ENVIRONMENTAL RISK MANAGEMENT AUTHORITY DECISION

Amended under s67A on 17 October 2012

18 June 2010

Application code:	ERMA200432
Application category:	Import into Containment any New Organism under section 40(1) of the Hazardous Substances and New Organisms (HSNO) Act 1996.
Applicant:	Institute of Environmental Science and Research Limited (ESR)
Purpose:	To import and hold in containment Risk Group 2 bacteria for laboratory based research and teaching purposes in order to develop and use diagnostic methods for diseases
Date application received:	24 May 2010
Consideration date:	18 June 2010
Considered by:	A Committee of the Environmental Risk Management Authority (the Authority)

1 Summary of Decision

1.1 Application ERMA200432 to import into containment bacterial species belonging to Risk Group 2[1] is **approved, with controls** (as detailed in Appendix 1 of this decision), having been considered in accordance with the relevant provisions of the Hazardous Substances and New Organisms (HSNO) Act 1996 (the Act) and the HSNO (Methodology) Order 1998 (the Methodology).

2 Legislative Criteria

2.1 The application was lodged pursuant to section 40(1) of the Act. The application was determined in accordance with section 45, taking into account the matters specified in section 44 and 37 and other matters relevant to the purpose of the Act, as specified in Part II of the Act. Unless otherwise stated, references to section numbers in this decision refer to sections of the Act.

2.2 Consideration of the application followed the relevant provisions of the Methodology, as specified in more detail below. Unless otherwise stated, references to clause numbers in this decision refer to clauses of the Methodology.

[1] As defined in the Australia/New Zealand Standard 2243.3:2002: Safety in Laboratories Part 3: Microbiological aspects and containment facilities, fifth edition, or any equivalent subsequent editions.

3 Application Process

Application Receipt

3.1 Application ERMA200432 was formally received on 24 May 2010.

Notification

3.2 Under section 53(2) of the Act the Authority has discretion to publicly notify an application to import into containment any new organism, if it considers that there is likely to be significant public interest in the application. In this case, the application was not publicly notified (following ERMA New Zealand guidelines) because the importation into containment of these Risk Group 2 microorganisms is not expected to be of significant public interest, nor is it likely that public notification would result in additional information relevant to the consideration of this application.

3.3 In accordance with section 58(1)(c) of the Act and clauses 2(2)(e) and 5 of the Methodology, the Ministry of Agriculture and Forestry (MAF) Biosecurity New Zealand, Department of Conservation (DOC), and the Ministry of Health (MoH) were notified and provided with an opportunity to comment on the ERMA200432 application. No issues were raised by the DOC, MAF and MoH.

Decision Making Committee

3.4 The application was considered by a decision making Committee of the Authority appointed in accordance with section 19(2)(b) of the Act. The Committee comprised the following members: Max Suckling (Chair) and Kieran Elborough.

Information Available for Consideration

3.5 The information available for the consideration of the application by the Committee included:

- Application ERMA200432 (Form NO2N) prepared by the applicant.
- A memorandum from the Agency to assist and support the Committee's decision making.

3.6 Recognised techniques were used in identifying, assessing, and evaluating the relevant information, as required under clause 24 of the Methodology. Techniques for identifying and preparing information on risks, costs and benefits were based on procedures specified in the ERMA New Zealand Technical Guides.

4 Sequence of the Consideration

4.1 In accordance with clause 24 of the Methodology, the approach to the consideration adopted by the Committee was first to examine the scope and purpose of the application, and the organisms applied for, then to look sequentially at identification, assessment and evaluation of risks, costs and benefits. Those risks identified as potentially significant were assessed in accordance with clause 12 of the Methodology. Costs and benefits were assessed in accordance with clause 13 of the

Methodology. Qualitative scales were used by the Committee to measure likelihood and magnitude of risks, costs and benefits.

4.2 Interposed with the assessment of risks, costs and benefits was the consideration of the adequacy of the proposed containment regime, and the ability of the organisms to escape and establish self-sustaining populations (as required by sections 37 and 44 and clause 10(e)). Management techniques were considered in relation to the identified risks. The containment regime was considered in the context of a risk management regime for controlling the identified risks and costs (clauses 12(d) and 24). In doing so, the Committee considered the matters in the Third Schedule (Part 2) of the Act in particular, imposing controls to limit the likelihood of any accidental release of any organism or any viable genetic material, to exclude unauthorised people from the facility, to control the effects of any accidental release or escape of an organism and to specify inspection and monitoring requirements for containment facilities. The Committee set controls to satisfactorily address these matters and additional controls were considered in relation to residual risks that required further consideration.

4.3 Benefits associated with this application were considered in accordance with clauses 9, 10, 13 and 14 of the Methodology and section 6(e) of the Act.

4.4 Finally, taking account of the risk characteristics established in accordance with clause 33 of the Methodology, the combined impact of risks, costs and benefits was evaluated in accordance with clause 34. The approach to the consideration follows the decision path outlined in the memorandum from the Agency.

5 Purpose of the Application

5.1 The purpose of this application from the Institute of Environmental Science and Research Limited (ESR) is to import and hold in containment Risk Group 2 bacteria for laboratory based research and teaching purposes in order to develop and use diagnostic methods for diseases (Appendix 1, Control 2). For example, developing diagnostic tests for food borne bacterial pathogens such as *Campylobacter* spp.

5.2 Risk Group 2 organisms are defined by AS/NZS 2243.3:2002 as pathogens that can cause human, plant or animal disease, but are 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.

5.3 The types of experiments that will be conducted include teaching and research into diagnostics (eg, morphological identifications, and biochemical, serological, molecular and animal exposure testing), systematics and taxonomy.

5.4 In accordance with section 45(1)(a)(i) of the Act, the Committee determined that this application was for two valid purposes within the scope of section 39 of the Act:

- section 39(1)(g): *maintaining new organisms in containment for diagnostic purposes*; and
- section 39(1)(h): *such other purposes as the Authority thinks fit*.

5.5 The Committee consider that Risk Group 2 bacterial species may be imported into containment for either one or both of these purposes.

6 Adequacy of Containment Regime

6.1 In carrying out its consideration, the Committee considered the adequacy of containment in accordance with section 45(1)(a)(iii) of the Act, and, the magnitude and likelihood of the risks, costs and benefits alongside each other and in an integrated fashion. This is because the magnitude interacts with the likelihood as recognised in clause 12(d) of the Methodology and in section 45(1)(a)(ii) of the Act.

Ability to adequately contain the organisms

6.2 In considering the adequacy of the containment regime and the ability of the organisms to escape from containment, the Committee considered the following:

i. the biological characteristics of the organisms;
ii. the containment regime; and
iii. the potential pathways for escape of the organisms from the containment facility.

i Biological characteristics of the organism

6.3 The kingdom Bacteria represents a large number of genetically diverse organisms that occupy a wide range of environmental niches, utilise various organic compounds for energy, have many structural forms and reproduce in many ways. All bacteria are prokaryotes, that is, they have no true nucleus or membrane bound organelles. They reproduce through binary fission in which cells are 'pinched off' forming clones.

6.4 Risk Group 2 bacteria will be imported as pure isolates or defined mixtures of pure cultures[2] and will be sourced from either recognised culture collections or experts in the field (including laboratories). Where possible, the bacteria will be identified to species level prior to importation. In some instances isolates may require testing and examination in New Zealand to determine their taxonomic identity.

6.5 It is likely that many of the organisms to be imported are established within animals or humans in the New Zealand population, however as this group of organisms is not always well documented or identified, an application has been made under the HSNO Act.

6.6 This approval covers a wide range of bacterial microorganisms. The Committee considered that it was possible to do a risk assessment of this range of microorganisms due to the biological characteristics of the Risk Group 2 bacteria and that the requirement that they meet the Australia/New Zealand Standard 2243.3:2002: Safety in Laboratories Part 3: Microbiological aspects and containment facilities, fifth edition, or any equivalent subsequent edition's definition of Risk Group 2 microorganisms.

[2] Pure isolates or defined mixtures of pure cultures will be imported as frozen or lyophilised liquid cultures, culture supernatants; bacteria growing on agar slopes, or sterile solid and liquid matrices.

6.7 In the event that a microorganism imported under this approval turns out not to meet the definition of a Risk Group 2 microorganism (this could occur due to new information or misidentification), users of this approval must cease work and inform both MAF and ERMA New Zealand (control 15). In support of this, control 6 requires that users of this approval record the name of the institute or individual who supplied the culture. Therefore, if suppliers publicise new information regarding an organism (for example observation of pathogenicity, misidentification or contamination) users of this approval will be able to determine if they are affected.

ii Containment regime

6.8 The Risk Group 2 bacteria shall be imported into and maintained within a containment facility registered under the Biosecurity Act 1993 in accordance with the MAF Biosecurity/ERMA New Zealand Standard: *Containment Facilities for Microorganisms* (the standard) at Physical Containment Level 2 (PC2). The requirements for PC2 are set out in the Australian New Zealand Standard AS/NZS 2243.3:2002 *Safety in Laboratories: Part 3: (Microbiological aspects and containment facilities*.

6.9 The Standard requires the facility to be constructed and operated in a manner to ensure that Risk Group 2 bacteria are securely contained within the facility, and contains adequate provisions to ensure that containment is maintained. These provisions cover access, staff training, contingency plans for recovery/destruction should any escape from containment occur, waste disposal, record keeping and packaging for organisms in transit.

6.10 The Committee consider that PC2 containment is appropriate for these Risk Group 2 microorganisms.

6.11 The containment facility will be run in accordance with the AS/NZS 2243.3:2002, which contains provisions relating to good laboratory procedure (control 3, Appendix 1). The Committee note that adherence to this standard requires that where there is a significant risk from the production of aerosols open container manipulations (whereby the culture is exposed to the atmosphere and includes plating and sub-culturing) should be conducted in a biological safety cabinet. To allow for the possibility that aerial dispersed propagules arise, control 7 (Appendix 1) stipulates the user of the approval has documented evidence that aerial propagules are not formed by the isolate being manipulated. Such documents are to be held by the user of the approval and must be available for auditing purposes.

iii Potential pathways for escape of organisms from the containment facility

6.12 The Committee considered the potential pathways of escape of the anaerobic microorganisms as:

- escape during transport to/from the containment facility;
- escape due to accidental/unintentional or deliberate removal from the containment facility by authorised people;
- escape due to accidental/unintentional or deliberate removal from the containment facility by unauthorised people; and
- escape from containment following natural disaster (eg flood or earthquake) or fire.

6.13 The Committee considered the ability of the microorganisms to escape containment during transport. Samples being transported are subject to the regulations set out in the Standard (control 3, Appendix 1) which details requirements such as packaging being 'of good quality, strong enough to withstand the shocks and loadings normally encountered during transport' and triple packaging.

6.14 The Committee noted the potential for inspection at the border to result in accidental release of the organisms. Control 5 (Appendix 1) places requirements on users of the approval to label packages with the ERMA New Zealand application code and a clearly visible direction that the package should only be opened in a registered containment facility.

6.15 The Standard also requires a contingency plan to be prepared for accidental release or spillage of microorganisms, fire, sabotage, theft or other emergency. In the event of a breach of containment, the approval user must notify the MAF inspector of the breach and any details of any action taken to restore containment within 24 hours (control 13, Appendix 1).

6.16 The Committee considered that given the nature of the organisms and the specific environmental conditions required for growth, and in many cases survival, escape from containment of these organisms would require a deliberate human act. The Committee therefore considered that escape from containment during transport or following a natural disaster is **highly improbable**.

6.17 The Committee considered that escape by deliberate or accidental removal by authorised or unauthorised persons, is limited by the containment regime, particularly

the security measures and audit components. In light of this, the Committee considered that escape by these pathways is **highly improbable**.

6.18 The Committee notes that this approval will also provide for the use of these microorganisms in teaching laboratories. Teaching laboratories being places where the primary purpose is to give instruction, training, or lessons.

6.19 The applicant noted that in teaching laboratories, students wear laboratory coats and handle organisms on agar petri dishes or small liquid volumes. Their exposures to Risk Group 2 bacteria would be very limited.

6.20 In addition, the Committee notes that the containment standards contain sufficient provisions to ensure students receive appropriate training before entering a PC2 containment facility.

6.21 The Committee noted that under this approval the applicant may undertake co-infection studies with Risk Group 2 bacteria and endoparasites (organisms that live inside another organism such as Bacteriophages) and exposure studies involving infection of insect, human and mammalian cell lines (Risk Group 1), or laboratory animals and insects with the Risk Group 2 bacteria.

6.22 The Committee has imposed controls 8-11 to ensure that infection and exposure studies with:

- endoparasites of bacteria eg bacteriophages and Bdellovibrio-like organisms with the approved organisms will be performed within a facility approved to the MAF/ERMA New Zealand Standard: *Containment Facilities for Microorganisms* at a minimum level of PC2 (control 8, Appendix 1);
- insect, mammalian and human cell line exposure experiments with the approved organisms will be performed within a facility registered to the MAF/ERMA New Zealand Standard: *Containment Facilities for Microorganisms* at a minimum level of PC2 (control 9, Appendix 1);
- vertebrate laboratory animal exposure experiments with the approved organisms will be performed within PC2 facilities approved to the MAF /ERMA New Zealand Standard: *Containment Facilities for Vertebrate Laboratory Animals*[7] *Microorganisms* at a minimum level of PC2 (control 10, Appendix 1);
- insect exposure experiments using the approved organisms will be performed within an approved facility to the MAF /ERMA New Zealand Standard: *Transitional and Containment Faculties for Invertebrates* at a minimum level of PC2 (control 11, Appendix 1).

6.23 The provisions within these standards, and adherence to PC2 containment and operational procedures are adequate to ensure that the animals and insects exposed to the approved micro-organisms are fully contained.

6.24 The Committee noted that this approval allows small scale fermentation of the organisms. ERMA New Zealand Policy Series: Protocol 3, April 2005, page 39 states that fermentations over 10 L in volume require a development approval. As large scale fermentations present additional risks to escape from containment due to the large volumes involved control 12 (Appendix 1) limits the fermentation of organisms held under this approval to a volume of 10 L.

6.25 The Committee concluded that escape from containment, by the Risk Group 2 bacteria in this approval, via the identified pathways, is **highly improbable**.

Conclusion on adequacy of the containment regime

6.26 The Committee has considered the ability of the organisms to escape containment given their biological characteristics, the proposed containment regime and the potential pathways of escape. Taking all of these considerations into account the Committee concluded that it is highly improbable that the organisms would be able to escape from containment by deliberate or accidental means and that the proposed containment regime is adequate to contain these organisms.

7 Ability of the Organism to Establish a Self-Sustaining Population

7.1 In accordance with sections 44 and 37 and clause 10(e) the Committee considered the ability of the organisms to form self-sustaining populations should they escape containment, and the ease of eradication of such populations.

7.2 The Committee noted that the organisms to be imported have the potential to form self-sustaining populations within the environment. However, the potential for these organisms to escape from containment and form a self-sustaining population is limited by the containment regime and good laboratory management practices.

7.3 The Committee also considered that it would be difficult to identify such a population if it were to establish, as it could not be distinguished from the hosts indigenous micro-flora. The Committee noted that effective treatment eg use of antibiotics may be available.

7.4 The Committee concluded that the establishment of a self-sustaining population is improbable and such a population would be difficult to distinguish from the host's native micro-flora.

8 Identification and Assessment of Potentially Significant Adverse Effects (Risks and Costs)

8.1 In accordance with clause 9(c) the Committee has categorised potential adverse effects into environmental, human health, Māori culture, market economy and social categories. These adverse effects have been considered in terms of the requirements of clauses 12, 13, and 14 including the probability of occurrence and the magnitude of adverse effects, whether or not they are monetary, and the distribution of costs and benefits over time, space and groups in the community. Risk characteristics are

considered in terms of clause 33. The degree of uncertainty attached to evidence is taken into account, as required under clauses 25, 29 and 30.

Potential adverse effects on human health and safety

8.2 The Committee considered that the ability of the organisms to cause adverse effect to human health and safety. The Committee noted that any adverse effects would be dependent on the highly improbable event of the organisms escaping containment. The Committee noted that the organisms are classified as Risk Group 2. Therefore, while they may be able to cause disease, they are unlikely to be a serious hazard to laboratory personnel, the community, animals or the environment, can be treated and/or prevented and present a limited risk of spread, therefore the magnitude of any potential adverse effects would be **minimal**. The Committee therefore concluded that the potential adverse effects on human health and safety resulting from exposure to these organisms is **negligible.**

Potential adverse effects on the environment

8.3 The Committee considered that the potential for the organisms to cause adverse effects on the environment was dependent on escape from containment, and pathogenic infection of a suitable host. The Committee considered that the likelihood of escape from containment was **highly improbable**.

8.4 The Committee considered the organisms may inhabit the intestinal tract of many animals, and do not cause disease in this capacity. The Committee also noted that as with humans, the organisms could potentially cause disease in animals. In addition, such a disease could also be treated, and would be limited to individuals rather than whole populations of animals. The Committee therefore, considered the magnitude of any potentially adverse effects on animals to be **minimal**.

8.5 The Committee considered the likelihood of these potential adverse effects occurring to be highly improbable as they are dependent on escape from containment and infection of a suitable host.

8.6 The Committee did not identify any potential adverse effects on plants or other aspects of the environment.

8.7 The Committee considered that the magnitude of any potential adverse effects on the environment is minimal, and likelihood of any potential environmental effects is **highly improbable**. The Committee concluded that the potential adverse effects on the environment are **negligible**.

Potential adverse effects on Māori and their culture and traditions

8.8 The Committee considered the potential Māori cultural effects of this application in accordance with clauses 9(b)(i) and 9(c)(iv) of the Methodology and sections 6(d) and 8 of the Act, using the assessment framework contained in the ERMA New Zealand User Guide "Working with Māori under the HSNO Act 1996" in assessing this application.

8.9 The Committee noted that the potential adverse effects on Māori and their culture and traditions are dependent on escape from containment and that the magnitude of such effects would be **minimal**. The Committee concluded that the potential adverse effects on Māori and their culture and traditions are **negligible**.

Potential adverse effects on the market economy

8.10 The Committee considered the information available and did not identify any potential adverse effects on the market economy.

Potential adverse effects on society and communities

8.11 The Committee considered the information available and did not identify any adverse effects to society and the community

9 Identification and Assessment of Potentially Significant Beneficial Effects

9.1 The Committee considered the potential beneficial effects associated with the application, in accordance with sections 5 and 6(e) of the Act and clauses 9(c), 10, 13, and 14 of the Methodology. The Committee identified the following direct beneficial effects:

- Improved surveillance programmes and import and export testing abilities;
- Opportunity to increase scientific knowledge and expertise of researchers and diagnosticians;
- Protection and assurance of the disease-free status of the New Zealand;
- Protection of the economy from a severe disease outbreak and consequently leading to a reduction in exports and more expensive imports; and
- Rapid diagnosis of suspected exotic diseases without having to be dependent on overseas laboratories.

9.2 The Committee considered these benefits combined are of **minor to moderate** value and are likely to be realised. Therefore, the benefits are **non-negligible**.

10 Establishment of the Approach to Risk in the Light of Risk Characteristics

10.1 Clause 33 of the Methodology requires the Authority to have regard for the extent to which a specified set of risk characteristics exist when considering applications. This provides a route for determining how cautious or risk averse the Authority should be in weighing up risks and costs against benefits. In the present application clause 33 is influenced by the organisms being "in containment" and the conclusion that the containment provisions and other controls will reduce most biological and physical risks to a low level.

10.2 The Committee determined that all identified risks and costs (adverse effects) were assessed, individually and collectively, as being **negligible**. Therefore, additional caution was not warranted.

11 Associated Approvals

11.1 The Committee noted the need for the applicant to obtain the following associated approvals:

- An import permit from MAF;
- Registration of the facility as a containment facility by MAF;
- Human ethics approval if using non-commercial human cell lines; and
- Animal ethics approval if animal exposure testing is conducted.

12 Overall Evaluation of Risks, Costs and Benefits

12.1 The overall evaluation of risks, costs and benefits set out below was carried out in accordance with section 45 of the Act and clause 26 of the Methodology, having regard to clauses 22 and 34 of the Methodology.

12.2 The Committee has assessed the potential adverse effects (risks and costs) of importing these organisms into containment as being **negligible.**

12.3 The Committee considers that the beneficial effects (benefits) are **non-negligible**.

12.4 The Committee has concluded that the establishment of self-sustaining populations of the microorganisms in New Zealand, should they escape, is **highly improbable**. The proposed containment regime, based on Standard 154.03.02 and additional controls, is adequate considering the risks posed by the organisms. Additionally, it is **highly improbable** that the organisms would be able to escape from containment.

12.5 The Committee was unable to find common units of measurement with which to combine risks, costs, and benefits in accordance with clause 34(a). There were no dominant sources of risk (clause 34(b)). Because the risks as a whole are negligible the decision is made in accordance with clause 26 (not clause 27) of the Methodology.

12.6 The Committee considered all of the controls, set out in Appendix 1, taking into account the cost effectiveness of the controls in preventing the escape of the organisms and effectively managing any risks. The Committee, having regard to these matters, is satisfied that the organisms can be adequately contained, and that it is evident that the beneficial effects (benefits) of the application outweigh the adverse effects (risks and costs).

13 Decision

13.1 Pursuant to section 45(1)(a)(i) of the Act, the Committee is satisfied that this application is for two of the purposes specified in section 39(1) of the Act, being:

- section 39(1)(g): *maintaining new organisms in containment for diagnostic purposes*; and/or
- section 39(1)(h): *such other purposes as the Authority thinks fit*.

13.2 Having considered all the possible effects in accordance with sections 45(1)(a)(ii), 45(4) and 44 and pursuant to clause 26 of the Methodology, and based on consideration and analysis of the information provided and taking into account the

application of risk management controls specified in this decision, the view of the Committee is that the adverse effects (risks and costs) associated with the importation into containment of these organisms are outweighed by the beneficial effects (benefits).

13.3 The Committee is satisfied that the containment regime, as set out in Appendix 1, will adequately contain the organisms as required by section 45(1)(a)(iii) of the Act.

13.4 In accordance with clause 36(2)(b) of the Methodology the Committee records that, in reaching this conclusion, it has applied the balancing tests in section 45 of the Act and clause 26 of the Methodology and has relied in particular on the criteria set out in the following sections of the Act:

- section 44 additional matters to be considered;
- section 45 determination of application;
- section 37 additional matters to be considered; and
- the Third Schedule-Part 2, matters to be addressed by containment controls for new organisms.

13.5 The Committee has also applied the following criteria in the Methodology:

- clause 9 - equivalent of sections 5, 6 and 8;
- clause 10 - equivalent of sections 36 and 37;
- clause 12 – evaluation of assessment of risks;
- clause 13 – evaluation of assessment of costs and benefits;
- clause 20 – information produced from other bodies;
- clause 21 – the decision accords with the requirements of the Act and regulations;
- clause 22 – the evaluation of risks, costs and benefits – relevant considerations;
- clause 24 – the use of recognised risk identification, assessment, evaluation and management techniques;
- clause 25 – the evaluation of risks;
- clause 26 - the risks are negligible and it is evident benefits outweigh costs;
- clause 29 and 32 – considering uncertainty;
- clause 33 – the risk characteristics; and
- clause 34 – the aggregation and comparison of risks, costs and benefits.

13.6 The application to import into containment cultures of Risk Group 2 bacteria for laboratory based research and teaching purposes in order to develop and use diagnostic methods for diseases is **approved, with controls**, in accordance with section 45(1)(a) of the Act. As required under section 45(2) the approval is subject to the controls listed in Appendix 1 of this decision.

_____ 18 June 2010

Max Suckling Date

Chair of the Committee

Approval code: NOC100010 (bacterial species belonging to Risk Group 2)

Amended October 2012 by;

- Deletion of a reporting control (and internal reference) which required the approval user to notify the EPA of the name and unique identifier of any organism imported under this approval within three months of importation.

Signed _____ 17 October 2012

Deborah Read Date

Chair of the Decision making Committee

Appendix 1: Controls Required by the Approval

In order to satisfactorily address the matters detailed in the Third Schedule Part II: *Containment controls for new organisms excluding genetically modified organisms,* of the Act, and other matters in order to give effect to the purpose of the Act, the approved organisms are subject to the following controls:

1. The approval user (organisation using this approval) must ensure compliance with the following controls.

2. This approval is limited to the importation into containment of Risk Group 2[3] bacteria for the purposes of laboratory-based research and teaching in order to develop and use diagnostic methods for diseases.

3. Subject to the other controls of this approval, the organisms must be held within a containment facility in accordance with the MAF-ERMA New Zealand Standard *Facilities for Microorganisms and Cell Cultures: 2007*[4] (the microorganism standard) at Physical Containment Level 2 (PC2), as defined in AS/NZS Standard 2243.3.2002, *Safety in Laboratories Part 3: Microbiological Aspects and Containment Facilities*[4] (the AS/NZS Standard).

4. The approval user must, the first time it uses this approval at each containment facility, notify ERMA New Zealand and the MAF Inspector in writing.

5. All packages of organisms must be clearly labelled with the HSNO Act approval code ERMA200432 and the direction that the primary package[5] must not be opened outside of a containment facility. That labelling documentation must be attached to the package in such a way that the primary package does not have to be opened to access it.

6. The name and address of the institute or individual that supplied the approved organisms must be recorded in the register of culture collection (as defined in the microorganism standard).

7. All 'open container[6]' manipulations of organisms must be performed in a biological safety cabinet in accordance with the requirements of the AS/NZSStandard unless documented evidence is provided that aerial dispersed propagules are not formed by that organism.

[3] Risk Group 2 organisms are pathogens that can cause human, plant or animal disease, but are 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] Any reference to this standard in these controls refers to any subsequent version approved or endorsed by ERMA New Zealand.
[5] Primary package means the package that comes into direct contact with the organisms.
[6] Open container manipulations are procedures whereby the culture is exposed to the atmosphere and includes plating and subculturing.

8. Co-infection studies with endoparasites of bacteria eg bacteriophages and *Bdellovibrio*-like organisms with the approved organisms must be performed within a facility approved to the MAF/ERMA New Zealand Standard: *Containment Facilities for Microorganisms*[7] at a minimum level of PC2.

9. Insect, mammalian and human cell line exposure experiments with the approved organisms must be performed within a facility approved to the MAF/ERMA New Zealand Standard: *Containment Facilities for Microorganisms*[7] at a minimum level of PC2.

10. Vertebrate laboratory animal exposure experiments with the approved organisms must be performed within facilities approved to the MAF /ERMA New Zealand Standard: *Containment Facilities for Vertebrate Laboratory Animals*[7] at a minimum level of PC2.

11. Insect exposure experiments using the approved organisms will be performed within PC2 facilities approved to the MAF /ERMA New Zealand Standard: *Transitional and Containment Faculties for Invertebrates*[7] at a minimum level of PC2.

12. Fermentations of approved organisms in liquid culture must not exceed 10 L in a single vessel.

13. Within 24 hours of the discovery of any breach of containment[8] the approval user must notify the MAF Inspector of the breach and details of any action taken to restore containment.

14. If an approval user becomes aware of any new information on the pathogenicity of any of the organisms they must:
    i. Notify ERMA New Zealand and the MAF Inspector within five working days; and,
    ii. Cease work on the organism until notified by ERMA New Zealand that the work may continue; and,
    iii. Hold any such organism in secure storage; and,
    iv. Destroy any such organism within the year of the date ERMA New Zealand was notified in accordance with this control unless a new application has been formally received by ERMA New Zealand.

[7] Any reference to this standard in these controls refers to any subsequent version approved or endorsed by ERMA New Zealand.
[8] A breach of containment includes: escape of organism(s), unauthorised entry to the facility, and/or the structural integrity of the facility being compromised.