



Decision

Date	10 July 2019
Application code	APP203820
Application type	To develop in containment any new organism under section 40(1) of the Hazardous Substances and New Organisms Act 1996
Applicant	AgResearch Limited
Date application received	30 May 2019
Consideration date	10 July 2019
Considered by	A decision-making committee of the Environmental Protection Authority (the Committee) ¹ : <ul style="list-style-type: none">• Dr Nick Roskrige (Chair)• Mr Tipene Wilson
Purpose of the application	To develop in containment <i>Meloidogyne minor</i> for host range testing on plant species.
The new organisms approved	<i>Meloidogyne minor</i>

Summary of decision

1. Application APP203820 to develop *Meloidogyne minor* in containment to provide an inoculum to carry out a series of host range tests on a range of plant species, was lodged under section 40(1) of the Hazardous Substances and New Organisms (HSNO) Act 1996 (the Act).
2. The application was considered in accordance with the relevant provisions of the Act and of the HSNO (Methodology) Order 1998 (the Methodology).
3. The Committee has **approved** the application in accordance with section 45(1)(a) of the Act, subject to the controls set out in Appendix 1.
4. The application was formally received for processing on 30 May 2019.

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

Application process

Notification

5. Section 53(2) of the Act provides that an application under section 40 of the Act may be publicly notified by the Environmental Protection Authority (EPA) if it considers that there is likely to be significant public interest.
6. The EPA Board has delegated the decision to publicly notify applications under section 53(2) to the Chief Executive, who sub-delegated that decision-making to the General Manager Hazardous Substances and New Organisms as of 17 March 2015. The application was not considered to meet the threshold of 'significant' public interest.

Comments from MPI and DOC

7. In accordance with section 58(1)(c) of the Act, the Ministry for Primary Industries (MPI) and the Department of Conservation (DOC) were advised and provided with the opportunity to comment on the application.
8. DOC support the application provided that the containment controls would prevent release of new organisms. They wondered if some representative native plants taxonomically related to known host species could be added to the proposed list of cultivated plants to be tested to detect impacts of this nematode.
9. MPI did not make any comments.

Information available for the consideration

10. The information available for the consideration comprised of the application form and a staff memorandum.
11. The Committee considered that it had sufficient information to assess the application. To the extent that the application may not meet any legislative information requirements, the Committee waives those requirements.

Sequence of the consideration

12. In its consideration of the application as per the requirements in the Act and the Methodology, the EPA 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 Schedule 3 (Part 2) 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 new organism was able to escape from containment
 - the new organism was able to establish an undesirable self-sustaining population
 - the new organism could be eradicated if it established an undesirable self-sustaining population.
13. Each point is addressed in the following sections of this decision.

Purpose of the application and scope of the approval

14. The applicant, AgResearch, sought approval to develop the incidentally imported nematode, *Meloidogyne minor*, in containment to provide an inoculum to carry out a series of host range tests on a range of plant species.
15. 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 Committee is satisfied that the purpose of this application falls within the scope of section 39(1)(a) of the Act: “the development of any new organism”; and section 39(1)(h) of the Act: “such other purposes as the Authority thinks fit”, being scientific research.
16. The Committee noted that the use of this approval is not limited to the applicant. Therefore other persons could use this approval provided that they comply with the approved organism description (Table 1); meet the purpose of this approval (for development of *M. minor* for host range testing on plant species); and that they meet the controls specified in Appendix 1. Therefore the Committee imposes control 10 requiring all approval users to notify the EPA and MPI that they intend to use this approval prior to first use.

Adequacy of the containment regime

17. Section 45(1)(a)(iii) of the Act requires that the Committee be satisfied that the new organism can be adequately contained.
18. To evaluate the adequacy of containment, the Committee assessed the ability of the new organism to escape from containment by taking into account:
 - the biological characteristics of the new organism that relate to containment
 - the containment regime
 - the potential pathways of escape from the containment facility.

Biological characteristics that relate to containment

19. The organism approved for development in containment is *Meloidogyne minor*.
20. The Committee noted that the new organism, *M. minor*, is currently present in New Zealand. The applicant will take samples from Hagley Oval in Christchurch into their PC2 containment facility to conduct host-range testing on various plant species.
21. The Committee noted that *M. minor* is contained with its host plants for most of its life, and causes severe damage. AgResearch will maintain a culture of *M. minor* to test the nematode’s impact on valuable plant species in the containment facility. The Committee considered that the inoculation of *M. minor* into various plant species will not increase the nematode’s ability to escape containment.
22. The natural movement of *M. minor* in the soil is considered very slow and similar to other *Meloidogyne* larvae which can move up to 16 cm per day. The development and movement of nematodes in the genus *Meloidogyne* are, in part, dependent to the temperature and moisture of the substrate, with optimum mobility of juveniles J2 between 15°C and 25°C.
23. Nematodes can be separated from their hosts by human intervention in a laboratory and grown under appropriate culture conditions. The likelihood of *M. minor* escaping and naturally infecting

another plant is low since juveniles are unlikely to survive outside an appropriate substrate and require a suitable host to grow in. However, the Committee noted that eggs might survive longer outside any appropriate substrate due to the gelatinous mass surrounding them.

24. The Committee noted that *M. minor* usually reproduces by facultative meiotic parthenogenesis, therefore, a single second-stage juvenile can start a new population. However, in the highly unlikely event of an escape, an egg or a J2 nematode could only lead to populations of the nematode establishing if they can find a host, leading to localised populations.
25. The Committee noted that the main source of dispersal is by human assistance rather than by natural means. Indeed two of the main natural hosts of *M. minor*, potato (*Solanum tuberosum*) and creeping bentgrass (*Agrostis stolonifera*), are created habitats. Infestations in sports fields are believed to have occurred via sport equipment or machinery contaminated with soil, replacement of turf, or via the import of infested sand.

Associated organisms

26. Spores of the fungus *Pasteria*, a known parasite of nematodes, were found on juveniles of *M. minor* in the United Kingdom.

The containment regime

27. The Committee has determined the set of controls to be imposed by the EPA, and these are detailed in Appendix 1.
28. The Committee noted 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, all approval users are 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 complied with. Further, the approval user must operate the containment facility in compliance with that documentation as per controls 3 and 4.
29. The Committee is satisfied that the controls set out in Appendix 1 establish a containment regime that manages the risk of *M. minor* escape from containment. The containment regime 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 organisms excluding genetically modified organisms) as detailed in Appendix 2 of the advice memorandum.
30. The Committee had to consider the potential of *M. minor* to escape containment.

The potential pathways for escape from containment

31. The Committee identified the likely pathways of escape of *M. minor* and assessed these pathways against the containment regime (including the requirements of the controls in Appendix 1) and the biological characteristics relating to containment.
32. The following potential pathways of escape were identified by the Committee:
 - escape during movement within, to, or from containment facilities
 - escape via accidental/unintentional or deliberate removal by unauthorised persons
 - escape via accidental/unintentional or deliberate removal by research staff or other facility personnel
 - escape in waste or contaminated equipment
 - escape due to the presence of undesirable organisms (vermin)
 - escape via failure of containment regime through inadequate maintenance/upkeep of regime

- escape via failure of containment regime following fire or natural disaster.
33. The Committee noted that the containment requirements (Appendix 1) include controls that address each of the identified pathways of escape. Those controls include specifications regarding moving the approved organism (controls 8, 12 and 13), limiting access to the facility (controls 14-16), removing equipment and waste from the facility (controls 17 and 18), dealing with undesirable organisms (control 19), entering and exiting the containment facility (control 7), training of laboratory personnel and other people entering the facility (control 20), design, construction and maintenance of the facility (control 5 and 6), and monitoring and inspection of the containment measures (controls 23 and 24).
34. The Committee noted that the controls are outcome based. Further they noted that approval users will need to demonstrate how they are meeting each control, including documenting the procedures that specify how they will meet the controls (control 3), and that they must operate in compliance with those documented procedures (control 4). The Committee also imposed control 2 specifying the parties responsible for ensuring compliance with the controls, and controls 9-11 specifying notifications to the EPA and MPI.

Conclusion on adequacy of the containment regime

35. The Committee concluded that it is highly improbable that *M. minor* 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
 - containment regime and controls.
36. Overall, the Committee is satisfied that *M. minor* can be adequately contained.
37. In particular, the Committee considered 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) of the Act).
38. Section 45(2) provides that an approval may include controls that provide for any other matters in order to give effect to the purpose of the Act. The Committee considered that no further additional controls are required to achieve the purpose of the Act, but imposed controls 3, 4, 10 and 11 for administrative purposes and to enable MPI to measure compliance with the controls.

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

39. In accordance with sections 37 and 44 of the Act and clause 10(e)(f) of the Methodology, the Committee took into consideration the ability of the new organism to form an undesirable self-sustaining population should it escape containment and the ease of eradication of such a population.
40. The Committee noted that in the unlikely event of an escape of *M. minor*, the establishment of a self-sustaining population will be dependent on the presence of a suitable host. If a new population established in the immediate vicinity of the containment facility, eradication of the population should be readily achieved. The potential establishment of a population of *M. minor* would be monitored by the applicant through its routine containment management processes, and such a population would be eradicated using nematicide treatments or physical removal of infected soil and ongoing monitoring to detect any population resurgence.

41. Any nematode that escapes containment inside its host could be managed by herbicide treatments since the nematodes are reliant on their plant hosts for survival and propagation.
42. Cultures of nematodes isolated from their plant hosts and propagated in the laboratory will be kept in artificial substrate. In the highly improbable event of an escape from a nematode culture, it is unlikely that such an organism will survive in the environment in the absence of specialised laboratory culturing growth media and equipment, and is unlikely to find a viable host plant to infect in the environment.
43. The Committee considered that in the highly improbable event of a breach of containment, all possible measures should be taken to either retrieve or eradicate the organisms as per controls 21 and 22 (requirements for contingency plans).

Identification and assessment of potentially significant adverse and beneficial effects

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

Potentially significant adverse effects of having *Meloidogyne minor* in containment

Potentially significant adverse effects on the environment

45. The potential for *M. minor* to cause adverse effects on the environment is limited by the containment requirements of this approval. No potentially significant effects of having these organisms in containment have been identified in relation to the environment.
46. In the highly improbable event of an escape from containment, the potential for *M. minor* to cause adverse effects on the environment through the establishment of populations of nematodes that could affect native species is significant due to the broad range of viable hosts.
47. The Committee found that, in the highly improbable event of an escape, there may be adverse effects to New Zealand's inherent genetic diversity if *M. minor* hybridises with native species. The Committee noted that this would only happen if native nematodes that can cross-breed with an exotic species via interspecific or intergeneric hybridisation are found in the same place.

Potentially significant adverse effects on human health and safety

48. *Meloidogyne minor* is not known to cause significant adverse effects on human health and safety.
49. No potentially significant adverse effects on human health and safety have been identified in relation to having *M. minor* in containment.

Potentially significant adverse effects on Māori culture and traditions

50. The Committee did not identify any adverse effects on Māori and their culture and traditions with their ancestral lands, water, sites, wāhi tapu, valued flora and fauna, and other taonga as *M. minor* will be held within an approved containment facility which has the appropriate structural requirements, operational procedures and controls to prevent escape.

Potentially significant adverse effects on the market economy

51. No potentially significant adverse effects on the market economy have been identified in relation to having the new organisms in containment.
52. In the highly improbable event of an escape from containment and the unlikely establishment of self-sustaining populations of *M. minor*, such populations could have adverse effects on the market economy through the establishment of populations of nematodes in sports grounds or agricultural fields.

Potentially significant adverse effects on society and communities

53. No potentially significant adverse effects on society and communities have been identified in relation to having the new organisms in containment.

*Potentially significant benefits of having *Meloidogyne minor* in containment*

54. The applicant noted that the purpose of having *M. minor* in containment is for host range testing purposes. They aim to determine susceptible agricultural host plants for *M. minor*, and their damaging thresholds.
55. Testing will also help determine the potential harmful impact the nematode could have on the pastoral sector using perennial ryegrass.
56. The results could be used in management strategies of the nematode.

Conclusion on the risks, costs and benefits

57. After considering the relevant information, the Committee did not identify any potentially significant adverse effects from developing incidentally imported *M. minor*. Therefore, the Committee considered that any adverse effects of the new organism would be negligible. Since the Committee 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.
58. After considering the relevant information, the Committee identified beneficial effects and considered that those beneficial effects would be non-negligible.

Evaluation and weighing of beneficial and adverse effects

59. The Committee considered that they had sufficient information to weigh the effects of the new organism in containment.
60. The Committee concluded that the potential adverse effects of developing the new organism in containment were negligible, and that the benefits were non-negligible.
61. Given that there were no adverse effects identified, consideration of whether the adverse effects may aggregate in order to assess any cumulative effects was not relevant.
62. The Committee took into account all the effects of the new organism, and all the measures available for risk management, and concluded that it was evident that the beneficial effects outweigh the adverse effects.
63. 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.
64. The Committee, having considered all the effects of the new organism in containment and the effects of any inseparable organism, and the matters outlined in section 45 of the Act, concluded that:

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

Achieving the purpose of the Act

65. 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).
66. In order to achieve the purpose of the Act, when considering the application the Committee recognised and provided for the following principles of the Act (section 5):
- the safeguarding of the life-supporting capacity of air, water, soil and ecosystems
 - 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.
67. The Committee took into account the following matters when considering the 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 a particular hazardous substance or 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
 - the principles of the Treaty of Waitangi (Te Tiriti o Waitangi).
68. The Committee is satisfied that this decision is consistent with the purpose of the Act and the above principles and matters.

Decision

69. 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 Act.

70. The Committee considered that the threshold for approval under section 45 of the Act has been met. It is satisfied that *Meloidogyne minor* can be adequately contained and that the beneficial effects of the organism outweigh the adverse effects of the organism, taking into account all of the following:

- all the effects of the organism and any inseparable organisms
- the matters in section 37, 44, and 45, and Schedule 3 (Part 2) of the Act
- the relevant matters in Part 2 of the Act
- the Methodology.

71. The Committee decided to exercise its discretion and approve to develop in containment *Meloidogyne minor* under section 45(1)(a) of the Act. The Committee noted that in accordance with section 45(2) of the Act, the approval has been granted with controls.



10 July 2019

Dr Nick Roskruge
Chair, Decision Making Committee
Environmental Protection Authority

Date

Table 1: Approval number for the new organism in application APP203820

Organism	Approval code
<i>Meloidogyne minor</i>	NOC100221

Appendix 1: controls used for risk assessment

Any person developing the approved organism under the approval granted by this decision (each referred to as the approval holder) must ensure compliance with the controls set out below in respect of any activity they carry out under this approval in a containment facility under their control.

Requirement for the containment of approved organisms

1. The approved organism(s) 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 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 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 organisms 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 organisms 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.
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 organisms

12. The approved organism(s) must be contained during movement within or to 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
- 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 disposal.
- 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).

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 each 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 the context otherwise requires, the words below have the stated meaning:

approved organism	New organisms approved under application APP202109.
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).
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).

new organism	<p>Defined by section 2A of the HSNO Act</p> <p>(a) an organism belonging to a species that was not present in New Zealand immediately before 29 July 1998</p> <p>(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</p> <p>(c) an organism for which a containment approval has been given under the HSNO Act</p> <p>(ca) an organism for which a conditional release approval has been given under the HSNO Act</p> <p>(cb) a qualifying organism approved for release with controls</p> <p>(d) a genetically modified organism</p> <p>(e) an organism that belongs to a species, subspecies, infra-subspecies, variety, strain, or cultivar that has been eradicated from New Zealand.</p>
organism	<p>Defined in section 2 of the HSNO Act:</p> <p>(a) Does not include a human being</p> <p>(ab) Includes a human cell</p> <p>(b) Includes a micro-organism</p> <p>(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</p> <p>(d) Includes an entity (other than a human being) declared to be an organism for the purposes of the Biosecurity Act 1993</p> <p>(e) Includes a reproductive cell or developmental stage of an organism.</p>
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).