Environmental Protection Authority
Te Mana Rauhī Taiao

DECISION

Date	2 March 2015
Application codes	APP201857 (importation of unmodified new organisms) APP201858 (importation of genetically modified organisms)
Application type	To import any new organism in containment under section 40(1) of the Hazardous Substances and New Organisms Act 1996
Applicant	University of Otago
Date applications received	7 November 2014
Consideration date	19 December 2014 – 20 January 2015
Considered by	A decision-making committee of the Environmental Protection Authority (the Committee)[1]: • Kevin Thompson (Chair) • Kerry Laing • John Taylor
Purpose of the applications	To import into containment new organisms for research and teaching purposes.

1. Summary of decision

1.1. Applications to import unmodified and genetically modified (GM) organisms (GMOs) into containment (APP201857 and APP201858, respectively) were lodged under section 40(1) of the Hazardous Substances and New Organisms Act 1996 (the Act).

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

1.3. The Committee **approved** the applications to import the new organisms (as described in Tables 1 and 2) in accordance with section 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 the application under delegated authority in accordance with section 18A of the Act.

2. Application process

Application Receipt

2.1. Applications APP201857 and APP201858 were formally received for processing on 7 November 2014.

Public notification

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

2.3. The applications were not considered to meet the threshold of significant public interest because the new organisms are not novel to New Zealand, and all research and teaching involving the new organisms will be conducted within containment facilities.

Comments from Ministry for Primary Industries and Department of Conservation

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

2.5. MPI expressed general concerns about the adequacy of the Quality Management System the applicant intends to use to meet the proposed containment controls, and questioned the degree of simplification of auditing procedures afforded by the approval of the applications. MPI comments were provided in full to the Committee.

2.6. DOC did not raise any concerns with the applications; rather, they considered the applications to be a pragmatic approach to simplifying the internal and external auditing processes that ensure compliance with containment controls.

2.7. The Committee is satisfied that these comments have been considered in making this decision.

Consideration period

2.8. The consideration of the applications by the Committee commenced on 19 December 2014 and concluded on 20 January 2015.

2.9. During the consideration period, the Committee toured the University of Otago bioscience laboratories that hold new organisms under existing HSNO approvals.

2.10. The Committee also evaluated evidence regarding the presence of *Drosophila melanogaster* in the New Zealand environment, as set out in section 4 of this decision.

Information available for the consideration

2.11. The information available for the consideration comprised;

- the applications and appendices;
- EPA staff advice (provided under section 58(1)(a) of the Act; includes MPI and DOC comments);

- additional relevant information provided by the applicant during the laboratory tours; and
- evidence for the presence of *Drosophila melanogaster* in the New Zealand environment.

2.12. The Committee considered that it had sufficient information to assess the applications.

Legislative criteria for the applications

2.13. Application APP201858 was not considered under section 42B of the Act as some of the proposed modifications did not meet the criteria of the HSNO (Low-Risk Genetic Modification) Regulations 2003. Consequently, the Committee considered both applications in accordance with section 45 of the Act, taking into account the matters specified in sections 37, 39, 44, Schedule 3 (Parts 1 and 2), the relevant matters in Part 2 of the Act, and the Methodology.

3. Purpose of the applications

3.1. Application APP201857 was submitted for the import into containment of unmodified Risk Group 1 and 2 microorganisms (as described in Table 1), unmodified cell lines/cells derived from animals (species within phyla Arthropoda or Chordata) and plants (species within class Angiospermae) and unmodified animals *Drosophila melanogaster*, *Xenopus laevis*, *Odontaster validus* and *Sterechinus neumayeri*, for research and teaching purposes.

3.2. Application APP201858 was submitted for the import into containment of the following GMOs, for research and teaching purposes:

- GM Risk Group 1 and 2 microorganisms (as described in Table 2);
- GM cell lines/cells derived from animals (species within phyla Arthropoda or Chordata, including human cell lines) and plants (species within class Angiospermae);
- GM animals *Mus musculus*, *Rattus norvegicus*, *Rattus rattus*, *Drosophila melanogaster*, *Caenorhabditis elegans*, *Danio rerio*, *Xenopus laevis*; and
- GM plants *Allium cepa*, *Arabidopsis thaliana*, *Brachypodium distachyon*, *Cicer arietinum*, *Lens culinaris*, *Lolium multiflorum*, *Lolium perenne*, *Lotus corniculatus*, *Lotus corniculatus* var. *japonicus*, *Medicago sativa*, *Medicago truncatula*, *Nicotiana benthamiana*, *Nicotiana tabacum*, *Pisum sativum*, *Solanum lycopersicum*, *Trifolium occidentale*, *Trifolium repens*.

3.3. Section 45(1)(a)(i) of the Act requires that the applications be for one of the purposes specified in section 39(1) of the Act.

3.4. The Committee was satisfied the applications are for a valid purpose; such other purposes as the Authority thinks fit, being research and teaching, as provided for in section 39(1)(h) of the Act.

4. Evaluation of evidence regarding new organism status of *Drosophila melanogaster*

4.1. On the commencement of the consideration, the Committee discussed whether or not *Drosophila melanogaster* (common fruit fly, or vinegar fly) is a new organism, and requested further information about the presence of *Drosophila melanogaster* in New Zealand.

4.2. EPA staff subsequently provided the Committee with the following relevant evidence under section 58(1)(b) of the Act:

- A. H. Sturtevant describes examining *Drosophila melanogaster* specimens from New Zealand in a Genetics article published in 1920;
- Henderson and Lambert (1982) describe collecting *Drosophila melanogaster* flies from Auckland in February 1982 for a study that investigated the mate recognition system of *Drosophila melanogaster*;
- Palanca et al (2013) describes trapping *Drosophila melanogaster* in the Auckland area to investigate how yeast isolates effect female *Drosophila melanogaster* attraction to fruit; and
- New Zealand government agencies Landcare Research and MPI (MPI Technical Paper No: 2012/05) have stated that the global distribution of *Drosophila melanogaster* includes New Zealand.

4.3. The Committee evaluated this evidence against the definition of a new organism set out in section 2A(1) of the Act, in particular noting section 2A(1)(a): a new organism is "*an organism belonging to a species that was not present in New Zealand immediately before 29 July 1998"*. The Committee agreed that all other section 2A(1) criteria were not applicable.

4.4. The Committee found that the evidence demonstrates that *Drosophila melanogaster* was present in New Zealand immediately before 29 July 1998. Therefore, the Committee considered that *Drosophila melanogaster* does not meet the definition of new organism as defined in section 2A(1)(a) of the Act, since the organism belongs to a species that was present in New Zealand immediately before 29 July 1998.

4.5. Taking into account all of the available information, the Committee determined that *Drosophila melanogaster* is not a new organism in accordance with section 26 of the Act. Therefore, the Committee decided that a containment approval was not required for unmodified *Drosophila melanogaster*.

5. Adequacy of containment and controls imposed

5.1. Section 45(1)(a)(iii) of the Act requires that the Committee be satisfied that the new organisms (as described in Tables 1 and 2) can be adequately contained. This is one of the criteria to be met before approving the applications.

5.2. To evaluate the adequacy of containment, the Committee assessed the potential for the new organisms to escape from containment taking into account the;

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

5.3. The Committee noted that the applicant has considerable experience in the operation of containment facilities.

Biological characteristics of the new organisms that relate to containment

5.4. The Committee noted that none of the unmodified new organisms (as described in Table 1) are novel as they have previously been assessed and approved under containment provisions of the Act[2]. The Committee also noted that all but two of the host organisms to be developed and imported (plant species *Cicer arietinum* and *Lens culinaris*) have also previously been assessed and defined as low-risk host organisms under the Act[3]. The biological characteristics of low-risk host organisms are such that these organisms have limited ability to escape containment facilities. The Committee concluded *Cicer arietinum* and *Lens culinaris* plant species exhibit biological characteristics that are consistent with low-risk host organisms.

5.5. The Committee noted that the GMOs to be imported will not contain modifications that increase the pathogenicity, virulence or infectivity of the host organism to laboratory personnel, the community or the environment; or modifications that increase the ability of the host organism to escape from containment (as described in Table 2).

The containment regime

5.6. Controls 1-24 (Appendix 1) were proposed by the applicant and imposed by the Committee (with minor amendments)[4] to address containment. These controls address the matters detailed in Schedule 3 (Parts 1 and 2) of the Act. These provisions address;

- 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.

[2] Includes deemed approvals.
[3] Category 1 or 2 host organisms as defined in the HSNO (Low-Risk Genetic Modification) Regulations 2003.
[4] The Committee made minor amendments to wording for clarity, updated the definition of 'disposal' in the accompanying interpretation table and removed 'MPI Inspector' from the interpretation table because the term is not mentioned in the preceding controls.

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

5.8. The Committee noted that each containment facility will be operated in agreement with the applicant's management plan and 'Containment and Quarantine Manual' (as described in paragraphs 48-52 of the EPA staff advice). These living documents constitute the Quality Management System which contains details on how the applicant will meet the controls of this approval. MPI reviews the Quality Management System as part of the approval process of the containment facility.

5.9. The Committee noted MPI's general reservations about the adequacy of the applicant's Quality Management System. However, the Committee was satisfied that the controls set out in Appendix 1 of this decision provides for each of the applicable matters specified in Schedule 3 (Parts 1 and 2) of the Act, and will establish a containment regime that prevents the escape of the new organisms from containment.

Potential pathways of escape of the new organisms from containment

5.10. The following potential pathways of escape were identified and addressed by the imposed 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 (e.g. vermin);
- escape via laboratory personnel;
- escape via failure of the containment regime through inadequate maintenance/upkeep; and
- escape via failure of containment regime following fire or natural disaster.

Escape during transport to/between containment facilities

5.11. Escape during transport to or between containment facilities was identified as a potential pathway for escape. The Committee imposed controls 12-13 to specify requirements for moving the new organisms to or between containment facilities, including maintaining containment and accompanying documentation.

Escape via unauthorised persons being present within the containment facility

5.12. Unauthorised persons were identified as providing a potential pathway of escape as they may deliberately or accidentally remove the new organisms from the containment facility. The Committee imposed controls 14-16 to specify requirements for access to the facility, including the requirements to exclude unauthorised persons, and the identification of entrances.

Escape in waste or on contaminated equipment

5.13. The removal of waste and contaminated equipment from the facility was identified as a potential pathway of escape. The Committee imposed controls 17 and 18 to specify requirements for removing

equipment (including personal protective equipment) and waste from the containment facility to prevent the escape of the new organisms. The Committee noted that when waste is treated off-site (to kill any approved organism or heritable material), the new organisms must be contained during transport to the treatment location.

Escape due to the presence of undesirable organisms in the facility

5.14. The presence of undesirable organisms, such as vermin, was identified as a possible pathway of escape. The Committee imposed control 19 to require the containment facility to be secured and monitored to ensure the exclusion of undesirable organisms that might compromise the containment of the new organisms.

Escape via laboratory personnel

5.15. Accidental/unintentional removal of the new organisms by laboratory personnel was identified as a potential pathway of escape. The Committee imposed control 7 to require persons entering and exiting the containment facility to do so in a way that does not compromise containment. The Committee imposed control 20 to require that any person entering the containment facility has sufficient training on the containment regime that they are able to meet their responsibilities.

Escape via inadequate maintenance or failure of containment measures

5.16. Escape as a result of failure of the containment regime through inadequate maintenance of the regime was identified as a potential pathway of escape. The Committee imposed control 6 to require the containment facility to be designed, constructed and maintained to prevent the new organisms from escaping. The Committee imposed control 23 to require the containment measures to be inspected, monitored and reviewed to ensure that containment is being achieved. Control 23 also requires that containment measures be inspected as soon as possible after any event that could compromise containment.

Escape via failure of containment regime following fire or natural disaster

5.17. 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. The Committee imposed control 23 to require the containment facility to be inspected as soon as possible after any event that could compromise containment – including fire, acts of God (such as flood, earthquake, tornado), or attempts to break into the facility.

Conclusion on adequacy of the containment regime

5.18. The Committee concluded that it was highly improbable that the new organisms could escape from containment, taking into account the;

- biological characteristics of the new organisms that relate to containment;
- containment controls; and

- potential pathways of escape of the new organisms from the containment facilities.

5.19. Therefore, the Committee concluded that the new organisms 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 (Parts 1 and 2) of the Act (as required under section 45(2) of the Act).

5.20. While 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 additional controls were required to achieve the purpose of the Act.

6. Effects of the organism and any inseparable organism

6.1. The Committee is required by section 45(1)(a)(ii) of the Act 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.

Effects of any inseparable organism

6.2. The Committee did not identify any inseparable organisms.

The ability to establish an undesirable self-sustaining population and the ease of eradication

6.3. Section 37 the Act requires the Committee to have regard to the ability of the new organisms to establish an undesirable self-sustaining population and the ease with which the new organisms could be eradicated if a population was established.

6.4. The Committee recognised that the new organisms have differing potentials to form self-sustaining populations in the New Zealand environment. However, the potential for these new organisms to escape from containment and then form undesirable self-sustaining populations is limited by the containment regime.

6.5. The Committee noted that controls 21 and 22 require contingency plans be documented for all approved organisms, and the implementation of those plans in the event of a breach of containment.

6.6. The Committee considered that in the highly improbable event of escape, a self-sustaining population of unmodified Risk Group 1 and 2 microorganisms could establish if they were to encounter a suitable environmental niche; however, this is considered unlikely as many of the microorganisms will be laboratory-adapted strains. The Committee 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 of unmodified Risk Group 1 and 2 microorganisms could be eradicated.

6.7. The Committee noted that GM microorganisms that have a greater ability to escape from containment than the unmodified host organism will not be imported under application APP201858. Further, the

Committee also noted that modifications that result in GM Risk Group 2 microorganisms gaining resistance to antibiotics used for clinical, veterinary, agricultural or horticultural treatment of infections caused by the host organism will not be imported. This means that should GM Risk Group 2 microorganisms escape containment, isolated populations (i.e. infections) are potentially eradicable with treatment. However, in the event that an undesirable self-sustaining population of GM microorganisms did establish, it may be difficult to eradicate such a microbial population.

6.8. The Committee recognised that unmodified and GM cell lines/cells rely on specific laboratory culture conditions for survival. Accordingly, the Committee considered that in the highly unlikely event of cells escaping containment, it is extremely unlikely the cells will survive and establish self-sustaining populations.

6.9. The Committee noted that unmodified aquatic animal species *Odontaster validus* and *Sterechinus neumayeri* are native to polar areas, and the natural aquatic environment of *Xenopus laevis* ranges between 16 – 26°C[5]. Therefore, in the highly unlikely event that these organisms were to escape containment, it is highly unlikely that they would encounter a suitable aquatic environment that would support self-sustaining populations.

6.10. The Committee noted that many of the GM animals to be imported are highly inbred strains and are poorly adapted to survival without human intervention. Accordingly, escaped GM animal strains are unlikely to survive outside of a containment facility, and even less likely to establish a self-sustaining population in the New Zealand environment. However, in the highly unlikely event that a GM animal did escape and subsequently form a self-sustaining population, the animals could be identified using molecular diagnostic techniques and eradicated using focused searches, insecticides, baits, or traps.

6.11. In the event that a self-sustaining population of GM plants did establish, the GM plants could be identified using molecular diagnostic techniques and eradicated using herbicides or manual destruction.

Assessment of adverse effects

6.12. The Committee considered the potential adverse effects of the new organisms 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.

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

[5] Low elevation streams and rivers in New Zealand typically fluctuate within a 10 – 20°C temperature range (APP201982).

Effects on the environment

6.14. The Committee considered the information provided on potential effects on the environment, and noted that all research involving the new organisms will be conducted in containment facilities with a Quality Management System which contains details on how the imposed controls (Appendix 1) will be met.

6.15. The Committee noted that the unmodified new organisms to be considered in application APP201857 (microorganisms, cell lines/cells and animals) do not pose a serious risk to the environment if they escape because of their limited ability to survive outside of a laboratory. The Committee also noted that the inadvertent import of higher risk group microorganisms will be limited by restricting importation to samples derived from apparently healthy animals (not humans) and plants, and environments with no recent reports of plant or animal disease.

6.16. The Committee noted that modifications that increase the pathogenicity, virulence or infectivity of the host organism to laboratory personnel, the community or the environment, and modifications that increase the ability of the host organism to escape from containment, are excluded.

6.17. The Committee noted that for any adverse effects on the environment to occur, the new organisms 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.

6.18. 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 import into containment of the new organisms.

Effects on human health and safety

6.19. The Committee noted that as the new organisms to be imported do not under normal circumstances infect or cause disease in humans, they are unlikely to pose a serious risk to laboratory personnel or the wider community.

6.20. The Committee acknowledged that laboratory personnel working with the new organisms are at risk of allergic or toxic reactions to the organisms, or injuries caused by the organisms (bites, cuts from claws etc.); however, personnel will be trained to safely handle the new organisms, and direct exposure will be limited by the controls proposed, personal protective equipment and good laboratory practices. Furthermore, all manipulations that involve Risk Group 2 microorganisms that are likely to form aerosols, or Risk Group 1 and 2 microorganisms that form spores will be performed in Biological Safety Cabinets.

6.21. The Committee recognised that unintended exposure to microorganisms of a higher risk grouping (i.e. zoonotic diseases), and cell lines that contain increased risk factors (i.e. infectious particles) introduces additional risk to laboratory personnel. However, these risks will be limited by;

- restricting importation to samples from apparently healthy animals (as described in paragraph 6.15);
- performing all open container manipulations of animal, plant or environmental samples that contain unidentified mixed cultures or microorganisms within a Class II Biological Safety Cabinet, sealed glove box or anaerobic hood; and
- restricting importation of established animal and human cell lines to cell lines from commercial sources or reputable scientific laboratories, only.

6.22. Further, the Committee considered it was highly improbable that adverse effects on human health will occur taking into account the imposed controls.

6.23. 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 import into containment of the new organisms.

Effects on Māori and their culture and traditions and the principles of the Treaty of Waitangi (Te Tiriti o Waitangi)

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

6.25. The University of Otago consulted with the Ngāi Tahu iwi representative on their delegated Institutional Biological Safety Committee (IBSC) with regard to using these applications. No concerns about the use of the applications on the University's Dunedin and Christchurch campuses were raised.

6.26. Further, the Committee recognised that dialogue between the approval user and Ngāi Tahu will endure for the life of this approval as a Ngāi Tahu iwi representative will form part of the IBSC Committee that will govern and administer this approval. The Committee also noted that the applicant has declared to undertake further Māori consultation before this approval is used at the University's Wellington campus.

6.27. The Committee considered that the new organisms 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, waahi 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 organisms, and considered the likelihood of escape as highly unlikely.

6.28. 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, waahi tapu, valued flora and fauna, and other taonga from the import into containment of the new organisms.

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

Effects on the market economy and society and community

6.30. The Committee took into account the effects of the new organisms on the market economy and society and community. The Committee noted that the new organisms will be held in containment facilities with a Quality Management System which details how the imposed controls (Appendix 1) will be met.

6.31. The Committee noted that none of the unmodified new organisms (as described in Table 1) are novel as they have previously been assessed under the Act, and that all but two of the host organisms to be developed and imported have also previously been assessed and defined as low-risk host organisms under the Act (plant species *Cicer arietinum* and *Lens culinaris* are present in New Zealand, and so unmodified plants of these species are not new organisms).

6.32. Therefore, the Committee concluded that the new organisms under this approval (as described in Tables 1 and 2) are not expected to cause greater potential adverse effects on the market economy or society and communities than the organisms currently held in containment facilities under other HSNO approvals (including the approvals described in Appendix 4 of the EPA staff advice).For any adverse effects on the market economy or society or communities to occur, the new organisms would first need to escape or be released from containment. The Committee considered that it was highly improbable that such an adverse effect may occur taking into account the imposed controls.

6.33. After assessing all the information, the Committee did not identify any non-negligible adverse effects on the market economy or society and communities from the new organisms in containment.

Conclusion on assessment of adverse effects

6.34. After considering the information provided, the Committee did not identify any non-negligible adverse effects of the importation into containment of the new organisms. Therefore the Committee considered that any adverse effects would be negligible.

6.35. Since the Committee did not identify any non-negligible adverse effects from the import into containment of the new organisms, the Committee was not required to take into account the probability of occurrence or magnitude of any adverse effects.

Assessment of beneficial effects

6.36. 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 import into containment of the new organisms.

6.37. The Committee identified the following potential beneficial effects of importing the new organisms into containment under the broad purpose of research and teaching, and one consistent set of containment controls:

- increased understanding in many areas of biology, including, but not limited to, genetics and molecular biology, microbiology, biochemistry, cancer research, human disease research, physiology, immunology, medicine, dentistry, and plant and animal science; and
- simplification of internal and external auditing processes that ensure compliance with containment controls.

6.38. The Committee noted MPI's reservations about the degree of simplification afforded by this approval as MPI considers a substantive amount of work is still needed before the applicant has a robust Quality Management System that meets the requirements of the imposed controls (Appendix 1). However, the Committee considered that the simplification of auditing procedures under one broad purpose (research and teaching) and one consistent set of containment controls is likely to be realised by this approval, which will provide the University of Otago with more time to continually improve the Quality Management System described in paragraphs 48-52 of the EPA staff advice, and to raise awareness of biosafety and containment controls within the University's research faculty. The latter focus will strengthen the University's biosafety culture and compliance with containment controls, which will result in significant environmental benefits by reducing the risk of unintentional non-compliance and escape from containment.

6.39. The Committee considered that ongoing gains in scientific knowledge of in many areas of biology and increased awareness of biosafety and containment controls within the applicant's research faculty will be of moderate benefit to New Zealand. The Committee noted that the applicant has a proven track record for producing quality scientific research and containment systems, and considered that it was highly likely that these benefits would eventuate. Therefore these beneficial effects were considered to be non-negligible.

Conclusion on assessment of beneficial effects

6.40. After considering the information provided, the Committee considered that the beneficial effects would be non-negligible.

7. Overall evaluation and weighing of beneficial and adverse effects

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

7.2. Overall, the Committee did not identify any non-negligible adverse effects from the import into containment of the new organisms.

7.3. 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.

7.4. The Committee concluded that the beneficial effects accruing from the import into containment of the new organisms were non-negligible.

7.5. Therefore, the Committee considered the beneficial effects of the import into containment of the new organisms outweighed the adverse effects.

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

7.7. The Committee, having considered all the effects of the new organisms and the matters outlined in section 45 of the Act, concluded that;

a) the applications were for one of the purposes specified in section 39(1);

b) the approved organisms could be adequately contained; and

c) the beneficial effects of importing the new organisms into containment outweighed the adverse effects of the approved organisms.

8. Achieving the purpose of the Act

8.1. 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).

8.2. In order to achieve the purpose of the Act, when considering these applications the Committee recognised and provided for the following principles (section 5 of the Act);

a) the safeguarding of the life-supporting capacity of air, water, soil and ecosystems; and

b) 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.

8.3. The Committee took into account the following matters when considering these applications in order to achieve the purpose of the Act (sections 6, 7 and 8 of the Act), and the Committee did not identify any such risk, cost, benefit or other impact;

- the safeguarding of the life-supporting capacity of air, water, soil, and ecosystems;
- 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, waahi tapu, valued flora and fauna, and other taonga;
- the economic and related benefits and costs of using the new organisms;
- 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).

8.4. The Committee was satisfied that this approval is consistent with the purpose of the Act and the above principles and matters under the Act and the Methodology. Any substantive issues arising from the legislative criteria have been discussed in the preceding sections of this approval.

9. Associated approvals

9.1. 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).

10. Decision

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

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

- all the effects of the new organisms;
- the matters in section 39, 44, 45, and Schedule 3 (Parts 1 and 2) of the Act;
- the relevant matters in Part 2 of the Act; and
- the Methodology.

10.3. The Committee decided to exercise its discretion and approve the importation into containment of the new organisms described in Tables 1 and 2 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 (Appendix 1).

Environmental Protection Authority
Te Mana Rauhī Taiao

Kevin Thompson **Chair, Decision Making Committee** **Environmental Protection Authority**	**Date 2/03/2015**

References

A.H. Sturtevant. Genetic studies on *Drosophila simulans*. I. Introduction. Hybrids with *Drosophila melanogaster*. Genetics 5:488 (1920).

N.R. Henderson and D.M. Lambert. No significant deviation from random mating of worldwide populations of Drosophila melanogaster. Nature 300:437-440 (1982).

L. Palanca, A.C. Gaskett, C.S. Günther, R.D. Newcomb, M.R. Goddard. Quantifying Variation in the Ability of Yeasts to Attract Drosophila melanogaster. PLOS 8(9):e75332 (2013).

The Taxonomic list of bugs. Landcare Research. Webpage: http://www.landcareresearch.co.nz/resources/identification/animals/bug-id/taxonomic-list-of-bugs/diptera/vinegar-flies. Accessed January 2015.

Pest Risk Assessment: Drosophila suzukii: spotted wing drosophila (Diptera: Drosophilidae) on fresh fruit from the USA. MPI Technical Paper No: 2012/05.

New organisms approved to be imported

Table 1: Unmodified new organisms approved to be imported:

Organism	Approval number
Risk Group 1 microorganisms (including Bacteria, Archaea, Viruses, Bacteriophages, Micro-eukaryotes, Algae, Fungi, Yeasts, phytoplankton, zooplankton, protozoa and micro-invertebrates) that are unlikely to cause disease in humans, plants, or animals. Microorganisms will imported as either axenic or mixed cultures, or within samples[6] derived from apparently healthy animals (not humans) and plants, and environments with no recent reports of plant and animal disease.	NOC100168
Risk Group 2 micro-organisms (including Bacteria, Archaea, Viruses, Bacteriophages, Micro-eukaryotes, Algae, Fungi, Yeasts, phytoplankton, zooplankton, protozoa and micro-invertebrates) that may cause disease in humans, plants, or animals, but are unlikely to be a serious hazard to laboratory workers, the community, animals, or the environment; for which there are effective treatment and preventative measures with respect to any infections that may be caused, and which present a limited risk of the spread of infection. Microorganisms will imported as either axenic or mixed cultures, or within samples[6] derived from apparently healthy animals (not humans) and plants, and environments with no recent reports of plant and animal disease.	NOC100169
Plant cells, including protoplasts, cultured cells, and tissue. Taxonomic level: Angiospermae	NOC100170
Animal cell lines (including immortalized and primary cell lines) from organisms within the Kingdom Animalia, Phylum Arthropoda, or Phylum Chordata.	NOC100171
Xenopus laevis Daudin 1802. Common name: African clawed frog.	NOC100172
Odontaster validus Koehler, 1906. Common name: Red cushion starfish.	NOC100173
Sterechinus neumayeri (Meissner, 1900). Common name: Antarctic sea urchin.	NOC100174

[6] Samples derived from animals, plants and the environment includes: dung, guano, saliva, blood, serum, gastro-intestinal tract and contents, tissue, hair, feathers, bone, soil, sediment, water, non-viable plant material.

Table 2: Genetically modified new organisms approved to be imported:

Host organism	Modifications	Approval numbers
Risk Group 1 microorganisms[7] (including Bacteria, Archaea, Viruses, Bacteriophages, Micro-eukaryotes, Algae, Fungi, Yeasts, Phytoplankton, Zooplankton, Protozoa and Micro-invertebrates) that are unlikely to cause disease in humans, plants, or animals.	Modifications may include: • the introduction, deletion or modification of nucleic acids (DNA or RNA); • deletions and point mutations with or without the addition of genetic material; • the introduction of wild-type genes and mutants thereof (including deletion, substitution, and chimaeric mutant genes); and • the expression of multiple transgenes. Modifications may be made using: • plasmid or bacteriophage-based cloning, binary, and protein expression vectors; • genome editing technologies; • purified nucleic acids with or without an origin of replication that functions in the host organism; • viral or transposon-based vectors, including replication-defective viral vectors such as lentiviral vectors, adenoviral vectors, and adeno-associated viral (AAV) vectors; and • replicative viral vectors (including baculovirus-based vectors). Vectors may contain regulatory elements including promoters, regulatory element binding sites, transcriptional activators, enhancers, terminators, multiple cloning sites, site directed recombination sequences, T-DNA border sequences; silencing elements (short interfering RNA, short hairpin RNA); and origins of replication. The vectors may also contain selectable marker genes; reporter genes; antibiotic resistance genes; transposons, recombination sequences and recombinases; retrotransposons or other transposable elements; protein targeting, localisation and secretory signals; internal ribosomal entry sites (IRES) solubility enhancement tags; protein purification tags, and affinity tags including epitope tags. Donor genetic material may consist of non-coding nucleic acids and/or nucleic acids that code for genes; gene regulatory elements; transposons, retrotransposons or other transposable elements; reporters or selectable markers. Donor genetic material may be sourced from plant, animal (including protozoa, zooplankton and phytoplankton), human,	GMC100216
Plant cells, including protoplasts, cultured cells, and tissue. Taxonomic level: Angiospermae		GMC100218
Risk Group 2 microorganisms[7] (including Bacteria, Archaea, Viruses, Bacteriophages, Micro-eukaryotes, Algae, Fungi, Yeasts, Phytoplankton, Zooplankton, Protozoa and Micro-invertebrates) that may cause disease in humans, plants, or animals, but are unlikely to be a serious hazard to laboratory workers, the community, animals, or the environment; for which there are effective treatment and preventative measures with respect to any infections that may be caused, and which present a limited risk of the spread of infection.		GMC100219
Mus musculus Linnaeus 1758. Common name: Mouse.		GMC100220
Rattus norvegicus Berkenhout 1759. Common names: Brown rat, Norway rat, laboratory rat.		GMC100221
Rattus rattus Linnaeus 1758. Common name: Black rat.		GMC100222
Drosophila melanogaster Macquart 1843 (syn. *Sophophora melanogaster*). Common names: fruit fly, vinegar fly.		GMC100223
Caenorhabditis elegans Maupas 1900. Common name: roundworm.		GMC100224

[7] Defined to *Genus species* taxonomic classification; and family, class, order and division taxonomic categories (as appropriate).

Host organism	Modifications	Approval numbers
Danio rerio Hamilton-Buchanan 1822. Common name: zebrafish.	insect, bacterial, archaeal, fungal (including yeasts), viral, or synthetic sources. The modifications will not include: • the production of infectious particles normally able to cause disease in humans, animals, plants, or fungi; • genes that encode for vertebrate toxins with an LD_{50} < 100 µg/kg; • genetic material derived from Māori; • genetic material derived from New Zealand native or taonga flora and fauna, unless consultation has been conducted with Ngāi Tahu representatives and, if appropriate, other iwi; • genetic material from species listed by the Convention on International Trade in Endangered Species (CITES) unless appropriate permission has been gained; • **modifications that increase the pathogenicity, virulence, or infectivity of the host organism to laboratory personnel, the community, or the environment**; or • **modifications that result in the GMO having a greater ability to escape from containment than the unmodified host organism**. In addition: **Modifications to Risk Group 1 microorganisms** will not include: • uncharacterised sequences from pathogenic microorganisms; or • modifications that result in a genetically modified microorganism that is more pathogenic, virulent, or infectious than a Risk Group 2 host organism. **Modifications to Risk Group 2 microorganisms** will only include nucleic acid that is sourced from Risk Group 1 microorganisms, or that is characterised to the extent that: (i) its sequence is known; and (ii) its gene function is understood; and (iii) its potential gene products are understood. Modified Risk Group 2 microorganisms will not include: • uncharacterised sequences from pathogenic microorganisms; • developments involving viral vectors whose host range includes human cells and that contain one or more inserted nucleic acid sequences coding for a product that can lead to	GMC100225
Xenopus laevis Daudin 1802. Common name: African clawed frog.		GMC100226
Animal cell lines (including immortalized and primary cell lines) from organisms within the Kingdom Animalia, Phylum Arthropoda, and Phylum Chordata. Animal cell lines may include induced pluripotent stem cell lines and embryonic stem cell lines.		GMC100227
Human cell lines (including immortalized and primary cell lines). Human cell lines may include induced pluripotent stem cells, but not human embryonic stem cell lines.		GMC100228
Allium cepa L. 1753. Common name: Onion.		GMC100229
Arabidopsis thaliana (L.) Heynh. Common names: Mouse-ear cress, thale cress, Arabidopsis.		GMC100230
Brachypodium distachyon L. Common name: purple false brome.		GMC100231
Cicer arietinum L. Common name: Chickpea.		GMC100232
Lens culinaris Medik. Common name: Lentil.		GMC100233
Lolium multiflorum Lam. Common names: Italian ryegrass, annual ryegrass.		GMC100234

Host organism	Modifications	Approval numbers
Lolium perenne L. Common names: perennial ryegrass or English ryegrass or winter ryegrass.	uncontrolled mammalian cell proliferation or be toxic to mammalian cells, or both; or • a pathogenic microorganism where the genetic modification results in resistance to antibiotics used for clinical, veterinary, agricultural, or horticultural treatment of infections caused by that microorganism. **Modifications to animals** will only include nucleic acid that is characterised to the extent that: (i) its sequence is known; and (ii) its gene function is understood; and (iii) its potential gene products are understood; and Modifications to animals may include the creation of genetically modified animals with new genotypes by the crossing of two genetically modified animals of different genotypes including different genetic modifications. In all cases, crossed animals will belong to the same species. Importation of animals arising from interspecific crosses is excluded under this approval. Modifications to animals will not include: • uncharacterised sequences from pathogenic microorganisms; • developments involving viral vectors with a host range that includes human cells and that contain one or more inserted nucleic acid sequences coding for a product that can lead to uncontrolled mammalian cell proliferation or be toxic to mammalian cells, or both; or • a pathogenic microorganism where the genetic modification results in resistance to antibiotics used for clinical, veterinary, agricultural, or horticultural treatment of infections caused by that microorganism. **Modifications to plants and plant cells** may include the insertion of sequences derived from microorganisms capable of causing disease in plants; including promoters from Cauliflower Mosaic Virus, and border and regulatory sequences from *Agrobacterium tumefaciens* or *Agrobacterium rhizogenes* (i.e. left and right border sequences required for the transfer of DNA into plant cells; promoters and three-prime non-coding sequences derived from Ti or Ri plasmid genes). In each case the genetic material will be well characterized and is not expected to increase the pathogenicity of the modified organism. Propagation of genetically modified whole plants by cloning or by generation from cultured plant cells or tissue culture is permitted only if the plant species are named as whole plants approved for genetic modification in this application. Modifications to plants and plant cells will not include: • uncharacterised sequences from pathogenic microorganisms;	GMC100235
Lotus corniculatus L. 1753 Common name: birdsfoot trefoil.		GMC100236
Lotus corniculatus var. *japonicus* Regel 1864. Common name: Lotus japonicus.		GMC100237
Medicago sativa L. 1753. Common names: lucerne, alfalfa.		GMC100238
Medicago truncatula Gaertn. 1791. Common name: Barrel medic.		GMC100239
Nicotiana benthamiana Domin. 1929.		GMC100240
Nicotiana tabacum L. 1753. Common name: Tobacco.		GMC100241
Solanum lycopersicum L. 1753. Common name: Tomato.		GMC100242
Trifolium occidentale D. E. Coombe 1961. Common name: Western Clover.		GMC100243
Trifolium repens L. Common name: White Clover.		GMC100244

Host organism	Modifications	Approval numbers
	• those that lead to the shedding of virus, virions, viroids, or prions; or • those that confer improved survival characteristics outside of the laboratory compared to the unmodified host organism. **Modifications to plant cells** will only include well characterised genetic material. Modifications to plants cells will not include uncharacterised sequences from pathogenic microorganisms. **Modified animal and human cell lines** to be imported will be established cell lines obtained from commercial sources or from reputable scientific laboratories, or will be primary cell lines developed with appropriate ethical approval in the country of origin. Cell lines may include embryonic stem cell and induced pluripotent stem cell lines of animal species and induced pluripotent stem cell lines derived from humans, but will not include embryonic stem cell lines derived from humans. Modifications to animal and human cell lines will not include: • uncharacterised sequences from pathogenic microorganisms; or • developments involving viral vectors with a host range that includes human cells and that contain one or more inserted nucleic acid sequences coding for a product that can lead to uncontrolled mammalian cell proliferation or be toxic to mammalian cells, or both.	

Appendix 1: Controls required by this approval[8]

Any person importing and/or developing the approved organisms 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 facility under their control.

Requirement for the containment of approved organisms

1. The approved organism(s) (as described in Tables 1 and 2) 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 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.

[8] Compliance with the controls imposed under this approval 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).

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, 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
    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

25. In these controls, unless otherwise specified below, a word has the same meaning as it is defined in the HSNO Act (if any).

26. Unless the context otherwise requires:

Term	Definition
approved organism(s)	New organisms approved for importation into containment under applications APP201857 and APP201858 (as described in Tables 1 and 2) for research and teaching purposes.
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).
HSNO Act	Hazardous Substances and New Organisms Act 1996.
MPI	Ministry for Primary Industries.
new organism	Defined by section 2A of the HSNO Act (a) an organism belonging to a species that was not present in New Zealand immediately before 29 July 1998 (b) an organism belonging to a species, subspecies, infra-subspecies, variety, strain, or cultivar prescribed as a risk species, where that organism was not present in New Zealand at the time of promulgation of the relevant regulation (c) an organism for which a containment approval has been given (ca) an organism for which a conditional release approval has been given under the HSNO Act (cb) a qualifying organism approved for release with controls (d) a genetically modified organism (e) an organism that belongs to a species, subspecies, infra-subspecies, variety, strain, or cultivar that has been eradicated from New Zealand.
organism	Defined in section 2 of the HSNO Act: (a) Does not include a human being (ab) Includes a human cell

	(b) Includes a micro-organism (c) Includes a genetic structure, other than a human cell, that is capable of replicating itself, whether that structure comprises all or only part of an entity, and whether it comprises all or only part of the total genetic structure of an entity (d) Includes an entity (other than a human being) declare to be an organism for the purposes of the Biosecurity Act 1993 (e) Includes a reproductive cell or developmental stage of an organism.
treat (with reference to waste)	Kill all approved organisms and make heritable material non-viable.
undesirable organism	Organisms such as rodents, insects, and birds within the containment facility that could compromise containment (dependent on what organism is being contained).
waste	Unusable or unwanted substances or materials (including water, liquids, solids or air).