Environmental Protection Authority
Te Mana Rauhī Taiao

New Zealand Government

Decision

Date	16 October 2020
Application number	APP204024
Application type	To develop in containment any new organism under section 40(1) of the Hazardous Substances and New Organisms Act 1996
Applicant	Hopkirk Research Institute
Date Application received	10 September 2020
Consideration date	16 October 2020
Considered by	A decision-making committee of the Environmental Protection Authority (the Committee)[1]: • Dr John Taylor (Chair) • Dr Louise Malone
Purpose of the application	To develop the Incidentally Imported New Organism[2], *Mycoplasma bovis* in containment to research the development of diagnostic tests.
The new organism approved	*Mycoplasma bovis* (Hale et al 1962) Askaa and Ernø 1976

Summary of the decision

Application APP204024 was lodged under section 40(1) of the Hazardous Substances and New Organisms (HSNO) Act 1996 (the Act) seeking approval to develop (by deliberate isolation, aggregation, multiplication, or other use of the organism) incidentally imported *Mycoplasma bovis* in containment.

[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] Incidentally imported new organism means a new organism that is imported in or on goods, but is not

a) an essential or constituent part of those goods

b) imported in or on the goods with the intention of concealing the presence of the new organism

c) a genetically modified organism

The application 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).

The Committee has **approved** application APP204024 in accordance with section 45(1)(a) of the HSNO Act, subject to the controls set out in Appendix 1.

1 Application process

1.1 The application was formally received for evaluation and consideration on 10 September 2020 under section 40(1) of the HSNO Act. The consideration of the application by the Committee commenced on 8 October 2020 and concluded on 16 October 2020.

1.2 The application was determined in accordance with section 45 of the HSNO Act, taking into account the matters specified in sections 37, 39, 43 and 45, Schedule 3 (Part 2), relevant matters in Part 2 of the HSNO Act, and the Methodology.

Public Notification

1.3 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 there is likely to be significant public interest.

1.4 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 the Acting General Manager did not identify any significant public interest in this application.

Comments from Department of Conservation and Ministry for Primary Industries

1.5 In accordance with section 58(1)(c) of the 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 during the pre-application draft stage (with the applicant's permission) and following formal receipt of the final application

1.6 DOC indicated that they did not have any biosecurity concerns regarding the application and did not oppose the approval of this application.

1.7 MPI suggested further details of containment of the new organism be added and also noted that a s53 permission under the Biosecurity Act 1993 from the Chief Technical Officer would also be required by the applicant. The applicant has addressed these comments in section 4 and in section 10 of the application. Following a final review after formal receipt of the application, MPI noted that taking into account the nature of the proposed activities in the application and risks associated with these, MPI considers that the proposed containment will manage the risks.

1.8 The Committee is satisfied that MPI and DOC comments have been taken into account in making this decision.

Information available for the consideration

1.9 The information available for the consideration comprised:

- the application and references provided therein;
- the EPA Staff memorandum.
- comments received from DOC and MPI

1.10 The Committee considered that it had sufficient information to assess the application.

Sequence of the consideration

1.11 In its consideration of the application as per the requirements in the Act and the Methodology, the Committee considered whether:

- the application is for one of the purposes specified in the Act
- the new organism can be adequately contained
- the controls provide for matters specified in Part 2 of Schedule 3 of the HSNO Act
- the beneficial effects of having the new organism in containment outweigh the adverse effects of the new organism and any inseparable organism
- the ability of the new organism to escape from containment
- the ability of the new organism to establish an undesirable self-sustaining population
- the ease with which the new organism could be eradicated if it established an undesirable self-sustaining population

1.12 Each point is addressed in the following sections of this decision.

2 Purpose of the application

2.1 The applicant seeks approval to develop[3] the Incidentally Imported New Organism (IINO), *M. bovis* in containment to research the development of diagnostic tests. To do this they require the ability to propagate and work with New Zealand-sourced strains of *M. bovis*. As the microorganism has been designated an IINO by MPI, a development approval from the EPA is required for this research activity.

2.2 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 HSNO Act. The Committee was satisfied that the purpose of this application falls within the scope of section 39(1)(a) “development of any new organism” and section 39(1)(h) of the Act: “such other purpose as the Authority thinks fit”, that being scientific research.

[3] As set out in the Interpretation section (2(1)) of the HSNO Act, **develop** – in relation to an incidentally imported new organism means the deliberate isolation, aggregation, multiplication or other use of the organism.

3 Adequacy of the containment controls imposed

3.1 Section 45(1)(a)(iii) of the HSNO Act requires that the Committee be satisfied that the organism (as described in Table 1) can be adequately contained.

3.2 To evaluate the adequacy of containment, the Committee assessed the ability of *M. bovis* to escape from containment by taking into account:

- the biological characteristics of *M. bovis* that relate to containment
- the containment regime; and
- the potential pathways for the escape of the organism from the containment facility.

Biological characteristics of the new organism that relate to containment

3.3 The applicant wishes to develop the IINO by undertaking *in vitro* experimental work that will involve the culture and storage of *M. bovis* samples collected from the New Zealand environment as well as *in vitro* use in co-culture to infect cell lines using standard tissue culture practices.

3.4 The *Mycoplasma* genus of bacteria is amongst the smallest bacteria that lack a cell wall and have a very small genome. The IINO *M. bovis* is an obligate pathogen and requires a mammalian host (primarily bovine) to complete its lifecycle and is closely associated with cells of the mucosa such as the respiratory and urogenital tracts. It is not known to cause serious disease in humans.

3.5 The development of the IINO to research diagnostic tests involves developing novel *in vitro* assays to detect *M. bovis* infected cells by;

- Developing methods to detect evidence of *M. bovis* infection that may be present in exosomes, extracellular vesicles released from cells following co-culture with the bacterium *in vitro*
- Undertaking an evaluation of molecular diagnostics tools to define the specificity and sensitivity of assays from these cell cultures

3.6 The applicant has described the use of an enhanced level of containment in the application for viable *M. bovis* samples and experimental material involving its use *in vitro*, including operational points relating to the handling of experimental material and associated biohazard waste. They have also stated that they will be developing validated protocols for the generation of non-viable material for experimental work in a lower level of containment. The proposed experiments will not result in an increase in the pathogenicity, virulence or infectivity of the incidentally imported new organism.

3.7 The Committee noted that the applicant already has experience in working with *M. bovis* collected from environmental samples in containment. The Committee also noted that the development work with *M. bovis* is being undertaken at an enhanced level of containment than would otherwise be required given the risk profile of the microorganism.

3.8 The Committee therefore noted that the IINO approved for development in this application will be undertaken under enhanced containment and would not be expected to escape containment.

3.9 No inseparable organisms were identified.

The containment regime

3.10 The Committee was satisfied that the applicant's proposed containment measures, together with the imposed controls (detailed in Appendix 1) will mitigate the risk of *M. bovis* escaping from containment. Furthermore, the Committee was satisfied that the containment regime (Appendix 1) provides for each of the applicable matters specified in Schedule 3 (Part 2) of the Act (*Matters to be addressed by containment controls for new organism excluding genetically modified organisms*), specifically:

- the construction and maintenance of the facility and equipment;
- management, identification and security;
- access for personnel and equipment;
- laboratory and inspection procedures;
- transport, identification and packaging of material leaving the facility;
- registers and documentation;
- treatment of waste (solids, liquids and air);
- contingency plans; and
- staff training.

3.11 The Committee notes that the controls are primarily outcome-focused, 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 that those procedures are effective and complied with, to operate the containment facility in compliance with that documentation as per **controls 3** and **4**.

3.12 All containment facilities are initially inspected, approved and regularly audited by MPI for compliance with the controls of this approval.

Potential pathways for escape from the containment facility

3.13 The following potential pathways of escape have been identified and are addressed by the controls:

- Escape during transport to/between containment facilities;
- Escape via unauthorised persons being present within the containment facility;
- Escape in waste or on contaminated equipment;
- Escape due to the presence of undesirable organisms (eg, vermin);
- Escape via laboratory personnel;
- Escape via inadequate maintenance or failure of containment measures;

- Escape via failure of containment regime following fire or natural disaster

3.14 Regardless of the pathway of escape (controls for which are described in further detail below), **controls 21 and 22** require that there must be a documented contingency plan for all approved organisms in the facility, which must be implemented immediately in the event of escape of any approved organism, or if any other breach of containment has occurred.

Escape during transport to/between containment facilities

3.15 Escape during transport to or between containment facilities has been identified as a potential pathway for escape. **Controls 8, 9, 12 and 13** address the requirements for moving the approved organism(s) to or between containment facilities (ie, formal receipt of consignments upon arrival), including maintaining containment and accompanying documentation (ie, appropriately detailed transfer forms).

Escape via unauthorized persons being present within the containment facility

3.16 Unauthorised persons have been identified as providing a potential pathway of escape, as they may deliberately or accidentally remove the approved organism(s) from the containment facility. **Controls 14-16** address requirements regarding access to the facility, including the requirements to exclude unauthorised persons (eg, by lock and key or swipe card), and the identification of entrances (including entrances that are primarily used as exits).

Escape in waste or on contaminated equipment

3.17 The removal of waste and contaminated equipment from the facility has been identified as a potential pathway of escape. **Controls 17 and 18** specify requirements for removing equipment (including personal protective equipment) and waste from a containment facility to prevent the escape of the approved organism(s). It is noted that waste can be treated off-site to kill any approved organism or heritable material) using heat (ie, autoclave or incineration) or chemicals (eg, sodium hypochlorite-household bleach), and the approved organism(s) must be contained during transport to the treatment location.

Escape due to the presence of undesirable organisms in the facility

3.18 The presence of undesirable organisms, such as vermin, has been identified as a possible pathway of escape. **Control 19** requires the facility be secured and monitored to ensure the exclusion of undesirable organisms that might compromise the containment of the approved organism(s). For example, various sites surrounding the containment facility might be serviced for pest control on a regular basis.

Escape via laboratory personnel

3.19 **Control 2** requires the approval user to ensure all laboratory personnel comply with the controls of this approval. Accidental or unintentional removal of approved organisms by laboratory personnel has been identified as a potential pathway of escape. **Control 7** requires that persons entering and exiting the containment facility do so in a way that does not compromise containment. **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. Training

could be performed in person or via online courses, and might include competency tests and annual refresher courses.

Escape via inadequate maintenance or failure of containment measures

3.20 Escape as a result of failure of the containment regime through inadequate maintenance of the regime has been identified as a potential pathway of escape. **Controls 5 and 6** require that the containment facility where the approved organism is held must be clearly defined described and documented, including location and boundaries, and must be designed, constructed and maintained to prevent the approved organism from escaping (ie, constructed to an appropriate New Zealand building standard), respectively. **Control 23** specifies that containment measures must be inspected, monitored and reviewed to ensure that containment is being achieved, and this could be realised by performing regular internal audits. **Control 23** also requires that containment measures be inspected as soon as possible after any event that could compromise containment. **Control 24** requires that rapid remedial action be taken should any such actions be identified, either under **control 23**, or by any other means.

Escape via failure of containment regime following fire or natural disaster

3.21 Escape as a result of failure of the containment regime following fire or natural disaster has also been identified as a potential pathway of escape. **Control 23** requires that containment facilities 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.

Conclusion on adequacy of the containment regime

3.22 The Committee concluded that it is highly improbable that *Mycoplasma bovis* would be able to escape from containment, taking into account:

- the biological characteristics of the new organism that relate to containment;
- the containment controls (Appendix 1); and
- the potential pathways of escape of the new organism from the containment facilities

3.23 Therefore, the Committee concluded that the new organism could be adequately contained. In particular, the Committee was satisfied that the controls imposed in Appendix 1 provide for each of the applicable matters specified in Schedule 3 (Part 2) of the Act (as required under section 45(2)(a) of the Act).

3.24 Section 45(2)(b) of the Act also provides that an approval may include controls that provide for any other matters in order to give effect to the purpose of the Act. Therefore the Committee imposed **controls 1, 2, 3, 4, 10** and **11** for administrative purposes and to enable MPI to measure compliance with the controls.

4 Ability of the organism to establish an undesirable self-sustaining population and the ease of eradication

4.1 In accordance with sections 37, 43 and 45(1)(a)(ii) of the HSNO Act and clauses 10(e) and 10(f) of the Methodology, the Committee took into consideration the ability of the new organism to form undesirable self-sustaining populations should they escape containment, and the ease of eradication of such populations.

4.2 The Committee noted that a self-sustaining population of the IINO *M. bovis* is already established in New Zealand Beef and Dairy herds and is subject to a phased eradication plan currently managed by MPI. The potential of the *M. bovis* to escape from containment and form an undesirable self-sustaining population is limited by the enhanced containment regime and the requirement for finding a suitable host organism. Furthermore, in the highly improbable event of the escape of *M. bovis* from the containment facility, subsequent detection and eradication would be highly likely and would be subject to this nationwide eradication plan.

4.3 The Committee noted that in the highly improbable event of an escape, it is highly improbable that a self-sustaining population could establish, as *M. bovis* is an obligate pathogen that requires a host to be able to establish a self-sustaining population.

4.4 The Committee considered that in the event of a breach of containment, all possible measures should be taken to either retrieve or eradicate the organism as per **controls 21** and **22** in (Appendix 1, requirements for contingency plans).

5 Assessment of potentially adverse and beneficial effects

5.1 The Committee is required by section 45(1)(a)(ii) of the HSNO Act to take into account all the effects of the organism and any inseparable organisms, and consider whether the potential beneficial effects of having the organism in containment outweigh the potential adverse effects of the organism and any inseparable organisms.

5.2 The Committee considered the potential adverse effects of the new organism on human health and safety, the environment, society and the community, Māori culture and traditions, the principles of the Treaty of Waitangi and the market economy.

5.3 When considering the adverse effects of the new organism, the Committee took into account the adverse effects (if any) of having the new organism in containment, the probability that the new organism may escape containment after considering all the controls to which the new organism would be subject to if the application was approved, and the effects of the new organism if they were to escape (section 45(4) of the HSNO Act).

Assessment of adverse effects

Potentially significant adverse effects on the environment

5.4 The potential for the new organism to have an adverse effect on the environment is limited by the containment requirements of this approval. The Committee considered the information

provided on potential effects on the environment, and noted that all research involving the IINO will be conducted within MPI-approved enhanced containment facilities and will be managed in accordance with facility operating procedures and manuals.

5.5 The Committee noted that development of the IINO will involve the deliberate isolation, aggregation, multiplication, or other use of the organism and will not involve developments that increase the pathogenicity, virulence or infectivity of the host organism to humans or other organisms in the environment. Development activities that involve genetic modifications are excluded.

5.6 The Committee noted that the IINO will be developed from samples collected in the New Zealand environment.

5.7 The Committee noted that for any adverse effects on the environment to occur, the new organism, would first need to escape or be released from containment. The Committee considered that it was highly improbable that such an adverse effect would eventuate taking into account the imposed controls.

5.8 Having considered the controls imposed (Appendix 1) on the applicant's enhanced containment regime and the biological characteristics of the organisms, the Committee considers the likelihood of escape as **negligible**.

5.9 As the new organism is being developed as an IINO and the developments described are not likely to confer any competitive advantage to the host organisms in the unlikely event of escape, the Committee therefore assesses the risk to the environment to be **negligible**.

5.10 After assessing all the information, the containment controls imposed, and the likelihood of escape from containment, the Committee did not identify any non-negligible adverse effects on the environment from the development of the new organism in containment.

Potentially significant adverse effects on human health and safety

5.11 The Committee noted that *M. bovis* does not, under normal circumstances, infect or cause disease in humans, and is unlikely to pose a serious risk to laboratory personnel or the wider community.

5.12 The laboratory personnel who will be working with *M. bovis* will be trained in its handling, therefore the Committee considers the potential for adverse effects on human health and safety to be **negligible**.

5.13 After assessing all the information, the Committee did not identify any non-negligible adverse effects on human health and safety that may result from the development of *M. bovis* in containment.

Potentially significant adverse effects on Maori and their culture and traditions and the principles of the Treaty of Waitangi (Te Tiriti o Waitangi)

5.14 The Committee took into account the effects on the relationship of Māori and their culture and traditions with their ancestral lands, water, sites, wāhi tapu, valued flora and fauna, and other taonga, and the principles of the Treaty of Waitangi.

5.15 Kaupapa Kura Taiao, the EPA's Māori advisory group, reviewed the application and did not have any concerns from a Māori perspective. They also noted that due to Māori interests in primary industries, particularly beef and dairy, the research project itself has potential benefits for Māori.

5.16 The Committee considered that the new organism would first need to escape from containment to cause adverse effects on the relationship of Māori and their culture and traditions with their ancestral lands, water, sites, wāhi tapu, valued flora and fauna, and other taonga, and the principles of the Treaty of Waitangi. The Committee considered that the imposed containment controls were sufficient to contain the new organism, and considered the likelihood of escape as highly unlikely.

5.17 After assessing all the information, the Committee did not identify any non-negligible adverse effects on the relationship of Māori and their culture and traditions with their ancestral lands, water, sites, wāhi tapu, valued flora and fauna, and other taonga from the development of the new organisms in containment.

5.18 Given the absence of identified effects to the outcomes of significance to iwi/Māori, the Committee considered the application to be broadly consistent with the principles of the Treaty of Waitangi.

Potentially significant adverse effects on the market economy and society and community

5.19 The Committee took into account the effects of the new organism on the market economy and society and community. The Committee noted that the new organism will be held in MPI-approved containment facilities which will be managed to meet the imposed controls (Appendix 1).

5.20 The Committee noted that the new organism to be developed is an IINO that has already established a self-sustaining population that has adversely impacted the market economy and society and community.

5.21 Furthermore, for any <u>further</u> adverse effects on the market economy and society and community to occur the new organism would need to escape or be released from containment. The Committee considered that it was highly improbable that an escape could occur, taking into account the imposed controls.

5.22 Therefore, the Committee concluded that the new organism to be developed as an IINO under this approval (as described in Table 1) is not expected to cause any further potential adverse

effects on the market economy or society and communities than the IINO currently present in the New Zealand environment and subject to a phased eradication plan.

5.23 Therefore, the Committee assesses the risks to the market economy and society and community to be **negligible**.

Assessment of beneficial effects

5.24 The Committee considered the potential beneficial effects on human health and safety, the environment, society and community, Māori culture and traditions, and the market economy from the development in containment of the new organism.

5.25 The Committee noted that this work aims to develop novel diagnostic testing methods for the detection of *M. bovis* infected cattle and would, therefore, be an important tool for the management of the Unwanted Organism that is currently subject to a phased eradication plan by MPI.

5.26 The committee noted that the applicant already has experience managing *M. bovis* in containment having held a s52 CTO permission and has experience in containing the IINO in appropriate containment facilities. Therefore these beneficial effects are likely to eventuate if this application is approved.

Conclusion on the risks, costs and benefits

5.27 After considering the information provided, the Committee did not identify any non-negligible adverse effects of the development in containment of the IINO, *M. bovis*. Therefore, the Committee was not required to take into account the probability of occurrence or magnitude of any adverse effects

5.28 After considering the information provided, the Committee considered that the beneficial effects of developing more effective and efficient diagnostic tests for the detection of *M. bovis* infection in beef and dairy herds would be **non-negligible**.

Evaluation and weighing of beneficial and adverse effects

5.29 The Committee considered that they had sufficient information to weigh the effects of the development of the new organism in containment.

5.30 Overall, the Committee did not identify any non-negligible adverse effects from developing the IINO, by the deliberate isolation, aggregation, multiplication, or other use of the organism, in containment.

5.31 Therefore, the Committee considered that any adverse effects would be **negligible**. Since it did not identify any adverse effects, the Committee was not required to take into account the probability of occurrence or magnitude of any adverse effects.

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

5.33 The Committee concluded that the beneficial effects accruing from the development of the new organism in containment were **non-negligible**.

5.34 Section 6(f) of the Act requires the Committee to take into account New Zealand's international obligations when determining this application. New Zealand has no obligations which are relevant to this approval.

5.35 The Committee, having considered all the effects of the new organism and the matters outlined in section 45 of the Act, concluded that:

- the application was for one of the purposes specified in section 39(1);
- the approved organism could be adequately contained; and
- the potential beneficial effects of developing the new organism in containment outweighed the potential adverse effects of the new organism.

6 Associated approvals

6.1 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 or relevant CTO permissions for working with an IINO).

7 Achieving the purpose of the HSNO Act

7.1 The purpose of the Act is 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 (section 4 of the Act).

7.2 In order to achieve the purpose of the Act, when considering this application the Committee recognised and provided for the following principles (section 5 of the Act):

- the safeguarding of the life-supporting capacity of air, water, soil and ecosystems; and
- the maintenance and enhancement of the capacity of people and communities to provide for their own economic, social and cultural well-being and for the reasonably foreseeable needs of future generations.

7.3 The Committee took into account the following matters when considering this application in order to achieve the purpose of the Act (sections 6, 7 and 8 of the Act):

- the sustainability of all native and valued introduced flora and fauna;
- the intrinsic value of ecosystems;
- public health;
- the relationship of Māori and their culture and traditions with their ancestral lands, water, sites, wāhi tapu, valued flora and fauna, and other taonga;

- the economic and related benefits and costs of using the new organism;
- New Zealand's international obligations;
- the need for caution in managing adverse effects where there is scientific and technical uncertainty about those effects; and
- the principles of the Treaty of Waitangi (Te Tiriti o Waitangi).

7.4 The Committee is satisfied that this decision is consistent with the purpose and principles of the Act, and that the process followed to make this decision satisfies the requirements of the Act and the Methodology.

8 Decision

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

8.2 The Committee considered that the threshold for approval under section 45 of the Act has been met. It was satisfied that the new organism could be adequately contained and that the beneficial effects of the new organism outweighed the adverse effects of the new organism, taking into account all of the following:

- all the effects of the new organism and any inseparable organisms;
- the matters in sections 37, 43, 45 of the HSNO Act;
- the relevant matters in Schedule 3 (Part 2) of the HSNO Act;
- the relevant matters in Part 2 of the HSNO Act; and
- the Methodology

8.3 Therefore, the Committee decided to exercise its discretion and **approve** the development (by deliberate isolation, aggregation, multiplication, or other use of the organism) of the incidentally imported new organism, *Mycoplasma bovis*, in containment, 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 **with controls** specified in Appendix 1.

Environmental Protection Authority
Te Mana Rauhī Taiao

Dr John Taylor **Chair, Decision Making Committee** **Environmental Protection Authority**	**Date 16 October 2020**

Table 1: Approved number for the new organism in application APP204024

Organism	Approval code
Mycoplasma bovis (Hale et al 1962) Askaa and Ernø 1976	NOC100531

Appendix 1: Controls required by this approval[4]

Any person developing the approved organism 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 organism(s) (see Table 1 of the decision document) 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, and
   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 containment facility where the approved organism(s) will be held must be clearly defined, described, and documented, including the location and boundaries.

6. The containment facility must be designed, constructed, managed, and maintained to prevent the approved organism(s) 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 MPI of any intended movement of approved organism(s) outside of the facility, or any proposed modification to the containment regime which may affect the integrity of containment of the approved organism(s), before the actions are undertaken.

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

[4] Compliance with the controls imposed in 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 approvals of containment facilities by MPI).

11. 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 organism(s)

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(s) must be accompanied by documentation stating the:

    a) identity of the approved organism(s);

    b) containment requirements;

    c) details of the sender; and

    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) is 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(s), must be treated to ensure that the approved organism or any heritable material is killed prior to disposal.

18. Any equipment, that may harbour the approved organism(s) or heritable material from the approved organism(s), must be treated to ensure that the approved organism(s) 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).

Requirements 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. There must be a documented contingency plan for all approved organism held in the 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, 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.

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 HSNO Act.

Term	Definition
approved organism	The new organism approved under application APP204024 (as described in Table 1 of the decision document).
breach of containment	Includes escape of approved organism(s) from containment facility, unauthorised entry to the containment facility, or the structural integrity of the containment 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	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).
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).

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 under the HSNO Act (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 microorganism (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.
unauthorised person	Unauthorised persons are those individuals not identified in the containment facility documentation as being allowed into the containment facility or any part thereof.
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).