Environmental Protection Authority
Te Mana Rauhī Taiao

DECISION

Date	31 July 2013
Application code	APP201737
Application type	To import into containment any new organism under s 40(1) of the Hazardous Substances and New Organisms Act 1996
Applicant	AgResearch Limited
Date application received	27 May 2013
Consideration date	8 July 2013
Considered by	A decision-making committee of the Environmental Protection Authority (the Committee)[1]: • Kevin Thompson (Chair) • Deborah Read • Helen Atkins
Purpose of the application	To import and hold in containment Risk Group 1 and 2 microorganisms (including bacteria, archaea, protozoa, fungi, bacteriophages, and viruses) as cultures or within samples derived from animals, plants and the environment, for laboratory based research

1. Summary of decision

1.1. The application to import Risk Group 1 and 2 microorganisms (as described in Table 2) into containment for laboratory research, was lodged under s 40(1) of the Hazardous Substances and New Organisms (HSNO) Act 1996 (the Act).

1.2. The application was considered in accordance with the relevant provisions of the Act and of the HSNO (Methodology) Order 1998 (the Methodology).

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

[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 s 18A of the Act.

2. Application process

2.1. The application was lodged on 27 May 2013 under s 40(1) of the Act.

Notification

2.2. Section 53(2) of the Act provides that an application under s 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.

2.3. The Chief Executive has delegation to decide whether to publicly notify an application to import into containment any new organism. The application was not publicly notified because the Chief Executive did not identify any significant public interest in this application.

Comments from MPI and DoC

2.4. As required by the Act and the Methodology, the Ministry for Primary Industries (MPI) and the Department of Conservation (DoC) were advised and provided with the opportunity to comment on the application. Neither DoC nor MPI raised any concerns about the application.

Information available for the consideration

2.5. The information available for the consideration comprised of the application and references provided therein, and the EPA staff advice report.

2.6. 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.

Sequence of the consideration

2.7. 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
- whether the new organisms can be adequately contained
- whether the controls provide for matters specified in Schedule 3 (Part 2) of the Act
- whether the beneficial effects of allowing the new organisms in containment outweigh the adverse effects of allowing the new organisms in containment
- the ability of the new organisms to escape from containment
- the ability of the new organisms to establish undesirable self-sustaining populations
- the ease with which the new organisms could be eradicated if they established an undesirable self-sustaining population.

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

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 s 39(1) of the Act.

3.2. The applicant (AgResearch) sought approval to import into containment Risk Group 1 and 2 microorganisms (as cultures or within samples, derived from animals, plants and the environment) for laboratory based research.

3.3. The Committee was satisfied that the purpose of this application falls within the scope of s 39(1)(h) of the Act: "*such other purpose as the Authority thinks fit*", being laboratory based research.

3.4. The Committee noted that the use of this approval is not limited to the applicant. As such other persons may use this approval provided that they comply with the approved organism description (Table 2); meet the purpose of this approval (for laboratory research); and that they meet the controls specified in Appendix 1. Therefore, the Committee imposed **control 10** requiring all approval users to notify EPA and the MPI Inspector that they intend to use the approval prior to first use.

4. Adequacy of the containment regime

4.1. Section 45(1)(a)(iii) of the Act requires that the Committee be satisfied that the new organisms can be adequately contained.

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

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

Biological characteristics that relate to containment

4.3. The organisms approved for importation into containment for laboratory research are: Risk Group 1[2] and 2[3] microorganisms[4], as defined by the Australian/New Zealand Standard 2243.3:2002 *Safety in laboratories*. The microorganisms can be in the form of cultures (axenic[5] or mixed) or within samples,

[2] A microorganism that is unlikely to cause human, plant or animal disease.

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

[4] Organisms that are microscopic or sub-microscopic, which means they are too small to be seen by the unaided human eye, includes eukaryotes, prokaryotes and viruses.

[5] Not contaminated by or associated with any other living organism.

and may only be derived from animals (not humans), plants, or the environment, where those plants and animals are not diseased or displaying signs of disease or illness.

4.4. Risk Group 1 and 2 are not taxonomic classifications, but are groupings based on risk characteristics. For this purposes of this approval the definition of Risk Group 1 and 2 organisms is taken from the Australia New Zealand Standard (ASNZS) 2243.3 2003 *Safety in laboratories*:

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

4.5. Microorganism cultures means pure isolates, mixtures of pure cultures or mixed cultures in the form of frozen or lyophilised liquid cultures, culture supernatants; bacteria growing on artificial media, or sterile solid and liquid matrices. Cultures may be axenic[6] or mixed (more than one species), and will not necessarily be identified to species level before import.

4.6. Samples containing the organism may only be collected from animals, plants, or the wider environment, where those plants and animals are not diseased or displaying signs of disease or illness. This includes, but is not limited to; dung, soil, water, gastro-intestinal tract and contents, saliva, non-viable plant material, and animal feed samples.

Organisms outside the scope of the organism description

4.7. The approval is limited to those organisms that fit within the organism description (4.3); for clarity, the following organisms are specifically excluded:

- microorganisms cultured from human clinical samples, or within human clinical samples
- microorganisms that belong to Risk Groups 3 or 4.

4.8. Any organisms that are outside the scope of the organism description may not be imported or cultured under this approval. The Committee noted that because the organisms can be imported within samples, there is the potential for organisms outside the scope of the approval to be inadvertently imported. Therefore the Committee considered that it was appropriate to give the following guidance:

[6] Not contaminated by or associated with any other living organism.

If the approval user becomes aware of the presence of any organisms outside the scope of the application they must notify the EPA and the MPI Inspector within five working days and either:

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

The containment regime

4.9. The Committee has determined the set of controls to be imposed by the EPA, and these are detailed in Appendix 1 of this decision.

4.10. The Committee was satisfied that the controls set out in Appendix 1 establish a containment regime that manages the risk of escape of the new organisms from containment. The Committee was satisfied that 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 the Staff Advice Report.

The potential pathways for escape from containment

4.11. The Committee identified the likely pathways of escape from containment of the new organisms proposed to be imported, and assessed these pathways against the containment regime (including the requirements of the controls in Appendix 1), and the biological characteristics of the organism relating to containment.

4.12. The Committee identified the following potential pathways of escape:

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

4.13. 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 approved organisms (**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**).

4.14. The Committee noted that the controls are outcome based, and that the 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 operating to 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

4.15. The Committee concluded that it is **highly improbable** that the new 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
- containment regime and controls.

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

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

4.18. Section 45(2) 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. 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.

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

5.1. In accordance with s 37 and 44 of the Act and clause 10(e)(f) of the Methodology, 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 a self-sustaining population of the imported microorganisms could establish, if they were to encounter a suitable environmental niche, however this is considered unlikely. Further, they noted that it would be difficult to identify such a population because it would be very similar to the existing micro-flora in the New Zealand environment. Consequently it is unlikely that an undesirable self-sustaining population could be eradicated.

5.3. However 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 21** and **22** (requirements for contingency plans).

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

6.1. The Committee is required by s 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. This assessment is shown in Table 1.

Table 1 Assessment of potentially significant adverse and beneficial effects from the new organisms

Potential effect	Significance	Discussion
Potentially significant **adverse** effect on the environment	Negligible	Adverse effects on the environment are limited by the containment of the organisms. The organisms to be imported are Risk Group 1 and 2 microorganisms, this means that they have the potential to cause disease, but are unlikely to be a serious risk to animals, plants or the wider environment under normal conditions. Any disease caused by these organisms is preventable, treatable, and presents a limited risk of spread. In the **highly improbable** event of escape from containment, the magnitude of any adverse effects of these organisms on animal and plant health would be **minimal.**
Potentially significant **adverse** effect on human health and safety	Negligible	Any disease caused by these organisms is preventable, treatable, and present a limited risk of spread. Therefore the magnitude of any adverse effects would be **minimal**. For adverse effects on the health of the public to occur the organisms would need to escape or be released from containment, and it is **highly improbable** that this will happen. Laboratory personnel working with the organisms may be exposed to the organisms, however this exposure is voluntary and personnel are trained to safely handle microorganisms. Direct exposure will be limited due to the controls and good laboratory practices. Therefore it is **improbable** that adverse effects on health of laboratory personnel will occur.
Potentially significant **adverse** effect on Māori culture and traditions	Negligible	While no direct adverse effects on Māori culture and traditions have been identified in association with this approval, any adverse effects on the environment would also result in adverse effects on valued flora, fauna and other taonga. As noted above, no potentially significant adverse effects on the environment have been identified.

Potential effect	Significance	Discussion
Potentially significant **adverse** effect on the market economy, and society and communities		None identified
Potentially significant **beneficial** effects (on the environment, human health and safety, Māori culture and traditions, the market economy, and society and the community)	Non-negligible	The following potential benefits have been identified: • On-going gains of scientific knowledge from the study of microorganisms, in particular those of importance in agriculture, food production and greenhouse gas emissions. • Establishment of a reference collection of bacterial cultures. • New Zealand scientists can continue to participate in international research programmes. The on-going gains in scientific knowledge and the ability for New Zealand research institutes to participate in international research programmes will be of **minor** to **moderate** benefit to New Zealand, and it is **highly likely** that these benefits will eventuate if this application is approved

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 importing the microorganisms into containment. Therefore the Committee considered that any adverse effects 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.

6.3. After considering the relevant information, the Committee identified beneficial effects including gains in scientific knowledge, and participation in international research programmes. The Committee considered that these beneficial effects would be **non-negligible**.

7. Evaluation and weighing of positive and adverse effects

7.1. The Committee considered that they had sufficient information to weigh the effects of the new organisms in containment.

7.2. The Committee concluded that the potential adverse effects of importing the new organisms into containment were **negligible,** and that the benefits were **non-negligible.**

7.3. 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.

7.4. The Committee took into account all the effects of the new organisms, and all the measures available for risk management, and concluded that it was evident that the positive effects outweigh the adverse effects.

7.5. 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.

7.6. The Committee, having considered all the effects of the new organisms in containment and the effects of any inseparable organisms, and the matters outlined in s 45 of the Act, concluded that:

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

8. Recommendation

8.1. The Committee noted that the scope of the organisms considered in this application was very broad; however they considered that the risks of the organisms were limited by the characteristics of those organisms.

8.2. The Committee noted that the HSNO Act was amended in April 2010 with the addition of s 42C which provides for the rapid assessment of applications to import non-genetically modified new organisms into containment when they meet 'low-risk' criteria specified in regulations made under s 42C(3) of the Act. The Committee consider that it may have been appropriate that this application be considered under the provisions of s 42C of the Act, however this was not possible because no regulations have been made under s 42C(3) of the Act to date.

8.3. The Committee recommend that low-risk regulations for the import of non-genetically modified new organisms be developed under s 42C(3) of the Act, so that the provisions of s 42C can be used in the future.

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 s 40 of the Act.

9.2. The Committee considered that the threshold for approval under s 45 of the Act has been met. It is satisfied that the organisms can be adequately contained and that the beneficial effects of the organisms outweigh the adverse effects of the organisms, taking into account all of the following:

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

9.3. The Committee decided to exercise its discretion and **approve** the import into containment of the organisms listed in Table 2, for laboratory research, under s 45(1)(a) of the Act. The Committee noted that in accordance with s 45(2) of the Act, the approval has been granted subject to the controls specified in Appendix 1.

Signed	**31 July 2013**
Kevin Thompson **Chair, Decision Making Committee** **Environmental Protection Authority**	**Date**

Table 2 New organisms and approval numbers for organisms in application APP201737

Organism	Approval code
Risk Group 1 microorganisms (as cultures or within samples, derived from animals (not humans), plants and the environment, where those plants and animals are not diseased or displaying signs of disease or illness).	**NOC100151**
Risk Group 2 microorganisms (as cultures or within samples, derived from animals (not humans), plants and the environment, where those plants and animals are not diseased or displaying signs of disease or illness).	**NOC100152**

Appendix 1: Controls required by this approval[7]

Any person importing 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 (listed in Table 2) must be contained.

Requirement for accountability for compliance with controls

2. The organisation, entity or person(s) responsible for the ownership, control and management of the containment facility where the approved organisms are held (including Board members and/or directors) must ensure compliance with the controls of this approval.

Requirement to specify how controls will be met

3. Procedures that specify how 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 may 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 organisms 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 organisms.
8. The approved organisms must be identifiable as a new organism and be able to be linked to this HSNO Act approval.

Requirements for notification to the EPA and/or MPI

9. Notification must be given to MPI of any 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 modifications 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.

[7] Compliance with the controls imposed 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 approval of containment facilities by MPI).

Requirements for moving approved organisms

12. The approved organisms 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 organisms 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 organisms, or heritable material from the approved organisms, must be treated to ensure that the approved organisms or any heritable material is killed prior to discarding.

18. Any equipment, that may harbour the approved organisms or heritable material from the approved organisms, must be treated to ensure that the approved organisms 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 organisms.

Requirement for instruction and training

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

Requirements for contingency plans

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

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

Requirements for internal inspections and monitoring

23. To ensure containment is being achieved, containment measures must be:
    a) Inspected, monitored and reviewed 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 and/or implemented as soon as possible.

Interpretation

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

approved organism	New organisms (as described in Table 2) approved under application APP201737
audit	A systematic documented review or examination and evaluation of evidence to determine the extent to which specific criteria are fulfilled.
authorised person	Authorised persons are those identified in the containment facility documentation as being allowed to be in the containment facility or any part thereof.
breach	Escape of organism(s), unauthorised entry to the facility or containment area, and/or the structural integrity of the facility being compromised.
containment	Restricting an organism to a secure location or facility to prevent escape (s 2 of the HSNO Act).
containment facility	A place approved by MPI in accordance with s 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 (s 2 of the HSNO Act).
disposal	(In relation to an approved organism) rendering the organism biologically inactive in such a manner as to prevent the occurrence of any future biological activity, or exporting the organism from New Zealand (s 2 of the HSNO Act).
decontaminate	Kill or remove all approved organisms and heritable material.
documentation	Written or electronic records (including manuals, lists, diagrams, maps, policies, procedures, plans and protocols, records of training, access).

EPA	The Environmental Protection Authority.
heritable material	(In relation to an approved organism) viable biological material, including gametes and spores, arising from that organism that can, without human intervention, regenerate the organism or reproduce a new generation of the same species of the organism (s 2, HSNO Act).
HSNO Act	Hazardous Substances and New Organisms Act 1996.
MPI	Ministry for Primary Industries.
MPI Inspector	A person appointed under the Biosecurity Act to undertake administering and enforcing the provisions of the Biosecurity Act.
maintenance	The process of maintaining (preserving or providing for the preservation of) or continuing a state of good repair.
treat (with reference to waste)	Kill all approved organisms and make heritable material non-viable.
undesirable organism	Organisms such as rodents, insects, and birds within the containment area/facility that could compromise containment (dependent on what organism is being contained).
waste	Unusable or unwanted substances or materials (including water, liquids, solids or air).