment
- the containment regime
- the potential pathways for the escape of the organism from the containment facility.

Biological characteristics of the organisms that relate to containment

4.4 The Committee noted that the applicant already manages the named host organisms in this application (Appendix 1), under Physical Containment Levels 1 and 2 (PC1 and PC2) as demonstrated by several approvals noted by the applicant in this application.

4.5 The Committee noted that the GMOs to be developed (see Appendix 1) will neither contain modifications that increase the pathogenicity, virulence or infectivity of the host organism to laboratory personnel, the community or the environment; nor contain modifications that increase the ability of the host organism to escape from containment.

4.6 No inseparable organisms were identified.

The proposed containment regime

4.7 The proposed development work will be carried out at the University of Auckland, in MPI-approved PC1 and PC2 laboratories. The University has many years of experience in the management of specialised laboratories for the culture of human and rodent cells. The Committee was satisfied that

the applicant's proposed containment measures and the imposed controls detailed in the application (Appendix 2) will mitigate the risk of the GMOs escaping from containment. Furthermore, the Committee was satisfied that the containment regime (Appendix 2) provides for each of the applicable matters specified in Schedule 3 (Part 1) of the HSNO Act (Matters to be addressed by containment controls for importing, developing for field testing of genetically modified organisms).

4.8 The Committee noted that the controls are primarily outcome-based, specifying outcomes that must be achieved, rather than prescribing a set method by which the outcome must be achieved. However, the approval user is required to document the procedures that specify how the controls will be implemented and complied with, and the quality control measures that will be used to ensure those procedures are effective, and to operate the containment facility in compliance with that documentation, as per **controls 3** and **4**.

The potential pathways for escape from the containment facility

4.9 The Committee identified the likely pathways of escape from containment of the organisms, and assessed these pathways against the containment regime (including the requirements of the controls in Appendix 2), and the biological characteristics of the organisms that relate to containment.

4.10 The Committee identified the following potential pathways of escape:

- movement within, to or from containment facilities
- unauthorised persons
- laboratory personnel
- waste or contaminated equipment/storage units
- undesirable organisms (i.e. vermin)
- failure of containment regime following fire, flood or natural disaster
- failure of containment regime through inadequate maintenance/upkeep of regime (including freezers thawing out).

4.11 The Committee noted that the containment requirements (Appendix 2) include controls that address each of the identified pathways of escape. Those controls include specifications regarding: moving approved organisms (**controls 10**, **13** and **14**); limiting access to the facility to exclude unauthorised persons (**controls 15-17**); entering and exiting the containment facility (**control 8**); training of laboratory personnel and other people entering the facility (**control 21**); removing equipment, solid waste and waste water from the facility (**controls 18** and **19**); dealing with undesirable organisms (**control 20**); the design, construction and maintenance of the facility (**controls 5, 6** and **7**); effective containment surveillance methods (**control 24**)**;** and rapid remedial actions, if required (**control 25**).

4.12 The Committee noted that the controls are primarily outcome-based, and that the approval users will need to demonstrate how they are meeting each control. This includes documenting the procedures that specify how they will meet the controls (**control 3**), and operating to those documented procedures (**control 4**). The Committee also noted that the containment procedures described by the applicant for their containment regime are consistent with controls 3 and 4, but it encourages the

applicant to continually seek to improve procedures to current best practice. The Committee also imposed **control 2** specifying the parties responsible for ensuring compliance with the controls, **control 5** specifying the demonstration of ongoing financial and management resources to maintain containment and **controls 10-12** requiring notifications to the EPA and MPI.

Conclusion on adequacy of the containment regime

4.13 The Committee concluded that the likelihood that the organisms would be able to escape from containment, taking into account the biological characteristics that relate to containment, potential pathways of escape from the containment facility and the containment regime and controls (Appendix 2) is **negligible**.

4.14 Therefore, the Committee was satisfied that the organisms can be adequately contained.

4.15 In particular, the Committee considered that the applicable matters specified in Schedule 3 (Part 1) of the HSNO Act (as required under section 45(2)(a) of the HSNO Act) are addressed by the controls specified in Appendix 2.

4.16 Section 45(2)(b) of the HSNO Act specifies that an approval may include controls that provide for any other matters in order to give effect to the purpose of the HSNO Act. The Committee considered that no further additional controls are required to achieve the purpose of the HSNO Act, but imposed **controls 3**, **4**, **5, 11** and **12** for administrative purposes and to enable MPI to measure compliance with the controls.

5. Ability of the organisms to establish a self-sustaining population and ease of eradication

5.1 In accordance with sections 37 and 44 of the HSNO Act and clauses 10(e) and (f) of the Methodology[2], the Committee took into consideration the ability of the new organisms to form undesirable self-sustaining populations should they escape containment, and the ease of eradication of such populations.

5.2 The Committee considered that in the highly improbable event of escape, whether a self-sustaining population of the organism could potentially establish. The Committee noted that some of the GM organisms to be developed are derived from commercially available cell lines or will be derived from human subjects and cultured in a specialised cell culture facility and are thus poorly adapted to survival without human intervention and routine maintenance in a specialised containment facility. Accordingly, a GM organism that is developed would be unlikely to survive outside of such a containment facility.

5.3 The Committee considered that in the event of a breach of containment, all possible measures should be taken to either retrieve or eradicate the organisms as per **controls 22** and **23** in Appendix 2 (requirements for contingency plans).

[2]Hazardous Substances and New Organisms (Methodology) Order 1998

6. Identification and assessment of potentially significant adverse and beneficial effects (risks, costs and benefits)

6.1 The Committee is required by section 45(1)(a)(ii) of the HSNO Act to take into account all the potential effects of the organisms and any inseparable organism (including impacts on: the environment; human health and safety, Māori and their culture and traditions, the market economy, and society and the community), and consider whether the potential beneficial effects of having the organisms in containment outweigh the potential adverse effects of the organisms and any inseparable organism. This assessment is shown in Table 1.

Table 1: Assessment of potentially significant adverse and beneficial effects from the organisms in containment

Potentially significant effect	Probability	Discussion
Potentially significant adverse effect on the environment	Negligible	Having considered the controls imposed (Appendix 2) on the applicant's containment regime and the biological characteristics of the organisms, the Committee considers the likelihood of escape as **negligible**. As these host organisms are laboratory cell lines and bacteria, and the organisms being modified are not likely to survive in the unlikely event of escape, the Committee therefore considers that the potential adverse effects on the environment are **negligible**.
Potentially significant adverse effect on human health and safety	Negligible	Operator exposure is voluntary and operator training and protocols are in place for the safe handling of the modified host organisms within the containment facilities. Clinical material will be screened for adventitious agents and appropriate best practice containment used for primary cell isolation. Rodents will be sourced from SPF colonies. Use of appropriate Personal Protective Equipment (PPE) and best practice guidelines for the physical containment and handling of replication-defective retroviral vectors and tranduced cell culture material will be commensurate with risk. The Committee therefore considers the adverse effects on human health and safety as **negligible**.

Potentially significant effect	Probability	Discussion
Potentially significant adverse effect on Māori culture and traditions	Negligible	Evaluation of the application by the EPA Kaupapa Kura Taiao team noted that the application was to develop cell line models to study oncogenesis and the function of tumour suppressor genes using replicative-defective viral-based gene delivery systems. The Cultural Risk Assessment (CRA) concluded that this proposal is **not** likely to put cultural well-being of Māori at risk by infringing Māori cultural beliefs and frameworks. Summary of comments of the CRA are included in the staff memorandum to this decision document. The Committee therefore considers the potential adverse effect on Māori culture and traditions as **negligible**.
Potentially significant adverse effect on the market economy	Negligible	The Committee noted that the unmodified host species are not novel, as they are not a new organism in New Zealand. Furthermore, they have also previously been assessed and identified as low-risk host organism via regulations under the Act. Therefore, the Committee views the potential for adverse effects on the market economy is **negligible**.
Potentially significant adverse effect on society and the community	Negligible	For the organisms to have any effect on society and the community, they would first need to escape from the containment facility and establish. The Committee considers such an event to be **negligible.**
Potentially significant adverse effect on New Zealand's international obligations	None identified	

Potentially significant effect	Probability	Discussion
Potentially significant beneficial effects on the environment, human health and safety, Māori culture and traditions, the market economy, and society and the community, and New Zealand's international obligations	Non-negligible	The following potential benefits have been identified: Increased capacity and capability within New Zealand to generate bespoke genetic modifications of mammalian cell line models. Improved understanding of the genetic basis of the progression of cell lines to a cancerous state that could potentially lead to the development of more accurate diagnostic tools and possible new medical treatments for people. The scientific research outcomes will also add to the profile of public good research in New Zealand. It is **likely** that these benefits will eventuate if this application is approved.

Conclusion on the risks, costs and benefits

6.2 After considering the relevant information, the Committee did not identify any potentially significant adverse effects from the development of GMOs in containment. Therefore, the Committee considered that any potential adverse effects would be **negligible**. Since the Committee did not identify any potential adverse effects, the Committee was not required to take into account the probability of occurrence or magnitude of any adverse effects.

6.3 After considering the relevant information, the Committee identified potential benefits to developing the GMOs in containment, and gains in scientific knowledge. Therefore, the Committee considered that these potential beneficial effects would be **non-negligible**.

7. Evaluation and weighing of potential positive and adverse effects

7.1 The Committee considered that it had sufficient information to weigh the potential effects of genetically modifying the host organisms in containment.

7.2 The Committee concluded that the potential adverse effects of developing GMOs in containment were **negligible,** and that the potential benefits were **non-negligible.**

7.3 Given that there were no potential adverse effects identified, consideration of whether the potential adverse effects may aggregate in order to assess any cumulative effects was not relevant.

7.4 In evaluating all the potential effects of the organisms and all the measures available for risk management, the Committee concluded that it was evident that the potential positive effects outweigh the potential adverse effects.

7.5 Section 6(f) of the HSNO Act requires the Committee to consider New Zealand's international obligations when determining applications. New Zealand has no obligations relevant to this approval.

7.6 The Committee, having considered all the potential effects of the organisms in containment and the effects of any inseparable organisms, and the matters outlined in section 45 of the HSNO Act, concluded that:

- the application is for one of the purposes specified in section 39(1)
- the potential beneficial effects outweigh the potential adverse effects of the new organisms
- the approved organisms can be adequately contained.

8. Associated approvals

8.1 The Committee noted that the approval granted under this decision does not affect the requirements of the Biosecurity Act 1993, including any authorisations or approvals that may be required under that Act (such as ongoing approval of containment facilities and manuals by MPI, or approval of import permit applications by MPI).

9. Decision

9.1 After reviewing all of the information contained in the application, the Committee was satisfied that the application met the requirements of section 40 of the HSNO Act.

9.2 The Committee considered that the threshold for approval under section 45 of the HSNO Act has been met. It is satisfied that the organisms can be adequately contained through compliance with the imposed controls (Appendix 2) and that the beneficial effects of developing the GMOs in containment outweigh the adverse effects, taking into account all the potential effects of the organisms and any inseparable organism (none identified); the relevant matters in Part 2 of the HSNO Act; the matters in section 37, 44, and 45; Schedule 3 (Part 1) of the HSNO Act; and the Methodology.

9.3 Therefore, the Committee decided to exercise its discretion and **approve** the development of the host organisms in containment (see Appendix 1 for approved organisms description) to genetically modify human and rodent cells, in containment, to develop cell line models (including immortalised cell lines) for biomedical research including the study of oncogenesis and the function of tumour suppressor genes using replication-defective retroviral-based gene delivery systems, under section 45(1)(a) of the HSNO Act. The Committee noted that in accordance with section 45(2) of the HSNO Act, the approval has been granted subject to the controls specified in Appendix 2.

5 November 2018

Dr Ngaire Phillips **Chair, Decision Making Committee** **Environmental Protection Authority**	**Date**

Appendix 1: Approval number for the organisms in application APP203324

Host organisms	Modifications	Approval Number
Escherichia Coli (Migula 1895) Castellani and Chambers 1919 (non pathogenic labortatory adapted strains)	Modifications may include: • Introduction of genes carrying potential cancer-causing mutations into human and rodent cell lines grown *in vitro*. • Introduction of oncogenes and tumour suppressor genes into human and rodent cell lines *in vitro*. • Introduction of gene-editing reagents into human and rodent cell lines *in vitro* in order to mutate, suppress or activate endogenous genes including oncogenes and tumour suppressor genes • Standard molecular biology reagents for manipulation of commercially available retroviral vector systems (e.g. 3rd and 4th generation lentiviral vector systems) including packaging cell lines and amplication. • Production (amplification and packaging) of retroviral viral constructs in 'helper' cell lines (eg. HEK 293T or derivatives). • Replication-defective retroviral vector plasmids with heterologous sequences that encode known and potential oncogenes or that can disable or down-regulate known and potential tumor suppressor genes or activate known and potential oncogenes. • Replication-defective retroviral vectors for use in cell line transduction: • Gene editing techniques and reagents ultlising retroviral vector systems for the transduction of cell lines including commercial libraries encoding Cas9 genes and a range of sgRNA. Other examples of Cas genes include, but are not limited to; Cas9n, dCas9-KRAB, dCas9-SAM and dCas9-VPR. • shRNA delivery by replication-defective retroviral systems to down-regulate target genes • Immortalisation of cell lines using standard reagents, methodologies and genes (eg, SV40 Large T antigen, hTERT, hTERT catalytic subunit with either p53 or RB siRNA, over expression of oncogene mutants (Ras or Myc T58A), etc) including the use of replication-defective retroviral vectors. Candidate oncogene sequences (encoded by cDNA or genomic DNA) include but are not limited to, the following; PML-RAR, TBLR1-RARA, TBLR1-RARB, MNX1-ETV6, MYC-ITD, MYCC, MYCN. Tumour suppressor gene include but are not limited to TP53, WT1 and BLM. Genes to be modified include; • vector sequences • eukaryotic, prokaryotic and viral enhancers and promoters • silencing elements (short interfering RNA, short hairpin RNA) • gene editing elements (single guide RNA and derivatives thereof) • recombination sites • internal ribosomal entry sites (IRES) • P2A or T2A cleavage sequences	GMD102408 GMD102409 GMD102410 GMD102411 GMD102412 GMD102413

Host organisms	Modifications	Approval Number
	• sequences for fusion protein tags • polyadenylation signals • selectable marker genes including genes for antibiotic resistance • reporter genes • other regulatory elements that are components of existing or new, commercially avaiable vectors Isolation of human DNA, RNA and cells for primary cell line generation sourced from patient samples will only occur with appropriate Human Ethics Committee approvals and following NEAC and HDEC requirements for human sourced clinical material. The modifications will not include • the production of infectious particles normally able to cause disease in humans, animals, plants, or fungi; • genes that encode for vertebrate toxins with an LD50 < 100 µg/kg; • genetic material derived from Māori although the applicant notes (section 5 of the application) that; if the patient is of Māori descent and would like to openly participate in studies, consultation with affected iwi will be obtained where necessary and, storage and use protocols will observe and follow tikanga Māori protocols as a condition of Human Ethics Committee approval; • genetic material derived from New Zealand native or taonga flora and fauna, • genetic material from species listed by the Convention on International Trade in Endangered Species (CITES) • modifications that increase the pathogenicity, virulence, or infectivity of the host organism to laboratory personnel, the community, or the environment; or • modifications that result in the GMO having a greater ability to escape from containment than the unmodified host organism.	

Appendix 2: Controls required by this approval

Any person developing the approved organisms under the approval granted by this decision must ensure compliance with the controls set out below in respect of any activity they carry out under this approval in a facility under their control.

Requirement for the containment of approved organisms

1. The approved organisms (see Appendix 1) must be contained.

Requirements 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 organism is 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 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
   c) incorporate any improvements to best practice.
4. The containment facility must be operated in compliance with the documentation specified in control 3.

Requirements for the containment regime

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.
6. The containment facility where the approved organism will be held must be clearly defined, described, and documented, including the location and boundaries.
7. The containment facility must be designed, constructed, managed, and maintained to prevent the approved organism from escaping.
8. Persons entering and exiting the containment facility must do so in a way that does not adversely affect containment of the approved organism.
9. The approved organism 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

10. Notification must be given to MPI of any intended 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, before the actions 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.

Requirements for moving approved organisms

13. The approved organism 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 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

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 is held must be identified and documented.

Requirements for removing equipment and waste from the containment facility

18. Any waste (including biological material) that may harbour the approved organism, or **heritable material** from the approved organism, must be treated to ensure that the approved organism or any heritable material is killed prior to disposal.

19. Any equipment, that may harbour the approved organism 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

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.

Requirements for instruction and training

21. 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

22. There must be a documented contingency plan for the potential escape of the approved organism held in the containment facility.

23. The contingency plan must be implemented immediately if there is any reason to believe the 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

24. 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.

25. Any remedial requirements identified under control 24, 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 HSNO Act (if any).

Unless the context otherwise requires, the words/phrases listed below have the following meaning:

approved organism	Any of the new organisms approved under application APP203165 (see Appendix 1).
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 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).
decontaminate	Kill or remove all approved organisms and heritable material.
disposal	The action or process of discarding or getting rid of something, including but not limited to burial, incineration, or placing in the general waste. [Excludes the act of transferring to another containment facility under section 29 of the Biosecurity Act]
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.
new organism	Defined by section 2A of the HSNO Act (a) an organism belonging to a species that was not present in New Zealand immediately before 29 July 1998 (b) an organism belonging to a species, subspecies, 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.

organism	Defined in section 2 of the HSNO Act: (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) declared to be an organism for the purposes of the Biosecurity Act 1993 (e) Includes a reproductive cell or developmental stage of an organism.
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 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).