ENVIRONMENTAL RISK MANAGEMENT AUTHORITY DECISION

Amended under s67A on 6 September 2007

14 December 2005

Application code:	NOC04018
Application category:	Import into Containment any New Organism under section 40(1)(a) of the Hazardous Substances and New Organisms (HSNO) Act 1996
Applicant:	Landcare Research New Zealand Limited, on behalf of the New Zealand National Herbarium Network
Applicant contact:	Aaron Wilton
Purpose:	To import into containment dried herbarium specimens of Kingdoms Plantae, Mycetae, Protista and Cyanobacteria, including seeds, pollen and spores, as reference material to study and improve understanding of the New Zealand flora
Date application received:	18 October 2005
Consideration date:	6 December 2005
Considered by:	A Committee of the Authority (the Committee)

1 Summary of decision

1.1 Application NOC04018 to import into containment dried herbarium specimens of the Kingdoms Plantae, Mycetae, Protista and Cyanobacteria, that contain viable material (e.g. seeds, pollen and spores), 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 for application

2.1 The application was lodged pursuant to section 40(1)(a) of the Act and determined in accordance with section 45, having regard to the matters specified in section 44 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.

3 Application process

Application receipt

3.1 Application NOC04018 was determined to be in compliance with section 40(2) of the Act and was formally received on 18 October 2005.

Notification

3.2 Under section 53(2) of the Act the Environmental Risk Management Authority (the Authority) has discretion as to whether to publicly notify an application to import into containment any new organism. In this case the application was not publicly notified because it was considered to be unlikely that there would be significant public interest in the application. This conclusion was based on the grounds that there are no novel features of the organisms, no unprecedented issues are raised by the application and the potential risks associated with these organisms were expected to be low.

3.3 In accordance with section 58(1)(c) of the Act and clauses 2(2)(e) and 5 of the Methodology, the Department of Conservation (DoC) and the Ministry of Agriculture and Forestry (MAF) Biosecurity New Zealand were notified of the receipt of this application and provided with an opportunity to comment. Comments were received from DoC and included in the Evaluation and Review (E&R) Report prepared by the Agency. The applicant was provided with an opportunity to respond to DoC's comments. Their response was also included in the E&R Report. MAF chose not to respond with any formal comments on the application. However, they were consulted regarding the application and provided advice on proposed additional controls.

3.4 With the consent of the applicant and in accordance with section 59(3) of the Act, ERMA New Zealand waived the requirement to fix a date for the consideration of the application within 30 working days after the receipt of the application (section 59(1)(d) of the Act). This time limit was extended by four working days for logistical reasons related to forming a decision-making committee.

Decision making Committee

3.5 The application was considered by a Committee of the Authority (the Committee), appointed in accordance with section 19(2)(b) of the Act and clause 43 of the First Schedule to the Act. For the purposes of determining this application the Committee comprised the following members: Dr Kieran Elborough (Chair), Mr Neil Walter and Professor George Clark.

3.6 The Committee considered the application by teleconference (for two members) and in person (for one member) on 6 December 2005.

Information available for consideration

3.7 The information available for the consideration of the application was:

- The application (Form NO2N) prepared by the applicant along with five appendices; and
- The E&R Report prepared by the Agency to assist and support the Committee's decision-making.

3.8 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 internal procedures as specified in the ERMA New Zealand Technical Guide publications.

4 Associated approvals

4.1 For clarity the Committee point out that any person exercising this approval must comply with all other relevant statutes, including the Biosecurity Act.

5 Sequence of the consideration

5.1 In accordance with clause 24 of the Methodology, the approach to the consideration adopted by the Committee was to look sequentially at the identification, assessment and evaluation of risks, costs and benefits. Those risks identified as significant were assessed in accordance with clause 12 of the Methodology. Management techniques were considered in relation to the identified risks. Costs and benefits were assessed in accordance with clause 13 of the Methodology. Qualitative scales used by the Committee to measure likelihood and magnitude of risks, costs and benefits were provided in Appendix 4 of the E&R Report. The approach to the consideration follows the decision path outlined in Appendix 1 of the E&R Report.

5.2 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 probability of the risks, costs and benefits alongside each other and in an integrated fashion. This is because the former interact with the latter and this is recognised in clause 12(d) of the Methodology and in section 45(1)(a)(ii) of the Act.

5.3 Management techniques were considered in relation to the identified risks. The Committee set controls to satisfactorily provide for the matters in the Third Schedule (Part II) of the Act and additional controls were considered in relation to residual risks that required further consideration.

5.4 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.

5.5 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.

6 Purpose of the application and scope of the approval

6.1 Landcare Research New Zealand Limited, on behalf of the New Zealand National Herbarium Network involving the Auckland War Memorial Museum Herbarium, Museum of New Zealand - Te Papa Tongarewa, Allan Herbarium, University of Canterbury Herbarium, Lincoln University Herbarium, Dame Ella Campbell Herbarium, two Forest Research Herbaria, University of Otago Herbarium, New Zealand Fungal Herbarium, University of Waikato Herbarium and the H.D. Gordon Herbarium, seek to import into containment, under section 40(1)(a) of the Act, dried herbarium specimens of the Kingdoms Plantae, Mycetae, Protista and Cyanobacteria, including seeds, pollen and spores, as reference material to study and improve the understanding of the New Zealand flora.

6.2 In accordance with section 45(1)(a)(i) of the Act, the Committee determined that this purpose falls within the scope of section 39(1)(g) of the Act: "maintaining new organisms in containment for diagnostic purposes" and section 39(1)(h) of the Act: "such other purposes as the Authority thinks fit."

6.3 The Committee noted the extremely broad organism description for the application, which includes four of the five Kingdoms of life. However, the scope of the approval is limited by the purpose of the application, which is to maintain the organisms as dried herbarium specimens. Propagation or multiplication of the herbarium specimens is expressly excluded from this approval (control 6.2; see Appendix 1 of this decision for all controls).

7 Associated organisms

7.1 The Committee noted that there is the potential for associated organisms to be inadvertently imported in packages containing herbarium specimens. The Committee considered that the risk of escape of the herbarium specimens and any associated organisms is greater if packages are opened at the border for inspection by MAF (as is MAF's standard procedure) because the inspections are performed outside the confines of a registered containment facility. Therefore a control has been imposed stipulating that any packages containing herbarium specimens (and any associated organisms and substrates) will not be opened at the border but will instead be directed straight to the containment facility as specified on the exterior of the packaging (along with the organism approval code) and in the accompanying documentation (control 6.3).

7.2 The Committee has imposed two further additional controls to reduce the risk of escape of viable associated organisms inadvertently imported with herbarium specimens. Firstly, all packages containing herbarium specimens must be frozen on arrival at the containment facility, in accordance with best practice methods for temperature and duration and as documented in the containment facility manual (control 6.4). This is a standard procedure used by herbaria to ensure that any associated pests are killed. Secondly, any

herbarium exercising this approval shall have a contingency plan documented in their containment manual for use in the event that any adventitious, associated organisms (other than the herbarium specimens) are detected as associates of the herbarium specimen. MAF Biosecurity New Zealand shall be notified promptly after the event is noticed (control 6.5).

7.3 Potential adverse environmental and human health effects from the introduction of associated or inseparable organisms are discussed in this decision in sections 10.7 - 10.9 and 10.10 - 10.12 respectively.

8 Adequacy of the containment regime

8.1 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. potential pathways for escape of the organisms from the containment facility.

i. Biological characteristics of the organisms

8.2 The biological characteristics of organisms of the Kingdoms Plantae, Mycetae, Protista and Cyanobacteria are described in full in section 2 of the E&R Report. In brief, Cyanobacteria are unicellular and colonial bacteria more commonly referred to as blue-green algae. Protista includes unicellular protozoans and unicellular and multicellular algae. Mycetae includes all fungi and Plantae includes all plants. Although some members of the four Kingdoms in their living state may have attributes that are considered toxic or pathogenic, the Committee considers that dried herbarium specimens are not of that nature.

8.3 The Committee noted that this approval stipulates that the organisms must be dried prior to importation (control 6.1), rendering a large proportion of the material non-viable and the viability of the material will also decrease over time. The Committee considered that if the specimens were not properly dried, this would be evident because they would become mouldy.

ii. Containment regime

8.4 The dried herbarium specimens shall be imported into and maintained within a containment facility registered under the Biosecurity Act 1993 in accordance with the MAF Biosecurity Authority/ ERMA New Zealand Standard 155.04.09: *Containment Facilities for New Organisms (including genetically modified organisms) of Plant Species* (Standard 155.04.09) and operated at Physical Containment level 1 (PC1) for plant containment facilities (see controls 1.1, 1.2 and 1.4 in Appendix 1 of this decision). The minimum requirements for PC1 plant containment facilities are specified in the Australian/New Zealand Standard 2243.3:2002: *Safety in Laboratories Part 3: Microbiological aspects and containment facilities*, fifth edition 2002 (AS/NZS 2243.3:2002). AS/NZS 2243.3:2002 also contains provisions

relating to good laboratory procedure, so any laboratory used for research involving herbarium specimens must comply with this standard (control 1.2).

8.5 The Committee was satisfied that Standard 155.04.09 for plants provides suitable containment measures for all herbarium specimens from the Kingdoms Plantae, Mycetae, Protista and Cyanobacteria, despite the fact that strictly speaking some of these organisms are classified as "microorganisms" rather than plants.

8.6 Standard 155.04.09 requires the facility to be constructed and operated in a manner to ensure that organisms are securely contained and held only within the facility. The provisions in Standard 155.04.09 to ensure that containment is maintained cover access to the facility, staff training, contingency plans, waste disposal, record keeping and packaging for organisms in transit.

8.7 An additional control has been imposed to ensure that all waste containing viable material, including any waste that may inadvertently contain viable material (for example, any waste collected during cleaning of the facility such as vacuum cleaner contents) is disposed of in accordance with the requirements of Standard 155.04.09 (control 6.9).

8.8 The Committee has also limited the importation source of herbarium specimens to government agencies and herbaria registered on *Index Herbariorum*[1] (control 6.3). This is to ensure that the specimens are properly dried and packaged prior to importation. As discussed in section 7.1 of this report, control 6.3 also specifies the labelling requirements for packages containing herbarium specimens. The control also stipulates that the packaging must be in accordance with the International Air Transport Association (IATA) Dangerous Goods Regulations packing instruction 650 as specified in Standard 155.04.09.

8.9 The Committee has imposed a control requiring any herbarium exercising this approval to notify ERMA New Zealand, MAF Biosecurity New Zealand and the Biosecurity Inspector of the facility when they first exercise the approval (control 6.8). This is for compliance monitoring purposes and the need to know who is using the approval in case a reassessment (section 62 of the Act) or amendment (section 67A of the Act) of the approval is warranted.

iii. Potential pathways for escape of organisms from the containment facility

8.10 The Committee considered the following potential pathways of escape of the herbarium specimens (as outlined in section 3 of the E&R Report):

i. Escape during transport to containment facilities.

[1] Holmgren, PK, Holmgren, NH 1998 (continuously updated). *Index Herbariorum: A Global Directory of Public Herbaria and Associated Staff*. New York Botanical Garden. http://sciweb.nybg.org/science2/IndexHerbariorum.asp

ii. Escape from containment facilities by accidental/unintentional or deliberate removal by staff.

iii. Escape from containment facilities by accidental/unintentional or deliberate removal by unauthorised persons.

iv. Escape from containment in the event of a natural disaster (flood, earthquake etc.) or fire.

v. Escape from containment via a spore or seed dispersal vector (wind, water, animals etc.)

vi. Escape into the environment during transport to or while being held in a non-containment facility for analysis or public display.

8.11 The Committee concluded that escape of the organisms via pathways i - v is highly improbable. This conclusion was formed on the basis of the provisions of the Standards imposed by control 1.2 that relate to packaging of the organisms for transport, waste disposal, management of the facility (including access to the facility and staff training) and contingency plans. This conclusion was also formed on the basis of the following controls: control 6.3, which aims to ensure that herbarium specimens are properly packaged prior to transportation and such packages are not opened at the border; control 6.9, which requires all potentially viable waste to be disposed of in accordance with Standard 155.04.09; and control 6.6, which aims to prevent entry of insects to the containment facility (that could possibly disperse viable herbarium specimen material) by prohibiting live plants from being kept where herbarium specimens are stored.

8.12 The Committee concluded that for pathway vi, escape during transport to a non-containment facility was highly improbable, and escape while being held in a non-containment facility for analysis or public display was improbable. This conclusion is based on the requirements of additional control 6.7. This control stipulates that prior to transferring viable herbarium specimens out of containment, the Biosecurity Inspector responsible for the supervision of the facility and MAF Biosecurity New Zealand shall be notified and approve of the intention to transfer the material, the purpose of the transfer, the duration of the transfer, the proposed non-containment facility where the material will be held and the containment measures that will be in place to prevent escape. Any transfer out of containment will be temporary. The material must be packaged and transported to and from the containment facility in accordance with the requirements of Standard 155.04.09. Material that is transferred out of containment for analysis shall only be handled by an approved user of the containment facility or by an appointed person under the supervision of an approved user of the containment facility, until the material is rendered non-viable. Material that is transferred out of containment for public display must be displayed in such a way that it cannot be accessed by the viewing public or animals (eg within a glass cabinet). For the duration of time that the material is held in a non-containment facility, it must be kept within the approved temporary containment area. Once the analysis or public display is completed, all of the specimen material must be packaged and transported back to the containment facility (in accordance with Standard 155.04.09).

8.13 Standard 155.04.09 requires contingency plans to be in place for use in the event of accidental release of plants or viable plant material outside the facility and for fire and other emergencies. Section 4.7 Contingency Plans, states "…action shall be immediately taken to prevent further release and where possible recover the released plants". The Committee further enhance this measure with controls that require the contingency plan to be implemented immediately following a breach (control 3.3) and notification to MAF Biosecurity New Zealand, the Biosecurity Inspector of the facility and ERMA New Zealand following such an occurrence (control 3.2).

Conclusion on adequacy of the containment regime

8.14 The Committee has considered the ability of the herbarium specimens to escape from containment, the containment conditions and the potential pathways of escape. Taking all of these considerations into account the Committee concludes that it is highly improbable that the herbarium specimens would be able to escape from containment and improbable that they would escape from non-containment facilities.

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

9.1 In accordance with sections 44 and 37 and clause 10(e) the Committee considered the ability of dried herbarium specimens from the Kingdoms Plantae, Mycetae, Protista and Cyanobacteria to form self-sustaining populations should they escape from containment and the ease of eradication of such populations.

9.2 The Committee considered that should an escape from containment occur, it is theoretically possible that organisms from the Kingdoms Plantae, Mycetae, Protista and Cyanobacteria could establish self-sustaining populations, because the environmental conditions for growth of these organisms occur in New Zealand. However, the Committee noted that, as outlined in sections 4.3 – 4.4 of the E&R Report, there are a number of factors that limit the amount of viable material available from which a population could form and several factors that affect the ability of the organisms to establish self-sustaining populations (such as specific pre-treatments required to induce germination of seeds and spores and environmental conditions required for growth). Considering all of these factors, the Committee concluded that it is very unlikely that a self-sustaining population would form.

9.3 The Committee considered that in the event that a population did establish, the ease of eradication would vary depending on the type of organism. For macroscopic organisms, eradication would be fairly easy, whereas microorganisms are likely to be difficult to detect and almost impossible eradicate.

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

10.1 The Committee considered the potential risks, costs and benefits relating to the application, identified and assessed in section 5 of the E&R Report. In accordance with sections 5 and 6 of the Act, and clause 9 of the Methodology, the potential adverse effects of this application were categorised and considered in terms of their area of impact ie the environment, human health and safety, Māori and their culture and traditions, the market economy and society and the community.

10.2 The potential risks, costs and benefits assessed here are those identified as significant, having regard for those matters set out in clauses 9 and 10 of the Methodology, which reflect sections 5, 6, 8 and 44 of the Act. Risks were considered in terms of the requirements of section 45(4) of the Act and clause 12 of the Methodology, including the assessment of consequences and probabilities, the impact of uncertainty and the impact of risk management. Costs and benefits were considered in terms of clause 13 of the Methodology. A "cost" is defined in clause 2 as "the value of a particular adverse effect expressed in monetary or non-monetary terms". Therefore, these have been assessed in an integrated fashion together with the risks of those adverse effects in the following assessment.

Adverse effects

Environment

Potential for the herbarium specimens to be pathogenic or toxic to plants or animals in New Zealand

10.3 The Committee has considered the potential for dried herbarium specimens of the Kingdoms Plantae, Mycetae, Protista and Cyanobacteria to be toxic or pathogenic to plants or animals in New Zealand.

10.4 The Committee noted that some of the organisms within these Kingdoms have attributes that are considered toxic or pathogenic in their living state. The Committee noted the large degree of uncertainty regarding the magnitude of any impact of such organisms on plants and animals in New Zealand should they be affected, which could range from **minimal** to **moderate**, depending on the level of pathogenicity or toxicity of the organism, what organisms were affected and how easily identifiable infected organisms were. However, it is considered **highly improbable** that this effect would occur because it is highly improbable that the herbarium specimens would escape from containment and improbable that they would escape from non-containment facilities (see section 8.14 of this decision) and in the event of escape, it is very unlikely that they would form self-sustaining populations (see section 9.2 of this decision). Therefore the Committee concluded that this risk is negligible.

Potential for disruption of New Zealand's flora and fauna environment

10.5 The Committee considered the potential for herbarium specimens of the Kingdoms Plantae, Mycetae, Protista and Cyanobacteria to in the first instance escape from containment, establish in the environment, and then to cause disruption of New Zealand's flora and fauna through competition with, and displacement of, native species or through hybridisation.

10.6 The Committee noted there is a degree of uncertainty regarding the magnitude of this adverse effect if it were to occur, which could range from **minimal** to **moderate** depending on the nature of the organism and its competitive ability. However, the Committee considered that it is **highly improbable** that this effect would occur because it is highly improbable that the organisms would escape containment (and improbable that they would escape from non-containment facilities) and very unlikely that they would form self-sustaining populations. Therefore the Committee considered this risk to be negligible.

Potential for inseparable or associated organisms to adversely affect native or valued plant or animal species

10.7 The Committee has considered the potential for inseparable and associated organisms of herbarium specimens (such as viruses, fungi or insect pests) to adversely affect native or valued species.

10.8 As discussed in sections 7.1 - 7.2 of this report, two controls have been imposed by the Committee to reduce the risk of escape of viable associated organisms inadvertently imported with herbarium specimens. These controls include freezing packages containing herbarium specimens on arrival at the containment facility (control 6.4) and having a contingency plan in place for use in the event that any adventitious organisms are detected as associates of the herbarium specimen (control 6.5). The Committee noted that any inseparable organisms will be subject to the same drying and freezing treatments as the herbarium specimens, which is likely to render most organisms non-viable. Any associated or inseparable organisms will also be subject to the same containment regime as the herbarium specimens.

10.9 In the event that inseparable or associated organisms escaped containment and adversely affected native or valued species, the magnitude of their effect would depend upon the nature of the associated organisms, what organisms were affected and how easily identifiable infected organisms were. Thus there is a degree of uncertainty associated with the magnitude of this effect, which could range from **minimal** to **moderate**. However, the Committee considers that the proposed containment regime is adequate to contain inseparable or associated organisms and therefore it is **highly improbable** that they would escape from containment and cause adverse effects on native or valued species. Overall this risk was considered to be negligible.

Human health and safety

Potential for herbarium specimens or inseparable or associated organisms to be pathogenic or toxic to humans

10.10 The Committee has considered the potential for the herbarium specimens or any inseparable or associated organisms to be pathogenic or toxic to humans.

10.11 Given the low likelihood of escape, the Committee considered that the most likely exposure pathway for herbarium specimens or any associated organisms to have adverse effects on human health is through exposure of people working with the specimens.

10.12 The Committee noted the potential health hazard associated with handling herbarium specimens either treated with or containing a toxic substance, as discussed in sections 5.10 - 5.12 of the E&R Report. The Committee considered that there is uncertainty regarding the magnitude of any adverse effect to human health, which could range from **minimal** to **minor**, depending on various factors such as the sensitivity of the person to the toxin/pathogen and the dose, route and duration of exposure. However, the Committee considered that following good herbarium practices as proposed by the applicant, such as using gloves to handle specimens with potential health hazards, would make adverse effects to human health **highly improbable**. Therefore the Committee concluded that the risk to human health is negligible.

Māori culture and traditions

10.13 The Committee considered the potential Māori cultural effects in accordance with clauses 9(b)(i) and 9(c)(iv) of the Methodology and sections 6(d) and 8 of the Act, and using the assessment framework contained in the ERMA New Zealand User Guide "Working with Māori under the HSNO Act 1996", and the ERMA New Zealand revised protocol "Incorporating Māori perspectives in Part V Decision-making".

10.14 Given that all of the adverse environmental effects were assessed as being negligible (as discussed in sections 10.3 - 10.9 above), the Committee considers that this application presents no potentially significant risk to the relationship of Māori and their culture and traditions with their ancestral lands, water, sites, waahi tapu, valued flora and fauna and other taonga, provided that all containment conditions and controls are strictly complied with.

Market economy

10.15 The Committee considered that there are no potential adverse market economy effects of approving the importation of dried herbarium specimens of the Kingdoms Plantae, Mycetae, Protista and Cyanobacteria.

Society and the community

10.16 The Committee considered that there are no potential adverse social or community effects of approving the importation of dried herbarium specimens of the Kingdoms Plantae, Mycetae, Protista and Cyanobacteria.

Beneficial effects

10.17 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, 10, 13, and 14 of the Methodology.

10.18 The Committee identified the following beneficial effects:

- Provision of a resource for research.
- Development of new keys and descriptions to accurately identify specimens and allow reliable access to information.
- New scientific knowledge in New Zealand, including potential publishing of information in peer review journals.
- Provision of an educational resource for teaching.

10.19 The Committee considers that these potential benefits are of a **moderate** to **major** magnitude and are **extremely likely** to be realised.

11 Establishment of the approach to risk in light of the risk characteristics

11.1 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 provision 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 application being "in containment" and the conclusion that the containment provisions and controls will reduce most biological and physical risks to a low level.

11.2 In relation to the biological and physical risks considered (and the risks to human health), the containment measures limit the extent to which exposure to the risks is involuntary. The Committee also considers that there are no significant risks which are not known or understood by the general public. It is considered that the potentially significant risks are dependent upon escape from containment of the organisms and the establishment of an undesirable self-sustaining population. Given the Committee's finding that escape from containment is improbable to highly improbable (see section 8.14 of this decision), and that it is very unlikely that any self-sustaining population would establish (see section 9.2 of this decision), although such a population could be undesirable, the extent to which these risk characteristics are present does not warrant caution additional to that required by section 7 of the Act.

12 Overall evaluation of risk, 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 proposed containment regime, based on the MAF Biosecurity Authority/ ERMA New Zealand Standard 155.04.09: *Containment Facilities for New*

Organisms (including genetically modified organisms) of Plant Species at PC1 for plant containment facilities, and the additional controls are considered to be adequate considering the risks posed by the herbarium specimens. Additionally, it is considered highly improbable that the organisms would be able to escape from this containment.

12.3 The Committee has assessed the potential risks of importing dried herbarium specimens from the Kingdoms Plantae, Mycetae, Protista and Cyanobacteria into containment including potential toxicity or pathogenicity of the organisms or any inseparable or associated organisms, to flora, fauna and humans, potential disruption of New Zealand's flora and fauna environment and potential for adverse effects to Māori culture or traditional relationships with ancestral lands, water, sites, waahi tapu, valued flora and fauna and other taonga. Taking into account the level of containment and the additional controls, these risks were assessed as negligible.

12.4 The potential benefits associated with importing the herbarium specimens include new scientific knowledge in New Zealand and the provision of a resource for research, teaching and the development of new keys and descriptions to accurately identify specimens and allow reliable access to information. The Committee considered that these benefits are extremely likely to eventuate and would be of moderate to major value.

12.5 The Committee has evaluated the potential of the organisms to establish undesirable self-sustaining populations should they escape containment in accordance with section 37 of the Act. The Committee has concluded that it is possible that a self-sustaining population of organisms from the Kingdoms Plantae, Mycetae, Protista and Cyanobacteria could establish outside of containment. However, given the low likelihood of viable material being available from which a population could form, and the potential requirements to induce germination and enable growth, the Committee considered it very unlikely that a self-sustaining population would establish. If such a population did form, whether it is undesirable or not would depend on the characteristics of the organism (pathogenicity, competitive ability etc).The Committee noted that should an undesirable self-sustaining population establish, the ease of eradication could range from easy to almost impossible, depending on the size (and therefore ease of detection) of the organism.

12.6 The Committee was unable to find common units of measurement with which to combine risks, costs, and benefits in accordance with clause 34(a) and 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.

12.7 The Committee considered all of the controls, set out in Appendix 1, and did so in the context of both 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 benefits of the application outweigh the 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, namely section 39(1)(g) of the Act: "maintaining new organisms in containment for diagnostic purposes" and section 39(1)(h) of the Act: "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 risks (or costs) of adverse effects associated with the importation into containment of dried herbarium specimens of the Kingdoms Plantae, Mycetae, Protista and Cyanobacteria, that contain viable material (e.g. seeds, pollen and spores), are outweighed by the benefits.

13.3 The Committee is satisfied that the containment regime, as set out in Appendix 1 of this decision, 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 II), 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 for importation into containment of dried herbarium specimens of the Kingdoms Plantae, Mycetae, Protista and Cyanobacteria, that contain viable material (e.g. seeds, pollen and spores), is thus **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.

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Dr Kieran Elborough Date 14 December 2005

Deputy Chair, New Organisms Standing Committee of the Authority

Approval code: NOC002466

Amendment: November 2006
Changes to controls:

- Addition of footnotes to the containment facility references and the Australian/New Zealand containment facility references to "future proof" the decision
- Standardise the wording of the breach of containment control
- Removal of the control regarding inspection of facilities by the Authority, its agent or enforcement officers

_____ Date: 6 September 2007

Dr Max Suckling
Chair, New Organisms Standing Committee

Appendix 1: Controls Required by this 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 To limit the likelihood of any accidental release of any organism or any viable genetic material[2]:

1.1 The approved organisms shall be imported into, and maintained within a containment facility which complies with these controls.

1.2 The construction, operation, and management of the plant containment facility shall be in accordance with the:

a) Ministry of Agriculture and Forestry (MAF) Biosecurity Authority/ERMA New Zealand Standard 155.04.09[3]: *Containment Facilities for New Organisms (including genetically modified organisms) of Plant Species* (Standard 155.04.09[3]).

b) Relevant sections of the Australian New Zealand Standard AS/NZS 2243:3 2002[3] *Safety in Laboratories: Part 3: (Microbiological aspects and containment facilities),* excluding those deviations specified in Standard 155.04.09[3].

c) Physical Containment Level 1 (PC1) for Plant Containment Facilities requirements of the above Standards.

1.3 The person responsible for the operation of the containment facility shall inform all personnel involved in the handling of the organisms of the Authority's controls.

1.4 The containment facility shall be approved by Ministry of Agriculture and Forestry (MAF), in accordance with section 39 of the Biosecurity Act and Standard 155.04.09[3].

[2] Viable Genetic Material is biological material that can be resuscitated to grow into tissues or organisms. It can be defined to mean biological material capable of growth even though resuscitation procedures may be required, e.g. when organisms or parts thereof are sublethally damaged by being frozen, dried, heated, or affected by chemical.

[3] Any reference to this standard in these controls refers to any subsequent version approved or endorsed by ERMA New Zealand .

2 To exclude unauthorised people from the facility:

2.1 The identification of entrances, numbers of and access to entrances, and the security requirements for the entrances and the facility shall be in compliance with the standards listed in control 1.2 of this document.

3 To control the effects of any accidental release or escape of an organism:

3.1 Control of the effect of any accidental release or escape of the organism shall be in compliance with the standards listed in control 1.2.

3.2 If a breach of containment occurs, the facility operator must ensure that the MAF Inspector responsible for supervision of the facility has received notification of the breach within 24 hours.

3.3 In the event of any breach of containment of the organism, the contingency plan for the attempted retrieval or destruction of the organism that has escaped shall be implemented immediately. The contingency plan shall be included in the containment manual in accordance with the requirements of the standards listed in control 1.2.

3.4 Any person exercising this approval shall comply with the requirements of the standards listed in control 1.2 relating to the maintenance of records demonstrating compliance with Standard 155.04.09[3], as required by the quality assurance programme, and documented in the containment manual.

4 Inspection and monitoring requirements for containment facilities:

4.1 The inspection and monitoring requirements for the containment facility shall be in compliance with the standards listed in control 1.2.

4.2 The containment manual shall be updated, as necessary, to address the implementation of the controls imposed by this approval, in accordance with Standard 155.04.09[3].

5 Qualifications required of the persons responsible for implementing these controls:

5.1 The training of personnel working in the facility shall be in compliance with the standards listed in control 1.2.

6 Controls additional to the requirements of Standard 155.04.09[3] (Matter 1):

6.1 Herbarium specimens imported in accordance with this approval shall be dried prior to being imported.

6.2 Material from herbarium specimens imported in accordance with this approval shall not be propagated or multiplied.

6.3 All packages of herbarium specimens imported in accordance with this approval shall only be imported from herbaria registered on *Index Herbariorum*[4] or from government agencies. The packages shall be clearly labelled on the exterior with the ERMA New Zealand organism approval code and the direction that the package should not be opened at the border, and shall only be opened within the approved containment facility listed on the permit to import (or on the transfer request form for transfers). The package shall be accompanied by the appropriate documentation specifying this direction and attached to the package in such a way that the package does not have to be opened to access the documentation. The packaging of herbarium specimens shall be in accordance with the requirements of the IATA[5] Dangerous Goods Regulations packing instruction 650 as specified in Standard 155.04.09[3], however, the labelling of the package shall be in accordance with this control. All transfers of herbarium specimens will also comply with this control.

6.4 Packages containing herbarium specimens imported in accordance with this approval shall be frozen on arrival at the containment facility in accordance with best practice methods for temperature and duration, which must be documented in the herbarium's containment manual.

6.5 Any herbarium exercising this approval shall have a contingency plan documented in their containment manual for use in the event that any adventitious organisms (other than the herbarium specimens) are detected as associates of the herbarium specimen. MAF Biosecurity New Zealand shall be notified promptly after the event is noticed.

6.6 No living or propagated plants are to be kept in any room within the containment facility that is used for storage of herbarium specimens.

6.7 Viable herbarium specimens (or parts thereof) imported in accordance with this approval may be transferred **temporarily** to non-containment facilities for analysis or public display, subject to the following conditions:

a) **Prior** to transporting the material out of containment, the Biosecurity Inspector responsible for the supervision of the facility and MAF Biosecurity New Zealand shall be notified and **approve** of the intention to transfer the material, the purpose of the transfer, the duration of the transfer, the proposed non-containment facility where the material will be held and the containment measures that will be in place to prevent escape while the material is held in the non-containment facility.

b) The material must be packaged and transported to and from the containment facility in accordance with the requirements of Standard 155.04.09[3].

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[4] Holmgren, PK, Holmgren, NH 1998 (continuously updated). *Index Herbariorum: A Global Directory of Public Herbaria and Associated Staff*. New York Botanical Garden. http://sciweb.nybg.org/science2/IndexHerbariorum.asp

[5] International Air Transport Association (IATA)

c) Material transferred for public display must be displayed in an enclosed case that prevents the material from being accessed by the viewing public or animals (eg a glass cabinet). Material transferred and used for analysis shall only be handled by an approved user of the containment facility or by an appointed person under the supervision of an approved user of the containment facility, until the material is rendered non-viable.

d) For the duration of time that the material is held in a non-containment facility, it must be kept within the approved temporary containment area.

e) Once the analysis or public display is completed, all of the specimen material must be packaged and transported back to the containment facility (in accordance with Standard 155.04.09[3]).

6.8 Any herbarium using this approval for the first time shall notify ERMA New Zealand and the MAF Inspector responsible for supervision of the facility of their intention to do so in writing

6.9 All waste containing viable material (derived from organisms imported in accordance with this approval), including any waste that may inadvertently contain viable material (for example, any waste collected during cleaning of the facility such as vacuum cleaner contents) shall be disposed of in accordance with the requirements of Standard 155.04.09[3].