ENVIRONMENTAL RISK MANAGEMENT AUTHORITY DECISION

Amended under s67A of the HSNO Act on 28 January 2009, 27 April 2009, 1 December 2009 and 19 May 2010

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24 September 2008

Application code:	NOC07009
Application category:	Import into Containment any New Organism under the Hazardous Substances and New Organisms (HSNO) Act 1996
Applicant:	MAF Biosecurity New Zealand
Purpose:	To import and hold exotic plant pathogenic and saprobic bacteria and fungi in containment, in order to develop diagnostic methods and for laboratory-based research purposes
Date application received:	14 August 2008
Consideration date:	22 September 2008
Considered by:	Committee of the Authority

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1 Summary of Decision

1.1 The application to import into containment exotic plant pathogenic and saprobic bacteria and fungi, in order to develop diagnostic methods and for laboratory-based research purposes 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. The application was 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.

2.2 Consideration of the application followed the relevant provisions of the Methodology, as specified in more detail below.

3 Application Process

Application receipt

3.1 Application NOC07009 was determined to be in compliance with section 40(2) of the Act and was formally received on 14 August 2008.

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 following ERMA New Zealand guidelines because it was considered unlikely that this application for containment would be of significant public interest.

3.3 In accordance with section 58(1)(c) of the Act and clauses 2(2)(e) and 5 of the Methodology, both the Ministry of Agriculture and Forestry (MAF) Biosecurity New Zealand (BNZ) and the Department of Conservation (DoC) were considered as having an opportunity to comment on the application. Comments received from both MAF and DOC have been taken into consideration.

Decision Making Committee

3.4 The application was considered by the New Organisms (Non-GMO) Standing Committee of the Authority appointed in accordance with section 19(2)(b) of the Act. The Committee comprised the following members: Kieran Elborough (Chair) and Manuka Henare.

Information Available for Consideration

3.5 The documents available for the consideration of the application by the Committee were:

- application NOC07009 (Form NO2N): Import into containment any new organism that is not genetically modified;
- scientific papers cited in the application;
- a memo from the Agency to the Committee to assist and support the Committee's decision-making; and
- comments received from agencies notified.

3.6 MAF did not oppose this application. MAF has provided comments in relation to the clarity of information, the adequacy of controls and suggested additional controls. MAF concerns involve the wide scope of the application as embodied by the purpose of the application and the adequacy of the containment standard. Both issues are addressed during relevant sections of this decision.

3.7 DOC did not oppose this application as they consider the containment system adequate to manage the risk of importation and noted the benefit of improved detection of exotic diseases. In addition DOC suggested a precautionary approach be taken when considering the possible negative impacts the micro-organisms may have on the natural environment. The Committee has taken such a precautionary approach with regard to areas where there is scientific and technical uncertainty of effects as required by Part 2 of the HSNO Act.

3.8 Recognised techniques were used in identifying, assessing, and evaluating the relevant information, as required under clause 24 of the Methodology.

4 Sequence of the Consideration

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

4.2 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 likelihood of the risks, costs and benefits alongside each other and in an integrated fashion. This is because the magnitude interacts with the likelihood as recognised in clause 12(d) of the Methodology and in section 45(1)(a)(ii) of the Act.

4.3 The Committee set controls to satisfactorily provide for the matters in the Third Schedule (Part II) of the Act.

4.4 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.

4.5 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.

5 Purpose of the Application

5.1 MAF Biosecurity New Zealand wishes to import into containment exotic plant pathogenic and saprobic bacteria and fungi, in order to develop diagnostic methods and for laboratory-based research purposes.

5.2 The Committee notes the concerns raised by the MAF submission that the purpose of the application is too ambiguous. Whilst the Committee recognises that the application purpose itself is broad, as a description it is very clear allowing applicants to import and hold exotic plant pathogenic and saprobic bacteria and fungi in containment, in order to develop diagnostic methods and for laboratory-based research purposes. The purpose when taken in conjunction with the organism description allows for the importation of fungal and bacterial species belonging to the Kingdoms Fungi, Chromista, Protozoa and Bacteria which are pathogenic to plants or

saprobes (excluding those classified as greater than Risk Group 2 and those pathogenic to people or animals).

5.3 The Committee was satisfied that the application was for a valid purpose under section 39(1)(h) of the HSNO Act being "*such other purposes as the Authority thinks fit*".

6 Adequacy of the Containment Regime

Ability to adequately contain the organisms

6.1 In considering the ability of the organisms to escape from containment, the Committee considered the following:

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

(i) Biological characteristics of the organisms

Kingdom Fungi

6.2 The applicant wishes to import from the Kingdom Fungi including the following phyla: Ascomycota, Basidiomycota, Chytridiomycota and Zygomycota, and the artificial taxonomic group Anamorphic fungi. Any species in these phyla which are human and animal pathogens are excluded under this approval.

6.3 Fungi are decomposers of organic matter and a major cause of plant disease. They exist primarily as filamentous hyphae, producing spores sexually and asexually. Their life modes varies from saprobic, endophytic, mutualistic, opportunistic pathogenic, to obligate pathogenic.

6.4 Dispersal occurs in a number of ways including: actively dispersed spores, passively as spores carried by wind, water splash, and through the movement of animals; by the growing of infected seeds, cuttings, bulbs, and other plant material and on contaminated tools and equipment.

6.5 Spore size generally varies from 10 to 100 µm (micrometres) in diameter. An atmospheric study by Bauer et al (2002) found the smallest spores to be around 2 µm in diameter.

6.6 The Committee notes that no species known to be human and animal pathogens will be imported under this application. The Committee also notes that any species classified as greater than Risk Group 2 cannot be imported under this application.

Kingdom Chromista

6.7 The applicant wishes to import from the Kingdom Chromista, including the following phyla: Oomycota, Hyphochytriomycota and Labyrinthulomycota. Any species in these phyla which are human and animal pathogens are excluded under this approval.

6.8 The chromists that are the focus of this approval were once classified as fungi and are either saprobic or cause plant diseases, such as the downy, mildews and *Phytophthora*. They exist primarily as filamentous hyphae, producing spores sexually and asexually. Their life modes vary from saprobic, opportunistic pathogenic, to obligate pathogenic.

6.9 They can be transmitted by various means such as the passive dispersal of spores in water or by the wind, and by animals; on infected seeds, cuttings, bulbs, and other plant material; on contaminated tools and equipment.

6.10 The Committee notes that no species known to be human and animal pathogens will be imported under this application. The Committee also notes that any species classified as greater than Risk Group 2 cannot be imported under this application.

Kingdom Protozoa

6.11 The applicant wishes to import from the Kingdom Protozoa including the Phyla Plasmodiophoromycota. Any species in this phylum which are human and animal pathogens are excluded under this approval.

6.12 Some of the protozoa that are the focus of this approval were once classified as fungi and are either saprobic or cause plant diseases, such as potato wart disease. They exist primarily as single cells, reproducing sexually and asexually.

6.13 They can be transmitted by various means, such as active dispersal of spores, or passively by water and animals; growing infected plant material; carried over by contaminated tools and equipment.

6.14 The Committee notes that no species known to be human and animal pathogens will be imported under this application. The Committee also notes that any species classified as greater than Risk Group 2 cannot be imported under this application.

Kingdom Bacteria

6.15 The applicant wishes to import from the Kingdom Bacteria including the following Phyla: Acidobacteria, Actinobacteria, Aquificae, Bacteroidetes, Chlamydiae, Chlorobi, Chloroflexi, Chrysiogenetes, Cyanobacteria, Deferribacteres, Deinococcus-Thermus, Dictyoglomi, Fibrobacteres, Firmicutes, Fusobacteria, Nitrospirae, Planctomycetes, Proteobacteria, Spirochaetes, Thermodesulfobacteria, Thermomicrobia, Thermotogae and Verrucomicrobia.

6.16 Bacteria are important decomposer, nitrogen fixers, and causal agents of plant diseases. They exist primarily as single cells, mainly reproducing asexually.

6.17 They can be transmitted by various means, ie passively in water droplets, windborne aerosols, by insects, infected seeds, cuttings, bulbs, and other plant material; and on contaminated tools and equipment.

6.18 The Committee notes that no species known to be human and animal pathogens will be imported under this application. The Committee also notes that any species classified as greater than Risk Group 2 cannot be imported under this application.

(ii) Containment regime

6.19 The Committee notes that all imported species will be housed in a facility registered according to the MAF Biosecurity New Zealand/ERMA Standard *Facilities for Microorganisms and Cell Culture: 2007* (the Microorganism Standard). Furthermore, the facility used by the MAF Plant Health and Environment Laboratory is current rated as physical containment level 2 (PC2 under the AS/NZS Standard 2243.3:2002 *Safety in Laboratories, Part 3 Microbiology*).

6.20 The Committee notes comments in the MAF submission that additional containment standards may be required in order to adequately contain the organisms to be imported. For example MAF points out that Chromista which include multicellular algae (eg. Giant kelp), are unable to be fully managed under the Microorganism standard. The Committee considers organisms such as this to be outside the scope of this application. The application purpose statement is "To import and hold exotic plant pathogenic and saprobic bacteria and fungi in containment, in order to develop diagnostic methods and for laboratory-based research purposes". The organisms to be imported are therefore limited to species that are either fungal or bacterial. All these species are micro-organisms and hence the Committee believes the Microorganism Standard coupled with the controls it has imposed are adequate to manage the risk of escape from containment.

6.21 The Committee considers that a minimum containment level of PC1 is an appropriate level for species classified as Risk Group 1. Further to this the Committee considers that a containment level of PC2 is appropriate for species which are known to be classified as Risk Group 2 or have not yet been classified to a risk group. These two levels of containment have been reflected in the controls. The Committee also notes that the production of aerial propagules must be taken into account when considering containment. Therefore open container manipulations for all organisms are required to occur inside a class II biological safety cabinet until it can be shown and documented that the organism is not producing aerially dispersed propagules. If an organism is both classified as Risk Group 1 and has been shown to produce no aerially dispersed propagules then further open container manipulations can be done outside of a class II biological safety cabinet. If an organism does not meet both criteria all open container manipulations must continue in a class II biological safety cabinet.

6.22 In addition the Committee notes that the containment facility is registered under the Microorganism Standard which 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 Microorganism Standard ensure that containment is maintained by controlling access to the facility, disease surveillance and quarantine measures, confirmation of identity, staff training, contingency plans, waste disposal, record keeping and packaging for organisms in transit. The Committee is satisfied

that the containment regime as outlined in this report will be effective in containing the species to be imported.

(iii) Potential pathways for escape of organisms from the containment facility

6.23 In accordance with Section 37 of the Act, the Committee considered the ability of the organisms to escape from containment. The pathways identified and the associated mitigating factors are discussed below.

6.24 The Committee has identified the following potential routes by which the organism may escape from containment:

a) Escape of organisms during transport to containment facilities;

b) Escape of organisms from containment facility due to accidental/unintentional or deliberate removal of the organisms by staff

c) Escape of organisms from containment facility due to accidental/unintentional or deliberate removal of the organisms by unauthorized persons

d) Escape of organisms through the release of viable air- or water-borne micro-organisms or propagules;

e) Escape of organisms through contaminated equipment or clothing;

f) Escape from containment following natural disaster or emergency.

6.25 The Committee notes the strict requirements surrounding the transport of organisms to containment facilities. For example, the Microorganism Standard requires that transportation of organisms to or between containment facilities complies with the International Air Transport Association (IATA) Dangerous Goods Regulations. The Committee considered that these measures reduce the likelihood of escape during transport.

6.26 The Committee notes that procedures are required to be in place that reduces the risk of unintentional or accidental escape of the organism from the containment facility. The Microorganism Standard requires training of all people working in the containment facility as well as internal audits to be carried out and records of all organisms held in the facility to be maintained. The Committee considered that these measures, coupled with good laboratory practices reduce the likelihood of accidental or unintentional removal by staff.

6.27 The Committee notes that measures that address the potential escape through the deliberate removal of the organism are required. The Microorganism Standard also requires signs to indicate restricted access, procedures to prevent unauthorised access to the containment facility, and entrances to be locked when not in active use. The Committee considered that these measures reduced the likelihood for organisms to be removed deliberately or accidentally by unauthorised persons.

6.28 The Committee notes that some of the organisms are capable of spreading via air- or water-borne micro-organisms or propagules. The Committee notes the design of the containment facility reduces the likelihood of escape. This includes requiring all

vented air to pass through a HEPA filter. In addition any sub-culturing and the initial stages of DNA extraction on the organisms are to be done in a Class II Biological Safety Cabinet. The Committee considers that these measures reduce the level of likelihood that the organism will escape via this pathway.

6.29 The Committee notes that the organism is capable of spreading via contaminated laboratory equipment or clothing. The Committee notes that all micro-organisms and biological waste are disposed of and/or treated according to the guidelines in the AS/NZS 2243.3: 2002 Standard. The Committee considers that this measure reduces the likelihood of escape via this pathway.

6.30 The Committee also notes that escape of organisms following fire or natural disaster would only occur if the event compromised the containment facility and the containment vessel the organism was held within.

Conclusion on the adequacy of the containment regime

6.31 The Committee has considered the ability of the organism to escape containment given its biological characteristics, the proposed containment regime and the potential pathways of escape. Taking all of these into consideration the Committee concludes that it is **highly improbable** that the organisms would be able to escape from containment.

6.32 The Committee has imposed additional control 6.1 requiring all users of the approval to notify ERMA New Zealand and MAF BNZ when they first exercise the approval. This is for compliance monitoring purposes and to ensure that ERMA New Zealand is aware of all users of the approval in case a reassessment[1] or amendment[2] of the approval is warranted.

7 Ability of the organism to establish an undesirable self-sustaining population

7.1 In accordance with sections 44 and 37 and clause 10(e), the Committee considered with regard to the species to be imported their ability to form an undersirable self-sustaining population should they escape from containment, and the ease at which these populations could be eradicated.

7.2 The Committee notes that the purpose of the application is to import into containment exotic plant pathogenic and saprobic bacteria and fungi, in order to develop diagnostic methods and for laboratory-based research purposes. In particular the committee notes the intention to import new organisms in order to allow that diagnostic tests be developed for potential pests of New Zealand's environment. Given their status as potential pests it is possible for them to establish in New Zealand should they escape. The Committee notes that many of these species require specific environmental conditions for transmission for example a specific vector. There is significant uncertainty around the likelihood of establishment however the Committee believes

[1] Section 62 of the Act.

[2] Section 67A of the Act.

that the likelihood will range from **unlikely** to **likely** depending on the species released and the number of propagules that escape containment.

8 Identification and assessment of potentially significant adverse effects (risks and costs)

8.1 In accordance with clause 9(c), the Committee has categorised potential adverse effects into environmental, human health and safety, Māori culture and traditions, society and communities, and the market economy. These adverse effects have been considered in terms of the requirements of clauses 12, 13, and 14 including the probability of occurrence and the magnitude of adverse effects, whether or not they are monetary, the distribution of costs and benefits over time, space and groups in the community. Risk characteristics are considered in terms of clause 33. The degree of uncertainty attached to evidence is taken into account, as required under clauses 25, 29 and 30.

The Environment

8.2 The Committee considered the potential for the species to have an adverse effect on the environment. The Committee noted that no species known to be human or animal pathogens will be imported. Therefore potential damage to the environment is limited to damage to native flora. The level of impact should such an effect occur would be highly dependent on the species which escaped and established. The Committee believes this impact could range from **minimal** to **minor** depending on the importance of the affected species. However, the Committee noted that taking into account the containment regime the likelihood of such risks occurring is **improbable** to **highly improbable**. This results in a level of risk **A - B**. The Committee concluded that this risk was negligible.

Human health and safety

8.3 The Committee noted that no species known to be pathogenic to humans are to be imported. The Committee therefore concluded that this effect was not significant and did not warrant further analysis.

8.4 The applicant has consulted local tangata whenua. No additional risks to the relationship of Māori and their culture and traditions with ancestral lands, waters, sites, waahi tapu, valued flora and fauna, and other taonga were identified by the tangata whenua.

Māori and their culture and traditions

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

8.6 The Committee considered the potential for adverse Māori cultural effects through displacement of taonga species with flow-on effects to both kaitiakitanga and to mauri of non-target taonga species. Consultation by the applicant did not produce any further cultural effects to be assessed.

8.2 Given the assessment presented in paragraph 8.2 of this report the Committee considered that the adverse effects to Māori were not significant and did not warrant further analysis.

Society and the community

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

The market economy

8.4 The Committee considered the potential for the species to have an adverse effect on the market economy. The Committee noted that no species known to be human or animal pathogens will be imported. Therefore potential damage to the market economy is limited to damage to crops and other economically important plants. The level of impact should such an effect occur would be highly dependent on the species which escaped and established. The Committee believes this impact could range from **minimal** to **minor** depending on the importance of the affected species. However, the Committee noted that taking into account the containment regime the likelihood of such risks occurring is **improbable** to **highly improbable**. This results in a level of risk **A - B**. The Committee concluded that this risk was negligible.

9 Identification and assessment of potentially significant beneficial effects

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

- Increased scientific knowledge and expertise of researchers and diagnosticians
- Improved detection of plant pathogens entering into New Zealand.

9.2 The Committee considered that the opportunity to hold these saprobic and plant pathogenic species in containment would provide increased research opportunities and allow for increased scientific knowledge and expertise by researchers and diagnosticians. This would in addition lead to improved detection of plant pathogens into New Zealand. The Committee considered the magnitude of this benefit to be **minor** and the likelihood of it being realised as **very likely**. This results in a level of benefit **E**. The Committee concluded that this benefit was non-negligible.

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

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

10.2 In relation to the biological and physical risks considered (including the risks to human health), the containment measures limit the extent to which exposure to the risks is involuntary. The Committee also considered 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 and the establishment of an undesirable self-sustaining population. Given the Committee's finding that the risk of escape from containment and establishing an undesirable self-sustaining population is highly improbable, the extent to which these risk characteristics are present does not warrant caution additional to that required by section 7 of the Act.

11 Associated approvals

11.1 The Committee noted the need for the applicant to obtain a permit to import these species from MAF, which will require adherence to the relevant Import Health Standard designed to mitigate the risk of any associated organisms.

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 Committee has assessed the potential risks of importing these organisms into containment as being negligible.

12.3 The Committee considers that the benefits are very likely to be realised and are non-negligible.

12.4 The Committee notes that the proposed containment regime, based on the Microorganism Standard and additional controls are considered to be adequate considering the risks posed by the organisms. Additionally, it is considered highly improbable that the organisms would be able to escape from the proposed containment system and establish an undesirable self-sustaining population.

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

12.6 The Committee considered all of the controls set out in Appendix 1, taking into account the cost effectiveness of the control in preventing the escape of the organisms and effectively managing any risks. The Committee, having regard to these matters, is satisfied that the organisms can be adequately contained, and that it is evident that the 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 one of the purposes specified in section 39(1) of the Act, namely 39(1)(h*): such other purposes as the Authority thinks fit*.

13.2 Having considered all the possible effects in accordance with sections 45(1)(a)(ii), 45(4) and 44 and pursuant to clause 26 of the Methodology, and based on consideration and analysis of the information provided and taking into account the application of risk management controls specified in this decision, the view of the Committee is that the risks (or costs) of adverse effects associated with the importation into containment of these species is outweighed by the benefits.

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

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

- section 44 additional matters to be considered;
- section 45 determination of application;
- section 37 additional matters to be considered; and
- the Third Schedule (Part 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 plant pathogenic and saprobic species excluding any species which are (a) pathogenic to humans; (b) pathogenic to animals; or (c) classified as greater than risk group 2, in the Kingdoms Fungi, Chromista, Protozoa and Bacteria 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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Kieran Elborough Date: 24 September 2008

Chair of the New Organisms (GMO) Committee

Approval code: NOC002529

Amendment: January 2009

Changes to controls:

- Control 2.2A has been amended to reflect the fact that packages should not be opened at the border.
- Control 2.6 has been added to restrict the use of this approval.
- Renumbering of controls.

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Kieran Elborough Date: 28 January 2009

Chair of the Committee

Amendment: March 2009

To make a minor technical amendment by:

- Replacing incorrect references to MAF Biosecurity New Zealand
- Removing redundant wording and simplifying wording
- Bringing the wording of controls in line with that of recent decisions

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Kieran Elborough Date: 27 April 2009

Chair of the Committee

Amendment: November 2009

To make a minor technical amendment by:

- Removing a redundant control

_____ 1 December 2009

Kieran Elborough Date:

Chair of the Committee

Amendment: May 2010

To make a minor technical amendment by:

- Removing a redundant control and simplifying wording

_____ 19 May 2010

Kieran Elborough Date

Chair of the Committee

References

Bauer, H, Kasper-Giebl, A, Löflund, M, Giebl, H, Hitzenberger, R, Zibuschka, F, Puxbaum, H 2002. The contribution of bacteria and fungal spores to the organic carbon content of cloud water, precipitation and aerosols. *Atmospheric Research* 64**:** 109-119.

Appendix 1: Controls Required by this Approval

The purpose of this approval is to:

> *To import and hold exotic plant pathogenic and saprobic bacteria and fungi in containment, in order to develop diagnostic methods and for laboratory-based research purposes.*

The organisms approved are:

> *Plant pathogenic and saprobic species in the Kingdoms Fungi, Chromista, Protozoa and Bacteria. Any species pathogenic to humans or animals or classified as greater than Risk Group 2 are specifically **excluded** from this approval.*

In order to satisfactorily address the matters detailed in the sections 32(2), 45(2) and the Third Schedule of the HSNO Act the organism(s) and any containment facility it is contained in are subject to all of the following controls:

1 Requirement to meet the Standards

1.1 The containment facility must be approved by MAF under section 39 of the Biosecurity Act.

1.2 For species classified as Risk Group 1 (as defined in AS/NZS 2243.3:2002[3]) the containment facility must at the minimum be constructed and operated in accordance with the:

a) MAF Biosecurity New Zealand/ERMA New Zealand Standard *Facilities for Microorganisms and Cell Culture: 2007* (the Microorganism Standard).[3]

b) Physical Containment Level 1 (PC1) requirements of the Australian New Zealand Standard AS/NZS 2243.3:2002 [3]

1.3 For species classified as Risk Group 2 or lacking a Risk Group classification (as defined in AS/NZS 2243.3:2002[3]) the containment facility must at the minimum be constructed and operated in accordance with the:

a) MAF Biosecurity New Zealand/ERMA New Zealand Standard *Facilities for Microorganisms and Cell Culture: 2007* (the Microorganism Standard).[3]

b) Physical Containment Level 2 (PC2) requirements of the Australian New Zealand Standard AS/NZS 2243.3:2002[3].

1.4 When being transported the packaging for the organisms must meet the relevant requirements of the Australian New Zealand Standard AS/NZS 2243.3:2002[3]

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

2 Controls additional to the Standards

2.1 The Operator must ensure that ERMA New Zealand and the MAF Inspector responsible for supervision of the facility are notified of the facility's intention to use this approval in writing prior to first use.

2.2 The Operator must ensure that the organisms do not escape in transit and will at the minimum ensure that:

a) All packages are labelled with the ERMA New Zealand **approval code** and specify the instruction that the package should not be opened at the border, and shall only be opened within a containment facility.

b) This labelling will be clearly visible and able to be read without the package being opened.

2.3 The Operator must ensure that no new organisms escape by performing all 'open container' manipulations of these organisms in a class II biological safety cabinet operated in accordance with AS/NZS 2243.3:2002 until such time that the Operator has assessed and documented that aerial dispersal propagules are not formed by the organism being examined. At such time that the Operator has assessed and documented that aerially dispersed propagules are not formed by the organism being examined then 'open container' manipulations of Risk Group 1 new organisms can occur outside of a class II biological safety cabinet. For the purposes of this approval, 'open container' manipulations do not include those carried out inside an anaerobic chamber.

2.4 *In planta* work can be carried out under this approval with the exception of the fungi orders; *Uredinales* (rusts) and *Ustilaginales* (smuts).

2.5 If a breach of containment occurs[4] the Operator must ensure that the MAF Inspector responsible for supervision of the facility has received notification of the breach within 24 hours.

[4] Breach of containment includes: escape of organism(s), unauthorised entry to facility, and/or structural integrity of facility compromised.