ENVIRONMENTAL RISK MANAGEMENT AUTHORITY DECISION

Amended under s67A on 6 September 2007 and 30 August 2011

Date signed: 15 May 2002

Application code	NOC01004
Application category	To import into containment any new organism under section 40(1)(a) of the Hazardous Substances and New Organisms (HSNO) Act
Applicant	Ministry of Agriculture and Forestry - National Plant Pest Reference Laboratory
Purpose	To import into containment plant viruses and viroids capable of mechanical transmission (in an 'inactive' state) for disease diagnostic tests on plant quarantine and surveillance samples, under section 40(1)(a) of the HSNO Act
Date received	05 February 2002
Consideration period	21 March – 26 April 2002
Considered by	The Non-Genetically Modified Organisms Standing Committee of the Environmental Risk Management Authority (the Authority)

1 Summary of Decision

The application to import into containment plant viruses and viroids (in the genera and other taxa specified in **Annex 2** of this decision) is approved, with controls (as listed in **Annex 1** of this decision), having been considered in accordance with the relevant provisions of the HSNO Act and the HSNO (Methodology) Order 1988.

In accordance with section 45(3) of the HSNO Act, the Committee must give reasons for the decision in writing. These reasons are summarised in the following sections.

2 Summary of Consideration Process & Relevant Legislative Criteria

Application receipt

The application was formally received on 05 February 2002. The application was lodged pursuant to section 40(1)(a) of the HSNO Act. ERMA New Zealand verified that the application contained adequate information to be processed on 08 February 2002.
The Authority has discretion as to whether or not receipt of an application to import into containment any new organism is publicly notified. In this case the application was not publicly notified (following the ERMA New Zealand Corporate Manual Item 3.2.23). Reasons for this judgement were provided as Appendix 3 of the staff E&R Report, and were based on the nature of risks involved as well as the level of public awareness and public interest in the plant disease diagnostic activities involved.

Consultation with departments and Crown entities

In accordance with clauses 2(2)(e) and 5 of the Methodology and section 58(c) of the HSNO Act, departments and Crown entities which were likely to have an interest in the application were notified of application receipt. As such, the Department of Conservation (DoC), the Ministry of Agriculture and Forestry (MAF) Biosecurity Authority, HortResearch and Crop & Food Research were sent a copy of the application and provided with the opportunity to comment on the application. Of these organisations, only HortResearch provided comment for the consideration process.

Information available for consideration

An Evaluation and Review (E&R) Report was prepared by ERMA New Zealand to assist and support the Committee's decision-making. The E&R Report consolidated and evaluated the relevant information in a format and sequence consistent with the decision-making requirements of the HSNO Act and of the Methodology. 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. The documents available for the evaluation and review of the application by ERMA New Zealand were the application (including copies of MAF NPPRL containment facility manuals for their Lincoln and Lynfield sites) and published references as cited in the application.

In addition to the E&R Report, application and published references, comments from HortResearch were provided separately to the Committee prior to their first decision-making consideration meeting on 21 March 2002. After the initial consideration meeting, the Committee requested further information (under section 58(1)(a) of the HSNO Act and clause 31 of the Methodology) as follows:

- Advice from ERMA New Zealand staff regarding the 'organism' status (as defined under section 2 of the HSNO Act) of the non-mechanically transmitted viruses subject to the application (including comment regarding development of organisms from 'non-viable' virus material);
- Advice from ERMA New Zealand regarding suggested wording for several containment controls.
- Advice from the applicant regarding identification of non-mechanically transmitted plant viruses subject to the application
- Clarification from the applicant regarding the physical form of samples subject to the application
- Comment from the applicant regarding the Physical Containment Level met by MAF NPPRL facilities to enable all stages in the diagnostic procedures to be conducted.
- Comment from the MAF Biosecurity Authority regarding logistics of verifying compliance with proposed controls, at the stage of an Import Permit Request (under the Biosecurity Act) for organisms falling within the scope of this application.

HortResearch were given the opportunity to provide comment on the additional information received, in their role as an interested party. Their feedback was received and provided to the Committee with the further information requested. The Committee required two follow-up consideration meetings (16 and 18 April 2002) in order to consider the additional information. The consideration process was finalised on 26 April 2002.

Decision-making Committee

The application was considered by the Non-Genetically Modified Organism Standing Committee of the Authority, appointed in accordance with section 19(2)(b) of the HSNO Act. The Committee comprised the following members: Ms Jane Lancaster (Chair), Dr Lindie Nelson and Professor George Clark.

Consideration approach and sequence

The decision was determined in accordance with section 45, taking into account additional matters to be considered under section 44, and matters relevant to the purpose of the HSNO Act, as specified under Part II of the Act. Unless otherwise stated, references to **section** numbers in this decision refer to sections of the HSNO Act.

Consideration of the application followed the relevant provisions of the Hazardous Substances and New Organisms (Methodology) Order 1998 (the Methodology), as specified in more detail below. Unless otherwise stated, references to **clause** numbers in this decision refer to clauses of the Methodology.

In accordance with clause 24 of the Methodology, the approach to consideration adopted by the Committee was to look sequentially at identification, assessment and evaluation of risks, costs and benefits. The containment regime imposed by the decision (as specified in Annex 1) and the ability of the organisms to escape containment and form self-sustaining populations were actively considered as part of this sequence. The containment regime was considered in the context of a risk management regime for controlling the identified risks (clauses 12 and 24). Those risks identified as significant were assessed in terms of clause 12 of the Methodology. Costs and benefits were assessed in accordance with clause 13 of the Methodology.

Risk characteristics were established in accordance with clause 33 of the Methodology, taking into account the containment regime. Finally, taking account of the risk characteristics, the combined impact of risks, costs and benefits was evaluation in accordance with clause 34.

The decision-making process is described in more detail in the following sections, with further reference to legislative requirements under the HSNO Act and Methodology.

Purpose of the Application

The purpose of the application was to seek permission for MAF NPPRL (primarily) and other organisations to import plant virus and viroid material to enable them to carry out disease diagnostic tests on plant quarantine and surveillance samples.

In accordance with section 45(1)(a)(i) of the HSNO Act, the Committee determined that the purpose was appropriate under section 39(1)(c) of the HSNO Act (ie maintaining new organisms for diagnostic purposes).

3 Identification of the risks, costs and benefits

The Committee conducted an identification of potential risks, costs and benefits related to the application, based on the requirements of the HSNO Act and the Methodology. Those risks, costs and benefits identified as being significant are highlighted and a discussion of their

assessment and evaluation is given in the following sections (following clauses 9 and 10 of the Methodology, which incorporate sections 5, 6 and 8 of the HSNO Act).

Risk assessment terminology

The Methodology defines costs as values of negative effects (expressed in monetary or non-monetary terms). Costs most often arise from risks. No costs were identified in relation to this application that did not arise from risks. Therefore both risks and costs are addressed under the term '**adverse effects**' in this decision. The Methodology defines benefits as values of positive effects (expressed in monetary or non-monetary terms). Benefits are addressed under the term '**beneficial effects**' in this decision. Qualitative scales used by the Committee to measure likelihood and magnitude of effect, are provided as **Annex 3** of this decision.

Adverse and beneficial effects were categorised in terms of their area of impact on:

- Environment
- Māori culture
- Economy
- Human health and safety
- Society and community

Identification of adverse effects (risks and costs)

Issues relating to the containment regime (including ability of the organisms to escape and establish a self-sustaining population and ease of eradication)

As part of the identification of adverse effects, issues affecting the adequacy of the containment regime and potential for population establishment and population eradication were identified (as required by sections 37 and 44 of the HSNO Act and clause 10(e) of the Methodology). Issues identified by the Committee as being significant are as follows:

- **Ability of the organisms to escape from containment facility**
    - Facility registration and physical containment level
    - Escape in transit (during import or transfer between facilities)
    - Handling of virus and viroid material within facility (including the scope of organisms approved)
    - Disposal of microorganisms and biological waste
    - Organism register requirements
    - Inadvertent or deliberate removal of organisms from facility
    - Contingency plans

- **Other matters**
  - Term of approval (taking into account 'grounds for reassessment')
  - Reporting requirements (to ensure compliance with controls and provide information on any grounds for approval)
  - Tracking which organisations use the approval
  - Tracking taxonomic nomenclature changes
- **Ability to establish outside containment**
  - Ability of mechanically transmitted viruses and viroids to infect plants
  - Chain of events required for infection and spread of organisms
- **Ease of eradication**
  - Ability to detect organism escape (ie a breach of containment)
  - Ability to detect the location of any self-sustaining population
  - Ability to eradicate any self-sustaining population

In addition to identification of specific containment and population establishment issues, the Committee identified adverse effects in terms of their primary area of impact (in accordance with the Methodology clauses 9(a) and (c) and 10). The Committee concurs with the identification of relevant issues provided in section 5.4 - 5.12 of the E&R Report. Those issues that the Committee considers are significant and therefore require further assessment and evaluation are highlighted below.

Adverse environmental effects

- Ability of organisms to be pathogenic to valued (particularly economic crops) or native flora and fauna (and disrupt ecosystems)
- Escape of organisms from containment and their consequent mechanical transmission to plants (eg by vectors or human intervention)
- Reduction of biodiversity of native/valued flora due to pathogenicity of viruses or viroids to valued or native flora and fauna

Adverse economic effects

- Ability of the viruses and viroids to cause economic damage to agricultural, forestry or horticultural crops and garden plants (including native flora), or cause damage to aesthetic/ recreational values - should a virus or viroid escape and establish in the uncontrolled environment.

Adverse Māori cultural effects

No significant adverse Māori cultural effects were identified. Therefore no separate assessment of adverse Māori cultural effects was conducted.

Adverse human health and safety effects

The viruses and viroids are non pathogenic to humans. No significant adverse effects to human health and safety were identified. Therefore no separate assessment of adverse human health and safety effects was conducted.

Adverse social and community effects

No adverse or beneficial effects on people and communities were identified, other than those that are addressed under other categories (environmental and economic). Therefore no separate assessment of adverse social and community effects was conducted.

Identification of beneficial effects

The Committee recognised the following beneficial effects associated with the application, in accordance with the Methodology clauses 9, 10, 13, and 14 and section 6(e) of the HSNO Act (as specified in section 5.13 – 5.18 of the E&R Report):

Beneficial environmental effects

- Environmental (biosecurity) benefits to New Zealand from improved quality of testing for plant viruses for both border control (plant quarantine) and surveillance purposes.
- Maintenance of environmental health, should diagnostic services result in improved control and/or eradication of plant viruses and viroids of native and valued plants
- Maintenance or enhancement of environmental values (ie benefits to society and communities, and potentially also to Māori culture, based on benefits to the environment)

Beneficial economic effects

- **Regarding surveillance activities**: Ability to diagnose plant diseases more quickly and accurately, thus increasing chance of early control or eradication of disease to economic plants.
- **Regarding plant quarantine activities**: Ability to diagnose plant diseases more quickly and accurately, thus potentially decreasing risk of releasing plant disease.
- Improved primary production capacity, should diagnostic services result in improved control and/or eradication of plant viruses and viroids of economic crops, and reduced loss of production while waiting for test results
- Early detection leading to more localised infestations and thus reduced costs of eradication

Beneficial Māori cultural effects

No significant beneficial Māori cultural effects were identified. Therefore no assessment of beneficial Māori cultural effects was conducted.

Beneficial human health and safety effects

No significant beneficial effects on human health and safety were identified. Therefore no assessment of beneficial human health and safety effects was conducted.

Beneficial social and community effects

No specific beneficial social and community effects were identified, other than those that are addressed under other categories (environmental, health and economic). Therefore no separate assessment of beneficial social and community effects was conducted.

4 Assessment of containment regime adequacy & potential for population establishment outside containment

In assessing adverse effects, the adequacy of the containment regime was considered (section 45(1)(a)(iii) of the HSNO Act) in relation to the ability of the organisms to escape containment; form self-sustaining populations, and the ease of eradication of any such populations (sections 37 and 44 of the HSNO Act). Risk management techniques were considered in relation to the identified risks (clause 24 of the Methodology).

Ability to escape containment

The Committee has specified controls in **Annex 1** of this decision that are required by this approval. The controls address the matters detailed in the *Third Schedule Part II: Containment controls for new organisms excluding genetically modified organisms* of the HSNO Act, and other matters in order to give effect to the purpose of the HSNO Act (section 45(2)). These controls incorporate requirements for management of risks (under clause 24 of the Methodology) posed by the importation and use of plant virus and viroid material. The containment controls have been imposed to ensure that exposure of laboratory workers and other persons, and the outside environment to risks posed by the organisms subject to this application is very unlikely.

In addition, the assessment of adverse effects (refer to section 5 of this decision) was taken into account when setting the containment requirements that are discussed in this section.

Facility registration

The basis of the containment regime is that the organisms shall be maintained in a containment facility that is registered by the MAF Biosecurity Authority in accordance with the MAF Biosecurity Authority/ERMA New Zealand Standard 154.03.02 (Containment Facilities for Microorganisms) (refer to **Control 1.2, Annex 1**). The reasons for imposing controls that are additional (and/or required clarification) to the minimum requirements specified in Microorganism Standard 154.03.02 are summarised in this section.

Physical containment level

General physical containment requirements for safe management of microorganisms in the laboratory environment are addressed in the Microorganism Standard 154.03.02. These cross-reference to detailed Physical Containment (PC) requirements in the Australian/New Zealand Standard AS/NZS 2243.3:2002 "Safety in Laboratories, Part 3: Microbiological aspects and containment facilities". In assessing the nature of the plant virus and viroid material, the Committee has set minimum PC levels for any facility holding material subject to this approval. While the general maintenance and use of the material for diagnostic procedures must be carried out at PC2, certain stages in diagnostic processes that do not involve infectious material may be carried out at PC1 (refer to additional **Control 1.13, Annex 1** for details).

The Committee notes that MAF NPPRL currently has two facilities where they intend to conduct diagnostic activities relating to this approval, at their Lincoln and Lynfield sites. These facilities are already registered as containment facilities for microorganisms [MAF reference codes 3473 (Lincoln) and 898 (Lynfield)]. The Lincoln site meets PC2 requirements, and the Lynfield site is in the process of being upgraded to PC2 level.

Escape in transit (during import or transfer between facilities)

As discussed in section 6.13 – 6.16 of the E&R Report, the general requirements for transport of microorganisms, as well as their transfer between containment facilities, are covered under sections 4.7 and 4.8 of the Microorganism Standard 154.03.02. To add clarity to the standard controls, the Committee imposed additional **Controls 1.5 – 1.7 (Annex 1)** regarding transport of the plant virus and viroid material.

Handling of virus and viroid material within facility

The general requirements for handling of microorganisms are covered in the Microorganism Standard 154.03.02. The Committee considered that a key issue regarding the ability to contain the organisms was to clearly define the scope of organisms subject to the application. Additional information was required by the Committee (refer to section 2 above for details) in order to establish whether or not a group of the organisms listed in the application did in fact trigger the definition of a viable 'organism' under the HSNO Act. The physical form in which the organisms would be imported and their mode of transmission (ie mechanical versus non-mechanical) were identified to be critical in the judgement whether or not the plant viruses and viroids were viable (and therefore 'new organisms'). It was concluded that plant viruses and viroids that were not mechanically transmitted did not meet the definition of organism in the physical form described, and therefore were outside the jurisdiction of the HSNO Act.

A further key issue identified by the Committee concerned the taxonomic level at which the plant viruses and viroids were identified. It was acknowledged that the taxonomy of viruses and viroids is particularly dynamic and that identification of individual species would be extremely problematic, and even impossible for some taxonomic groups involved. The Committee therefore accepted that it is not justified to specify individual plant viruses and viroids at the species level. The organism scope was therefore limited to the genera and other taxa as identified in Annex 2 of this decision, with the proviso that the organisms meet the controls listed in Annex 1 of this decision (in particular, the scope of organisms approved is specified in **Control 1.4, Annex 1**)

The Committee sought verification from ERMA New Zealand staff and the MAF Biosecurity Authority that compliance with Control 1.4 could be ensured (on a case-by-case basis), at the stage that MAF Biosecurity Authority receive any Import Permit Request relating to organisms covered under this approval. It was confirmed that compliance matters could be met and that the issue would be coordinated in accordance with Memorandum of Understanding (and associated operational agreements) between the MAF Biosecurity Authority and ERMA New Zealand.

An additional control was included to make absolutely clear that activation and regeneration of plant viruses and viroids by cloning is not covered by this approval (refer to **Control 1.12, Annex 1**). The Committee notes that any such genetic modification would require human intervention and would hence require a separate approval under the HSNO Act. The Committee acknowledges that inclusion of this control results from their particularly cautionary approach in approving this application, and is justified based on the potential risks to the environment, should the plant viruses and viroids be activated and regenerated by recombinant techniques. The Committee does not wish to insinuate that MAF NPPRL intend to undertake such activities.

In addition to clarifying the scope of organisms subject to the approval, the Committee imposed additional controls regarding the storage, handling, and use of organisms for

diagnostic activities (refer to additional **Controls 1.8 – 1.11, Annex 1**). As discussed in section 6 of the E&R Report, the Committee concurs that these controls are justified based on the generic range and pathogenic nature of organisms subject to the approval, the fact that no time limit has been imposed, and the fact that the applicant considers the requirements constitute standard laboratory practice.

Disposal of microorganisms and biological waste

As discussed in section 6.21 – 6.22 of the E&R Report, the general requirements for disposal of microorganisms and biological waste are covered under sections 4.6 and 4.8 of the Microorganism Standard 154.03.02. To add clarity to the standard controls, the Committee imposed a control referring to the minimum requirement for disposal of the microorganisms and biological waste (refer to **Control 1.3, Annex 1**).

Organism register requirements

As discussed in section 6.23 – 6.25 of the E&R Report, general register issues for microorganisms are covered in section 4.4 of the Microorganism Standard 154.03.02 (including the date of import, date of transfer or receipt of microorganisms from another facility and date of final disposal). To add clarity to the standard controls regarding register issues, the Committee imposed **Control 4.4** (refer to Annex 1). Refer also to discussion on reporting requirements under the heading 'Other matters' below, which includes reporting on the organism register.

Inadvertent or deliberate removal of organisms from facility/ Contingency plans

The Committee considers that accidental or deliberate removal of the organisms from containment would be very unlikely, based on the applicant's experience and the containment regime imposed. To add clarity to the standard controls regarding contingency measures in Microorganism Standard 154.03.02, the Committee imposed **Controls 1.1, 3.1-3.3 and 4.3** (refer to Annex 1).

Other matters

The Committee has the ability under section 45(2) to impose controls which address other matters than those set out under the Third Schedule of the HSNO Act, in order to give effect to the purpose of the HSNO Act. The Committee considered that such matters were relevant to this approval, as specified below.

The Committee considers that this approval should be revisited from time to time to ensure that the controls are appropriate and are effectively managing the risks. This is a particular issue in this case given the generic nature of the scope of the approval, the risks involved in the (unlikely) event of the escape of viable organisms, and the extensive suite of controls attached to this approval. To achieve this the Committee opted to not impose a fixed term for the approval, but to instead provide for periodic reporting by users of the approval. These reports can then be the basis on which the Authority can initiate the reassessment of the approval if circumstances indicate that such a reassessment is desirable. Accordingly, the Committee has imposed an additional control (refer to **Control 6.1, Annex 1**).

Based on the above control, the Committee is satisfied that sufficient information will be provided to ERMA New Zealand to enable an assessment of grounds for reassessment (under section 62 of the HSNO Act) to be provided to the Authority on (at least) a five-yearly basis.

The Committee notes that internal processes will need to be put in place within ERMA New Zealand to trigger a regular consideration of grounds for reassessment of Application NOC01004.

Another key issue the Committee considered was whether or not to allow organisations other than MAF NPPRL to use the approval. As summarised in section 6.9 – 6.12 of the E&R Report, while MAF NPPRL currently conducts the majority (approximately 90%) of virus and viroid diagnostic testing in New Zealand; similar diagnostic work is also carried out by HortResearch (Auckland and Havelock North), Crop & Food Research (Lincoln), and the University of Auckland (Auckland). Additional organisations may wish to conduct diagnostic work on a small scale in the future (eg Riversun Nurseries (Gisborne), Massey University (Palmerston North) and the University of Otago (Dunedin)). The Committee considered that as long as the controls are complied with, that excluding these organisations from using the approval is not justified. However, the Committee considers it is important for ERMA New Zealand to track what organisations do instigate use of this approval in the future. Therefore an additional control was specified, as **Control 6.2, Annex 1**.

Finally, changes in taxonomic nomenclature was identified as an issue requiring an additional control. As specified in section 4.11 – 4.15 of the E&R Report, reclassification at the genus level for viruses and viroids is reasonably common via a three-yearly review of viral taxonomy by the International Committee on Taxonomy of Viruses (ICTV). In order to maintain the list of organisms subject to this approval in a current state, the Committee considers it would be appropriate for any users of the approval to provide ERMA New Zealand with updated nomenclature changes, as specified under **Control 6.3, Annex 1**.

Summary of ability to escape containment

The Committee considers that with the containment controls it has imposed, as discussed above and detailed in **Annex 1** of this decision, the organisms can be adequately contained. It is very unlikely for viable plant virus or viroid material to escape or be removed inadvertently from containment. Although the likelihood of a breach of containment is low, the possible impact of such a breach could be substantial in economic terms. Therefore it remains a significant risk. On this basis the risk is not negligible (refer to assessment of adverse effects, section 5 below, for more detail regarding risks).

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

In accordance with sections 44 and 37 of the HSNO Act, the Committee considered the ability of the organisms to establish undesirable self-sustaining populations, should they escape from containment, and the ease with which such populations could be eradicated. In evaluating these matters the Committee took into account the nature of the organisms (clause 22 of the Methodology).

The Committee concurs with the E&R Report (section 6.47 – 6.52), that if the plant virus and viroid material is imported and maintained under the containment controls imposed in Annex 1 of this decision, it is very unlikely that any of the organisms subject to this application would breach containment. In the unlikely event that this occurred, only mechanically transmissible viruses and viroids would have the ability to infect plants.

Based on the unlikely chain of events required for infection and spread of any such plant disease to occur, it is considered very unlikely that a self-sustaining population would

establish in the uncontrolled environment. If detected readily, it is possible that any such plant disease could be eradicated. However, the Committee also notes uncertainty regarding detection and eradication. Therefore, the containment controls associated with this approval are set at a level so to ensure that inadvertent loss of material from containment is very unlikely. As noted above, the possible risks of population establishment could be substantial in economic terms. On this basis the risk of population establishment is not considered to be negligible (having taken into account the ease of eradication). Refer to assessment of adverse effects, section 5 below, for more detail regarding risks.

5 Assessment of adverse effects

Adverse environmental effects

In accordance with clauses 9(a), 9(c), 10, 12 and 13 of the Methodology, the Committee has assessed and evaluated adverse environmental effects associated with this application. In considering the nature of adverse environmental effects (clause 12(a) or the Methodology), the Committee notes that the pathogenic nature of the viruses and viroids poses risks to native and valued plant biodiversity, in the unlikely event that they breach containment in a viable state and form self-sustaining populations.

The Committee concurred with the assessment of environmental effects provided in section 7.2 – 7.10 of the E&R Report. In terms of the probability of occurrence and magnitude of adverse effects (clause 12(b) of the Methodology), the Committee notes that in their active state, only six viruses have been classified by MAF as having the potential to cause a major disruption in New Zealand to market access and/or significant economic impacts on the production of a particular commodity/commodities and/or the environment. Of these six species, only Potato Andean mottle virus is listed as being mechanically transmitted *in vivo*. The Committee considers the other species would not be able to infect plants without human intervention. The remainder of organisms subject to the application are considered by MAF in the category of having the potential to cause unacceptable economic impacts on the production of a commodity/ commodities and/or the environment. Adverse economic effects are assessed separately, below.

In the unlikely event that mechanically transmissible viruses were released and plants infected, the magnitude of their effect would depend upon the disease, what host plants were infected, and how widespread the disease became. Thus there is a degree of uncertainty associated with the magnitude of effect, which could feasibly range between minor to major (clause 12(e) of the Methodology). The Committee notes that the plants most likely to be infected would be specific economic crops. Based on the ecology of the mechanically transmissible viruses, it is unlikely that they would attack native flora. However there is uncertainty with regards to this conclusion, as host-range testing has not been conducted against native plant species. The Committee considers impacts at other trophic levels are unlikely and would have minor environmental impact.

In considering risk management options (clause 12(d) of the Methodology), as concluded in section 4 above, the Committee considers it is very unlikely that any of the organisms subject to this application would breach containment, and similarly very unlikely that a self-sustaining population would establish in the uncontrolled environment (in the very unlikely event that containment were breached). Occurrence of a new disease on the commercial crop species that are within the host range of the plant viruses and viroids concerned is likely to be able to be rapidly detected and thus infected plants could be removed or destroyed. However,

uncertainty exists (clause 12(e) of the Methodology) regarding the likelihood of detection of a self-sustaining population in the uncontrolled environment. The Committee notes that eradication, while technically feasible, would depend on the ability to detect any breach of containment and the subsequent location of any self-sustaining population.

In summary, the Committee considers that the magnitude of any adverse effects on native or valued flora and fauna would be minimal or minor in the very unlikely event of escape from containment. Although there is uncertainty about the effects of the host range of the organisms on native flora, the organism would have to first escape, and then would need to establish significantly in known hosts, from whence it could be eradicated. The Committee considers that given the proposed containment regime and potential for controlling and/or eradicating any such disease in the field, that the environmental risks are low (clause 12(d) of the Methodology).

Adverse economic effects

The Committee considered adverse economic effects in accordance with clauses 9, 10, 12 and 13 of the Methodology. In considering the nature of adverse economic effects (clause 12(a) or the Methodology), the Committee notes that the pathogenic nature of the viruses and viroids would pose economic risks, in the unlikely event that one of the organisms breach containment and attack a valued (or economically significant native) plant species.

The Committee concurs with the assessment provided in section 7.23 of the E&R Report, that in the very unlikely event that a virus or viroid escaped containment and established in the uncontrolled environment there, could be significant economic damage to agricultural, forestry or horticultural crops and garden plants (including native flora). There is uncertainty over the possible extent of this damage and it could range from minor to major (clauses 12(b) and 12(e) of the Methodology). The Committee considers that given the proposed containment regime and potential for controlling and/or eradicating any such disease (clause 12(d) of the Methodology) that the economic risks could potentially be low to moderate (clause 12(c) of the Methodology).

6 Assessment of beneficial effects

The Committee considered beneficial effects associated with this application in accordance with clauses 9, 10, 13 and 14 of the Methodology and sections 5 and 6(e) of the HSNO Act.

Beneficial environmental effects

The Committee concurs with the assessment provided in sections 7.25 – 7.27 of the E&R Report, that primary beneficial environment effects are:

- Environmental (biosecurity) benefits to New Zealand from improved quality of testing for plant viruses for both border control (quarantine) and surveillance purposes. Faster and more accurate testing will provide environmental benefit by reducing the likelihood of incursion and thus reducing the risk associated with viruses and viroids entering or establishing in New Zealand. These beneficial effects are very likely to be realised and will be of moderate to major. There is little uncertainty associated with these beneficial effects.
- Improved environmental health, should diagnostic services result in improved control and/or eradication of plant viruses and viroids of native and valued plants.

These beneficial effects are uncertain in terms of likelihood of occurrence and magnitude of effect.

- Maintenance or enhancement of environmental values (ie benefits to society and communities, and potentially also to Māori culture, based on benefits to the environment). These beneficial effects are uncertain in terms of likelihood of occurrence and magnitude of effect.

On balance, the Committee considers environmental benefits are likely to range from moderate to major (clause 13(b) of the Methodology). Environmental benefits are considered to be primarily non-monetary in nature, although indirect economic benefits may accrue (clause 13(a) of the Methodology). These benefits are likely to have impact over a wide area, with potential regional and national benefits to particular individuals, groups and communities that value the environment (clause 13(c) of the Methodology).

Beneficial economic effects

The Committee concurs with the assessment provided in sections 7.29 – 7.35 of the E&R Report, that primary beneficial economic effects are:

- The ability to diagnose plant diseases more quickly and accurately (there may be no feasible alternative to this testing regime)
- Decreasing likelihood of releasing plant disease from quarantine containment
- Increasing likelihood of early control or eradication of disease to economic plants, leading to more localised infestations and thus reduced costs of control or eradication
- Improved primary production capacity, should diagnostic services result in improved control and/or eradication of plant viruses and viroids of economic crops, and reduced loss of production while waiting for test results

The Committee acknowledges that MAF NPPRL is the government organisation responsible for carrying-out testing of imported and surveillance plant material for the presence of plant viruses and viroids in New Zealand. In many instances, there is no feasible alternative to this testing regime. Where possible, imported plants are sourced from registered pathogen-free stocks. However, there will always be a need to audit imports of such plants to ensure their health. In some instances, it may be possible to send diseased material overseas for testing. However, such facilities frequently do not exist and if they do their prohibitive cost prevents their general use. Moreover, New Zealand has little or no control over the priority accorded to the samples sent or over the quality of testing applied.

The Committee considers that the economic benefits (or reduced costs) associated with improved quarantine and surveillance procedures are very likely to be realised. The qualitative magnitude of economic benefits could range from minimal to major (clauses 13(a) and 13(b) of the Methodology). No attempt has been made to quantify the magnitude of economic benefits. There is little uncertainty associated with the likelihood of realisation, but moderate uncertainty associated with the exact magnitude of the beneficial economic effect(s). These effects are likely to have impact over a wide area, with potential regional and national economic benefits to communities and industries (clause 13(c) of the Methodology).

7 Approach to risk

Under clause 33 of the Methodology, the Authority must have regard to the extent to which the following risk characteristics exist:

(a) exposure to the risk is involuntary

(b) the risk will persist over time

(c) the risk is subject to uncontrollable spread and is likely to extend its effects beyond the immediate location of incidence

(d) the potential adverse effects are irreversible

(e) the risk is not known or understood by the general public and there is little experience or understanding of possible measures for managing the potential adverse effects.

The Committee considers that under a worst-case scenario, an affirmative response could be made in response to matters 33(a) – (d) (ie risks would be irreversible, uncontrollable and persist over time). The Committee considers that the general public would have an understanding of the nature of the risks, and that there is reasonable experience and understanding of measures for controlling such plant diseases. The Committee is willing to tolerate these risk characteristics because the potential economic cost of these organisms "escaping" into the environment in an active state is balanced by the benefit of having access to such material during diagnostic testing. That is, the more potentially costly a virus or viroid might be if introduced into New Zealand, the more important (and beneficial) it is to have access to a reference sample of the organism for quarantine or surveillance programmes. The Committee notes that in many instances, there is no feasible alternative to MAF NPPRL's diagnostic testing regime for plant viruses and viroids. Furthermore, environmental and economic benefits are very likely to be realised as an outcome of the plant disease diagnostic activities concerned.

8 Overall evaluation of risks, costs and benefits

In accordance with clauses 21 and 36(2)(b) of the Methodology, the Committee records that the following criteria in the HSNO Act and Methodology have been particularly relied on:

- The application has been considered in the context of the purpose and principles of the HSNO Act (sections 4 - 8 inclusive of the HSNO Act).
- Pursuant to section 45(1)(a)(i) of the HSNO Act, the Committee is satisfied that this application is for one of the purposes specified in section 39(1) of the Act, being section 39(1)(c) of the HSNO Act (ie maintaining new organisms for diagnostic purposes).
- The Committee considered all the possible beneficial and adverse effects of the organisms (and any inseparable organisms) in accordance with sections 45(1)(a)(ii) and (iii) of the HSNO Act. In evaluating adverse and beneficial effects (ie risks, costs and benefits) the following information has been taken into account (in accordance with clause 22 of the Methodology): (i) the nature and characteristics of the organisms, (ii) the applicant's assessments and risk management proposals, (iii) the Evaluation and Review (E&R) Report provided for ERMA New Zealand (which was collated using a recognised risk management

process in accordance with clause 24 of the Methodology), and (iv) further information commissioned under sections 58(1)(a) and (c) of the HSNO Act.

- The Committee has recognised and taken into account hazards and areas of impact as listed in clauses 9 and 10 of the Methodology, particularly in relation to evaluating adverse and beneficial effects on the environment, human health, economy, Māori culture, society and communities.
- The Committee has taken into account the characteristics of risks, costs and benefits in accordance with clauses 12, 13 and 34 of the Methodology, particularly in relation to the nature, likelihood, magnitude and spread of adverse and beneficial effects.
- The degree of uncertainty attached to scientific evidence relating to risks has been considered in accordance with clause 25 of the Methodology. In terms of clause 29(a) of the Methodology, the Committee notes that the level of material uncertainty associated with this application is small.
- In its approach to risk, the Committee had regard to the risk characteristics set down in clause 33 of the Methodology, and concluded that characteristics listed in clause 33(a) – (d) might apply in a worst-case scenario. However, the Committee is willing to tolerate these risk characteristics (and associated costs) when weighed against benefits (as summarised below).
- The Committee is satisfied that the organisms can be adequately contained (sections 45(1)(a)(iii) and 44(b) of the HSNO Act), under the controls required by this decision (refer to **Annex 1**). In relation to the additional matters to be considered under section 37 of the HSNO Act, the Committee considers that it is very unlikely for the plant virus and viroid material subject to this approval, to escape or be removed inadvertently from containment and form a self-sustaining population. However, the Committee notes that eradication, while technically feasible, would depend on the ability to detect any breach of containment and the subsequent location of any self-sustaining population.
- The Committee has formed the view that risks associated with the application are **not negligible**. Therefore, the application has been considered in terms of **clause 27** of the Methodology. The Committee considers the benefits associated with the importation and use of the viruses and viroids in containment outweigh the risks (and associated costs). The potential economic cost of these organisms "escaping" into the environment in an active state is balanced by the benefit of having access to such material during diagnostic testing. That is, the more potentially costly a virus or viroid might be if introduced into New Zealand, the more important (and beneficial) it is to have access to a reference sample of the organism for quarantine or surveillance programmes.

9 Decision

The application for importation into containment of plant viruses and viroids (in the genera and other taxa specified in **Annex 2** of this decision) is **approved** in accordance with section 45(a) of the HSNO Act. As required under section 45(2) the approval is subject to **controls** (as listed in **Annex 1** of this decision).

_____ Date: 15 May 2002

Jane Lancaster
Chair, Decision-making Committee of the Authority

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
- Standardise the wording for the notification of the first time use of this approval
- 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

Amendment: August 2011

Deletion of reporting control 6.1 -
By 31 December 2007, and thence at five-yearly intervals, a report shall be submitted to ERMA New Zealand and the MAF Biosecurity Authority by any user of this approval. For any user of this approval, such as MAF NPPRL that has more than one facility, either a separate report shall be provided from each of their facilities, or collated into one report from the user organisation as a whole. The report shall provide:

a) Information that is likely to be relevant in an assessment by ERMA New Zealand of whether or not a 'Grounds for Reassessment' is justified, including:

- Any significant new information relating to the new organisms status or the characteristics or effects of the organisms approved.
- Any change in nature or scope of import into containment.

- Any significant change in the technology and/or techniques used for diagnostic activities that affects compliance with controls.

Deletion of reporting control 6.2

The applicant (MAF NPPRL), or any other user of this approval, shall notify ERMA New Zealand of changes in nomenclature (genera and other taxa as listed in Annex 2) of the viruses and viroids imported or transferred under this approval (in which case ERMA New Zealand will consider an amendment to the organism description under section 67A of the HSNO Act).

Correction of cross referencing errors in the controls.

Deletion of the out of date Annex 2 - Organisms approved under this decision for Application NOC01004 (subject to controls in Annex 1, above).

_____ 30 August 2011

Richard Woods Date

Chair, Decision Making Committee
Environmental Protection Authority

Annex 1: Controls required by approval of Application NOC01004

In order to satisfactorily address the matters detailed in the *Third Schedule Part II: Containment controls for new organisms excluding genetically modified organisms*[1] of the HSNO Act, and other matters in order to give effect to the purpose of the HSNO Act (section 45(2)), the Authority's approval of this application is 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 person responsible for a particular research area and/or 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.

1.2 The containment facility in which the organisms are maintained shall be registered by the Ministry of Agriculture and Forestry (MAF) Biosecurity Authority in accordance with the MAF Biosecurity Authority/ERMA New Zealand Standard 154.03.02[3] (Containment Facilities for Microorganisms). The construction and operation of the containment facilities ('the facility') in which the organisms are maintained, shall be in accordance with the relevant standard listed above. Requirements for microorganism Physical Containment (PC) are addressed under Control 1.14, below.

1.3 Disposal of microorganisms and biological waste shall comply with the requirements of the standards listed in Control 1.2. The minimum requirement is for such material to be classed as infectious and disposed of as described in section 9 of the AS/NZ standard 2243.3:2002[3].

Additional controls relating to the scope of organisms approved, transport, storage and handling requirements:

1.4 The scope of organisms is limited to those plant viruses and viroids[4], that are:

a) capable of mechanical transmission. Where there is uncertainty about whether or not a virus or viroid is capable of mechanical transmission, it must be treated as being mechanically transmissible, and

b) in an inactive state in dried plant tissues or plant tissues homogenised in extraction buffer and dried (ie importation of live plant material containing actively replicating viruses and viroids is excluded), and

c) only to be used for the purpose of developing serological and molecular diagnostic tests for plant viral and viroid diseases.

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[1] Bold headings refer to matters to be addressed by containment controls for new organisms excluding genetically modified organisms, specified in the Third Schedule (Part II) of the HSNO Act 1996.

[2] Viable Genetic Material is biological material that can be resuscitated to grow into tissues or organisms. It is defined to mean biological material capable of growth even though resuscitation procedures may be required, eg 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.

[4] **Explanatory note:** The issue of whether or not viruses and viroids fall within the scope of this approval is a compliance matter that we expect the MAF Biosecurity Authority will consider on a case-by-case basis at the stage of an Import Permit request. This issue will be coordinated in accordance with the Memorandum of Understanding (and associated agreements) concerning the inter-relationship between ERMA New Zealand and the MAF Biosecurity Authority. Discussed further in section 4 of this decision.

1.5 All plant virus and viroid material shall be imported directly from either recognised culture collections or from recognised experts in plant viruses and/or viroids (refer also to Control 4.3).

1.6 The minimum requirement for packaging for transportation of the viruses and viroids by all modes (ie air, land and sea) from overseas and for transfers between facilities, is for the organisms to be packaged according to Packaging Instruction No. 602 of the International Air Transport Association (IATA) Dangerous Goods Regulations. All packages must be clearly labelled with the name, address and phone number of both the sender and the recipient.

1.7 During transport, packages containing organisms subject to this approval shall not be opened. Packages must only be opened in a registered PC2 containment facility (as defined under Control 1.2).

1.8 Virus- and viroid-infected material subject to this approval shall not be used to deliberately infect new, live plant hosts.

1.9 Each sample of virus or viroid subject to this approval must be limited to no more than 1 gram (ie multiple samples are allowed).

1.10 No live plants shall be permitted in the same rooms within the facility as the organisms covered by this approval.

1.11 All virus- and viroid-infected samples shall be kept in double-sealed containers and when not in use shall be stored in a locked metal cabinet.

1.12 The activation and regeneration of plant viruses and viroids subject to this application by cloning of the whole genome (or parts of the genome that lead to infectious particles) is prohibited (unless otherwise approved under section 40 of the HSNO Act).

1.13 All diagnostic procedures involving viable virus or viroid material shall be carried out at Physical Containment Level 2 (PC2) [as specified in the AS/NZS 2243.3:2002[3] standard "Safety in Laboratories, Part 3: Microbiological aspects and containment facilities"]. Extraction of nucleic acid for molecular analysis (eg PCR) shall occur in a PC2 containment laboratory. Processes subsequent to this and involving non-infectious material may be carried out in Physical Containment Level (PC1). Serological procedures (eg ELISA) shall occur in Physical Containment Level 2 (PC2), until after homogenised sample material has been removed post incubation. Processes subsequent to this and involving non-infectious material may be carried out in Physical Containment Level (PC1). Samples shall be transported in closed containers between Physical Containment Level 2 (PC2) and Physical Containment Level 1 (PC1) laboratories. Disposal of viable virus and viroid material and biological waste shall be as per control 1.3 (above).

2 To exclude unauthorised people from the facility:

2.1 Construction and operation of the containment facility shall comply with the requirements of the standards listed in control 1.2 relating to the identification of entrances, numbers of and access to entrances and security requirements for the entrances and the facility.

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

3.1 Construction and operation of the containment facility shall comply with the requirements of the standards listed in Control 1.2 relating to controlling the effects of any accidental release or escape of an organism.

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 Any user of this approval must develop a contingency plan for inclusion into the containment facility manual in accordance with the requirements of standards listed in Control 1.2. In the event of any breach of containment of the viruses or viroids, the contingency plan for the attempted retrieval or destruction of any viable material of the organism that has escaped shall be implemented immediately.

4 Inspection and monitoring requirements for containment facilities:

4.1 The operation of the containment facilities shall comply with the requirements contained in the standards listed in Control 1.2 relating to the inspection and monitoring requirements for containment facilities.

4.2 The containment manual shall be updated, as necessary, to address the implementation of the controls imposed by this approval, in accordance with the Standards listed in Control 1.2.

4.3 An organism register will be kept by any user of this approval of all viruses and viroids maintained under this approval, in accordance with the Standards listed in Control 1.2. The register shall include the identity and origin [including source (as per Control 1.5) and country] of each virus and viroid, as well as its date of import, date of transfer or receipt from another facility, and date (and method) of final disposal.

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

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

6 Other matters:

Reporting

6.1 Any person 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.

Annex 2: Qualitative scales for describing adverse & beneficial effects

The following qualitative scale has been used to describe the likelihood of an adverse or beneficial effect occurring:

Table 1: Likelihood of effect

Descriptor	Description
Very unlikely	Not impossible, but only occurring in exceptional circumstances
Unlikely	Could occur, but is not expected to occur under normal conditions

Equally likely or unlikely	50:50 chance of occurring
Likely	Will probably occur at some time
Very likely (almost certain)	Is expected to occur

The following qualitative scale has been used to describe the magnitude (or measure of the severity) of an adverse effect occurring:

Table 2: Magnitude of adverse effect

Descriptor	Examples of descriptors for type and extent of adverse effect
Minimal	Slight or insignificant, repairable or reversible, very localised (affecting only a few individuals, single plants/animals or individual businesses), no flow-on effects, acute rather than chronic, not affecting native or valued species
Minor	Small, reversible and short term, localised to small land area or local community, acute, possible affecting valued species but not native species
Moderate	Medium or mid range, largely but not completely reversible or medium term effect, some limited flow-on effects, slight effect on native species, affecting plants/animals/people/small industry over a wide area, but not necessarily over the whole country
Major	Large, long term effect, but no species loss, affecting the whole country, both acute and chronic health effects possibly leading to small number of deaths or reduced life expectancy
Massive	Huge and widespread, irreversible, national impact, considerable secondary effects, acute and chronic health effects leading to deaths, species loss, serious social and cultural damage with displacement of persons and loss of livelihood, major economic disaster

The word scale used to describe the likelihood of beneficial effects is the same as stated in Table 1 above. The following qualitative scale has been used to describe the magnitude (or expected value) of a beneficial effect occurring:

Table 3: Magnitude of beneficial effect

Descriptor	Examples of descriptors for type and extent of beneficial effect
Minimal	slight or insignificant, short term, very localised (affecting only a few individuals, single plants/animals), no flow-on effects
Minor	small, reversible, localised to small land area, a group of individuals, a single company/organisation or a local community
Moderate	medium or mid range, medium term, affecting plants/animals/people/small industry over a wide area, but not necessarily over the whole country, some flow-on effects, regional short/medium term reduction in a weed/pest
Major	large, affecting large communities and industries, some national impact
Massive	huge and widespread, long term, national impact, extensive secondary or flow-on effects, eradication of a weed/pest, large increases in employment, development of a new industry