

# Approval

<b>Date of Decision</b>	16 October 2020
<b>Application number</b>	APP204024
<b>Application type</b>	To develop in containment any new organism under section 40(1) of the Hazardous Substances and New Organisms Act 1996
<b>Applicant</b>	Hopkirk Research Institute
<b>Date Application received</b>	10 September 2020
<b>Consideration Date</b>	16 October 2020
<b>Decision made by</b>	A decision-making committee of the Environmental Protection Authority (the Committee) <sup>1</sup> : <ul style="list-style-type: none"> <li>• Dr John Taylor (Chair)</li> <li>• Dr Louise Malone</li> </ul>
<b>Purpose of the Application</b>	To develop the Incidentally Imported New Organism <sup>2</sup> , <i>Mycoplasma bovis</i> in containment to research the development of diagnostic tests.

## Decision

1.1. After reviewing all the information contained in the application, the Committee was satisfied that the application met the requirements of section 40 of the Act. Therefore, the Committee decided to exercise its discretion and **approve** the development (by deliberate isolation, aggregation,

<sup>1</sup> 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.

<sup>2</sup> 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

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.



16 October 2020

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**Dr John Taylor**

**Date**

**Chair, Decision Making Committee  
Environmental Protection Authority**

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

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

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## Appendix 1: Controls required by this approval<sup>3</sup>

*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.

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<sup>3</sup> 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).

10. The EPA and MPI must be notified in writing before this HSNO Act approval is used for the first time.
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
<b>approved organism</b>	The new organism approved under application APP204024 (as described in Table 1 of the decision document).
<b>breach of containment</b>	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.
<b>containment</b>	Restricting an organism to a secure location or facility to prevent escape (section 2 of the HSNO Act).
<b>containment facility</b>	A place approved by MPI in accordance with section 39 of the Biosecurity Act 1993, for holding approved organisms.
<b>contingency plan</b>	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.
<b>controls</b>	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).
<b>disposal</b>	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]
<b>documentation</b>	Written or electronic records (including manuals, lists, diagrams, maps, policies, procedures, plans and protocols, records of training, access).
<b>heritable material</b>	(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).

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