ERMA New Zealand
Evaluation & Review Report

Application for approval to import into containment dried herbarium specimens from the Kingdoms Plantae, Mycenae, Protista and Cyanobacteria

Application Code: NOC04018

Prepared for the
Environmental Risk Management Authority

Key Considerations

The key considerations associated with this application are:

- The application is for four Kingdoms (Plantae, Mycenae, Protista and Cyanobacteria) and therefore covers a wide variety of organisms. In order to manage a diverse collection of dried specimens of four of the five Kingdoms of life in containment, additional controls are proposed. The fifth Kingdom, Animalia, is excluded from this application.

- The MAF Biosecurity New Zealand/ERMA New Zealand Standard 155.04.09: *Containment Facilities for New Organisms (including genetically modified organisms) of Plant Species*, is proposed as the containment standard for the organisms in this application. The project team considers that organisms that may otherwise be contained under the microorganisms standard (MAF Biosecurity New Zealand/ERMA New Zealand Standard 155.03.02: *Containment Facilities for Microorganisms*) are able to be contained under the plants standard because they are herbarium specimens. Additionally, some of the smaller organisms may not be very different from some plant spores or seeds in terms of their size and consequent requirement for containment.

- The applicant wishes to be able to temporarily transfer herbarium specimens (or parts thereof) to non-containment facilities for use in public displays and for analysis. The project team has considered this as a potential pathway for escape into the environment and has proposed an additional control to mitigate the risk posed by this activity.

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1 Introduction

Aim of the Evaluation and Review Report

1.1 The purpose of this Evaluation and Review (E&R) Report is to assist and support decision-making by the Environmental Risk Management Authority (the Authority) by consolidating information provided by the applicant and obtained from other sources into a format and sequence that is consistent with the decision-making requirements of the Hazardous Substances and New Organisms (HSNO) Act 1996 (the Act) and of the HSNO (Methodology) Order 1998 (the Methodology). The E&R Report does not make recommendations, nor direct or prejudge the decision that the Authority might make on the application. The relevant decision path with explanatory notes is provided in Appendix 1 of this report.

1.2 The project team consisted of the following ERMA New Zealand staff members:

- Sarah McLean Applications Advisor (New Organisms)
- Dr Abdul Moeed Senior Scientific Advisor (New Organisms)
- Peter Jackson Māori Advisor

1.3 This E&R Report was reviewed by Dr Geoff Ridley and Mr Shaun Slattery, and reviewed and signed out on 22 November 2005 by Dr Libby Harrison, Group Manager, New Organisms.

Decision path

1.4 This application is required to be considered by the Authority in accordance with section 40 of the Act as dried herbarium specimens from the Kingdoms Plantae, Mycenae, Protista and Cyanobacteria may contain viable material such as seeds, spores or pollen, that are new organisms according to section 2A of the Act.

1.5 The decision path to be used in the consideration of this application is for *applications to import into containment a new organism (non-GMO)*. A copy of this path and explanatory notes are appended to this report (Appendix 1). The source of this decision path is the ERMA New Zealand Protocol on Decision Paths, Protocol 2.

Application receipt and public notification

1.6 A draft of the application was received in 2004 and assigned application code NOC04018. The application was formally received on 18 October 2005.

1.7 The Authority has discretion, upon receipt of an application *to import into containment any new organism*, to decide whether or not it is publicly notified (section 53(2) of the Act).

1.8 In this case the application was not publicly notified because it was considered to be unlikely that there would be significant public interest in the application as the activity covered by the application has a historical basis and it is being formalised under the Act. This conclusion was based on the grounds that there are no novel

features of these organisms and no unprecedented issues are raised by this application. The risks associated with these organisms are expected to be low. The project team also considered that is was very unlikely that public submissions would contribute materially to the Authority's consideration of this application.

Purpose of application NOC04018

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

1.10 The project team considers that this purpose falls within the scope of both section 39(1)(g) of the Act: "maintaining new organisms in containment for diagnostic purposes" and section 39(1)(h) of the Act: "such other purposes as the Authority thinks fit."

Supporting information

1.11 Application NOC04018 (Form NO2N): *To Import into Containment any New Organism that is not Genetically Modified* was supplied by the applicant along with five appendices, including two supporting references (appendices 4 and 5) and the following documents:

- Appendix 1: Draft Containment Manuals for Allan Herbarium[1] and the Plant Biosystematics Laboratory;
- Appendix 2: New Zealand National Herbarium - Standard for the Transfer of Herbarium Specimens; and
- Appendix 3: Response from Ngāi Tahu to the draft application.

Government agencies' comments

1.12 The Ministry of Agriculture and Forestry (MAF) Biosecurity New Zealand and the Department of Conservation (DoC) were notified of the receipt of this application and provided with the opportunity to comment.

1.13 DoC responded by email on 14 November 2005 with the comments reproduced in Appendix 2 of this report. The applicant took the opportunity to respond to these comments and this response is reproduced in Appendix 3. Both DoC's comments and the applicant's response are discussed within this report, where appropriate.

[1] Landcare Research's herbarium.

1.14 MAF chose not to respond with any formal comments on the application. However, they were consulted regarding the application and provided advice on proposed additional controls.

2 Organism description

Identification of the organism to be imported

2.1 The applicant proposes to import into containment dried herbarium specimens from the Kingdoms Plantae, Mycetae, Protista and Cyanobacteria that contain viable material (eg seed, pollen, spores).

2.2 The project team notes that this is an extremely broad organism description. However, the herbarium specimens would be dried prior to importation (see proposed additional control 6.1 in section 10 of this report), rendering a large proportion of the material non-viable. The applicant's proposed containment manual mentions herbarium specimens are air dried at 35ºC. The project team considers that the time it might take to dry a specimen will vary depending on the water content of the specimen and may take several days. In view of this, proposed control 6.1 stipulates only that samples must be dried but not the duration and temperature for drying. MAF queried how they and the herbaria would know that the specimens have been dried to an accepted standard. In response to this the applicant noted that specimens that are not adequately dried go mouldy and would therefore be easily identifiable. They also stated that it is very likely that such specimens would be detected by the institute sending the material.

2.3 As the organisms are to be imported as herbarium specimens, and there is no intention to grow or multiplied (see proposed additional control 6.2), the viability of the material would also decrease with the length of time it is stored (Harrington, 1972). The project team has proposed an additional control to prevent the herbarium specimens from being propagated or cultured (proposed additional control 6.2, section 10).

Biological characteristics

2.4 This application involves a diverse collection of dried specimens from four of the five Kingdoms of life. The project team notes that there is divergent views on the names of taxa assigned to various organisms and in that context living organisms are subdivided into five major Kingdoms, including the Cyanobacteria (or Monera), the Protista, the Mycenae, the Plantae, and the Animalia (members of Animalia are not part of this application). Each kingdom is further subdivided into separate phyla or divisions. Generally, animals are subdivided into phyla, while plants are subdivided into divisions.

2.5 In brief, Cyanobacteria are unicellular and colonial bacteria more commonly referred to as blue-green algae. Protista includes unicellular protozoans and unicellular and multicellular algae. Members in this Kingdom are considered the simplest of the eukaryotes and in some ways this Kingdom is home for the leftover organisms that are not classified elsewhere. Protista have been considered by some as neither plants

nor animals, and they are not fungi either. Mycenae includes fungi. Plantae includes all plants.

2.6 Although some members of the four Kingdoms in their living state may have attributes that are considered toxic or pathogenic, it is considered that herbarium specimens are not of that nature.

Inseparable and associated organisms

2.7 According to the applicant, herbarium specimens to be imported are likely to include other organisms and associated substrates. The specimens may have inseparable organisms in the form of endophytic fungi. Lichens (which are covered by this application) are a symbiotic or dual organism of which the fungal component is inseparable while the algal and cyanobacterium components can live independently. Some herbarium specimens may contain the substrate upon which the organism grew ie dead material including wood, soil, rock and rarely animal material (hair, chiton, bone). However, the applicant notes that any inseparable organisms or associated substrates would have undergone the same drying treatment as the herbarium specimens prior to import (proposed additional control 6.1, as discussed in section 2.2 above), so most of the material would be non-viable. Any inseparable organisms or associated material would be contained in exactly the same manner as the herbarium collection (see section 3 below for the proposed containment regime) and could not be resuscitated without deliberate human intervention, which is not intended (see proposed additional control 6.2, section 10).

2.8 There is also the potential for organisms to be inadvertently imported in packages containing herbarium specimens. The project team notes that in order to fulfil their duties under the Biosecurity Act 1993, MAF's standard practice is to open packages containing herbarium specimens at the border and inspect them for any associated organisms. However, the inspection process is expensive for the herbaria and can damage the specimens. The risk of escape of the organisms is more likely if packages are opened at the border for inspection because the inspections are performed outside the confines of a registered containment facility. After discussions with ERMA New Zealand Agency staff, MAF have agreed that packages containing herbarium specimens (and any associated organisms and substrates) will not be opened at the border but will instead be directed straight to the containment facility. The project team has proposed an additional control to this effect (6.3) as discussed in section 3.14 of this report.

2.9 The applicant also notes that as a standard herbarium procedure, packages containing herbarium specimens are frozen after import to kill any associated invertebrates. The Herbarium Handbook, published by the Kew Royal Botanical Gardens, notes that deep freezing is a successful, safe and reliable method for decontamination of herbarium specimens (Bridson and Forman, 1994). The Handbook recommends freezing herbarium specimens at -18ºC for a 48-hour period to ensure that associated pests are killed. MAF also recommended that this time and temperature be stipulated in an additional control. However, the project team recognises that different temperatures and durations for freezing specimens can produce the same result. Also, the applicant noted that "some herbaria will have freezers that can only operate to approximately -18C as they will be using standard domestic freezers. I understand that these freezers are supposed to operate at -18C but many will not." Therefore the

project team has proposed an additional control requiring packages containing dried herbarium specimens to be frozen on arrival at the containment facility, without specifying a temperature or duration (proposed additional control 6.4, section 10).

2.10 The project team considers that these additional controls would reduce the risk of releasing viable unwanted associated organisms imported with the herbarium specimens.

2.11 During discussions between Agency staff and MAF, MAF noted that if this application was approved, any person exercising the approval would need to have contingency plans in place for use in the event that any unexpected and unwanted organisms are found in any packages containing herbarium specimens and that MAF should be notified in such an event. Accordingly, the project team has proposed an additional control requiring any herbarium exercising the approval to have a contingency plan documented in their containment manual for use in the event that any adventitious organisms other than the herbarium specimens are detected as associates and to notify MAF Biosecurity New Zealand promptly after the event is noticed (proposed additional control 6.5, section 10 of this report).

2.12 Potential adverse environmental and human health effects from the introduction of associated or inseparable organisms is discussed in sections 5.8 - 5.9 and 5.10 - 5.12 respectively, of this report.

3 Containment of the organism

3.1 The project team has proposed a set of controls to manage the risk of escape of the herbarium specimens and these are listed in section 10 of this report.

3.2 In assessing the ability of the organisms to escape from containment, the project team considered:

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

Proposed containment regime

3.3 The dried herbarium specimens would be imported into a containment facility registered by MAF under the Biosecurity Act 1993 in accordance with the MAF Biosecurity Authority/ ERMA New Zealand Standard 155.04.09: *Containment Facilities for New Organisms (including genetically modified organisms) of Plant Species* (Standard 155.04.09). The facilities would comply with Physical Containment level 1 (PC1) for plant containment facilities. The minimum requirements for PC1 plant containment facilities are specified in the Australian/New Zealand Standard 2243.3:2002: *Safety in Laboratories Part 3: Microbiological aspects and containment facilities*, fifth edition 2002 (AS/NZS 2243.3:2002). AS/NZS 2243.3:2002 also contains provisions relating to good laboratory procedure. Although the herbarium specimens will not be stored within a laboratory, there is the potential for research (such as DNA analysis) using the specimens to involve laboratory work. Therefore the project team proposes that a control mandating adherence to Standard 155.04.09

and to any relevant sections of AS/NZS 2243.3:2002 (as noted in Standard 155.04.09) including the requirements for PC1 for plant containment facilities be imposed if the application is approved (proposed control 1.2, section 10).

3.4 The project team notes that some organisms from the Kingdoms Plantae, Mycenae, Protista and Cyanobacteria could be classified as "microorganisms" and would therefore usually be contained in accordance with the MAF Biosecurity Authority/ ERMA New Zealand Standard 154.03.02: *Containment Facilities for Microorganisms* (Standard 154.03.02). However, the project team notes that Standard 154.03.02 for microorganism and Standard 155.04.09 for plants are very similar. The project team also notes that microorganisms covered by this application may not be much different than some plant spores or seeds in terms of their size and consequent containment requirements. Therefore the project team considers that Standard 155.04.09 would provide an appropriate level of containment for all herbarium specimens from the Kingdoms Plantae, Mycenae, Protista and Cyanobacteria.

3.5 Standard 155.04.09 requires a containment manual to be prepared, implemented and maintained as a quality assurance programme for the containment facility. Standard 155.04.09 also requires contingency plans to be in place for use in the event of accidental release of plants or viable plant material outside the facility and for fire and other emergencies. Section 4.7 Contingency Plans, states "…action shall be immediately taken to prevent further release and where possible recover the released plants". The project team has viewed a copy of the draft containment manuals for Landcare Research's Allan Herbarium, where the herbarium specimens will be held, and their plant biosystematics laboratory, used for systematic research, including examination of herbarium specimens and freshly collected samples (application Appendix 1). These manuals provide information on procedures and protocols for conducting work and contingency plans for escapes. The contingency plans include appropriate procedures for spills, fire, sabotage, theft and any other emergencies, which the project team considers to be adequate. The project team notes that the production of a containment manual including contingency plans will be a condition of MAF registration for any containment facility.

3.6 As discussed above, the herbarium specimens would be dried prior to importation (additional control 6.1) and frozen on arrival at the containment facility (additional control 6.4). The project team notes that the applicant wishes to use the herbarium specimens (or parts thereof) outside of a containment facility for public display and analysis. The containment measures for this are discussed below in sections 3.28 - 3.33 of this report.

3.7 The project team considers that the containment regime proposed by the applicant would be effective in containing the herbarium specimens.

Biological characteristics of the organism- suitability for containment

3.8 The applicant described the biological characteristics of the herbarium specimens and their ability to escape containment in sections 3 and 4 of the application.

3.9 The applicant notes that the herbarium specimens will be dried prior to import (see proposed additional control 6.1, section 10 of this report), which will render most of

the material non-viable. However, on occasion, the herbarium specimens may contain viable seeds, spores or pollen. There is no intention to ever grow viable material (proposed additional control 6.2, section 10).

3.10 According to the applicant, the likelihood of viable material being part of the herbarium specimens is extremely low – for instance, for viable seed to be present the specimen needs to be collected when the seed (or spore) was mature (Metsger and Byers, 1999), then the seed must have survived the drying and pressing process, and any subsequent freeze-thaw cycles used by herbaria to prevent insect pest damage. Even when viable material is initially present on herbarium specimens, the length this material remains viable after collection will be short as herbarium conditions do not provide optimal condition to maintain viability of seeds, pollen and spores.

3.11 Taking this information into account, the project team considers that the organisms in the current application would be able to be contained in a PC1 plant containment facility.

Pathways for escape of the organism from containment

3.12 In accordance with Section 44(b) of the Act, the project team has considered the ability of the herbarium specimens to escape containment and in doing so has identified the following potential pathways of escape.

Escape during transport to containment facilities

3.13 DoC also identified this as a pathway of escape from containment and noted that "the applicant has not proposed a mechanism to contain herbarium specimens while in transit". Therefore they recommended that "transport of all herbarium specimens shall be within a sealed container". The project team notes that herbarium specimens will be imported subject to the relevant requirements of Standard 155.04.09 (proposed control 1.2, section 10 of this report). Section 4.6 of this Standard addresses the containment requirements that must be met when transporting the organisms into and between containment facilities. The transport of these organisms would be subject to packaging instruction No. 650 of the International Air Transport Association (IATA) Dangerous Goods Regulations. This packaging instruction requires the organism to be triple packaged, with the packaging constructed and closed so as to prevent any loss of contents during transportation. In response to DoC's comments, the applicant noted that "a proposed standard for the transportation of specimens was included with the application [Appendix 2 of the application]. The proposed standard is based on international best practice for shipping specimens."

3.14 In addition to the IATA packaging requirements, the project team has proposed an additional control requiring all packages of herbarium specimens to only be imported from herbaria registered with *Index Herbariorium*, which is a detailed directory of the public herbaria of the world and the staff members associated with them (Holmgren and Holmgren, 1998), or from government agencies (proposed additional control 6.3, section 10). To be registered with *Index Herbariorium* you need to have an established herbarium with more than 5000 specimens. The applicant also noted that "we receive specimens from government botanists who are not associated with a herbarium, but have the training and skills to collect and prepare material correctly". The project team considers that requiring the specimens to be imported from herbaria

registered with *Index Herbariorium* or from government agencies would ensure that the specimens are properly dried and packaged prior to importation. The control also specifies that packages containing herbarium specimens must be clearly labelled on the exterior with the ERMA New Zealand approval code and the direction that the package should not be opened at the border, and shall only be opened within the approved containment facility listed on the permit to import (or on the transfer request form for transfers). The package must also be accompanied by the appropriate documentation specifying this direction and attached to the package in such a way that the package does not have to be opened to access the documentation. This labelling requirement overrides the labelling requirements specified in the IATA Dangerous Goods Regulations. This control also applies to all transfers of herbarium specimens.

3.15 Given the measures required by Standard 155.04.09 and proposed additional control 6.3, the project team consider that an escape during transportation to or between containment facilities is highly improbable.

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

3.16 The project team has considered the potential for the organisms to escape through incorrect handling of the herbarium specimens. DoC noted that "the applicant has not proposed a strategy to reduce the likelihood of the inadvertent removal of viable material from the facility. Therefore, the Department recommends that the applicant develop a standard operating procedure (SOP) to handle herbarium specimens". In response to this, the applicant suggested some procedures for handling specimens that could be documented in the herbarium's containment manual (see Appendix 3 of this report). The project team agrees with DoC that having in place procedures to handle herbarium specimens will reduce the risk of inadvertent removal of viable material from the facility. The project team notes that having such procedures in place is a requirement of Standard 155.04.09 (proposed control 1.2, section 10). The Standard specifies the use of procedures to ensure that no accidental or unintended removal of organisms from the facility occurs. These procedures cover all aspects of operation and management of the facility, including control of access, vermin control, waste disposal, and staff training on the principles of containment and the procedures that ensure containment. In order to enhance the staff training requirement, the Authority, if considering approving the application, might wish to consider a control that requires the person in charge of the facility to ensure that all staff are aware of the containment controls for the approval (proposed control 1.3, section 10).

3.17 DoC also noted the potential for viable material to be removed from the facility on clothing or shoes. They therefore recommended that "facility personnel shall wear an overcoat that is kept within the facility and appropriately decontaminated before washing and that there shall be SOP to ensure that the shoes are clean before leaving the facility". In response to this, the applicant stated "we consider that this exceeds the PC1 for Plants requirements and that dry seeds and spores are unlikely to adhere to clothing". The project team concurs with the applicants statement and considers that the requirements of Standard 155.04.09 discussed above (section 3.16), which include a requirement for staff training on the principles of containment and the procedures used to ensure containment, is sufficient to ensure that viable material is not

inadvertently removed from the facility. Therefore the project team considers that any additional controls on cleaning shoes and wearing overcoats are not necessary.

3.18 The applicant states that New Zealand herbaria are maintained in accordance with processes and procedures used in herbaria internationally, which aim to prevent damage to specimens, removal of material from specimens and contamination of specimens. The applicant notes that in normal practice only a few herbarium specimens would be opened on benches within the containment facility at any one time thereby reducing the possibility of escape.

3.19 DoC noted the potential for viable material to be removed from the facility with waste. Therefore they recommended that "all waste within the facility shall be appropriately treated to inactivate viable material, all cleaning equipment used within the facility shall be kept exclusively for use within it and any material leaving the facility shall be treated as above." The project team agrees that there is the potential for escape of the organisms from containment with waste material.

3.20 Standard 155.04.09 requires all biological waste and plant material to be disposed of in accordance with the AS/NZS 2243.3:2002. The project notes that in their draft containment manual, the applicant states that biological waste, material that may be contaminated with biological waste and waste collected during facility cleaning (eg the vacuum cleaner contents from the floor) would be disposed of by a commercial contractor approved to handle biologically hazardous waste. The project team has proposed an additional control requiring all waste containing viable material, including any waste that may inadvertently contain viable material (for example, any waste collected during cleaning of the facility such as vacuum cleaner contents) be disposed of in accordance with the requirements of Standard 155.04.09 (proposed additional control 6.9, section 10). The project team considers that this control would mitigate the risk of the organisms escaping the facility with waste material, and a control on cleaning equipment is not necessary.

3.21 Given the requirements of Standard 155.04.09, including the need for staff training and contingency plans for use in the event of escape (see section 3.5 of this report) and the proposed additional control to ensure that all waste potentially containing viable material is disposed of in accordance with Standard 155.04.09, the project team considers that escape from containment following accidental or deliberate removal by staff is highly improbable.

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

3.22 The project team has considered the possibility of accidental or intentional removal of the organisms from the containment facility by unauthorised persons. While this possibility cannot be totally eliminated, theft or sabotage resulting in release of the herbarium specimens is considered to be very unlikely, because of the following factors:

- Access to the facilities is restricted to authorised personnel only (section 4.3 of Standard 155.04.09, proposed control 1.2, section 10).
- The entrances to the facility shall be kept locked except when in active use (section 4.3 of Standard 155.04.09, proposed control 1.2, section 10).

- It is considered very unlikely that strong public interest will be generated by these organisms as they are not genetically modified.

3.23 Given these factors, the project team considers it highly improbable that the herbarium specimens would escape from containment through accidental or deliberate removal by unauthorised persons.

Escape from containment following natural disaster (flood, earthquake etc.) or fire

3.24 As discussed in section 3.5 of this report, the applicant is required to have in place contingency plans for use in the event of fire or any other emergencies. The project team have proposed controls that require the contingency plans to be implemented immediately following any breach of containment (proposed control 3.3, section 10) and notification to MAF and ERMA New Zealand following such an occurrence (proposed control 3.2, section 10). Therefore the project team considers that although there is the residual possibility that, in an extreme event, the herbarium specimens could accidentally escape, escape following natural disaster or fire is highly improbable.

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

3.25 The project team has considered the potential for the herbarium specimens to escape containment via natural seed and spore dispersal agents. According to the applicant, many spore bearing organisms release their spores through moisture induced rupturing of cells or moisture induced movements (eg see Hale, 1983; Richardson, 1981; Schofield, 1985) which cannot operate in the dry conditions of the herbaria. However, as noted by DoC, not all species covered by this application require moisture to release their spores. DoC also noted that "in fact there are many species that releases [sic] spores upon drying". Therefore DoC considers that "the dry conditions within the herbarium are not sufficient to prevent the release of spores from all the organisms that are the subject of this application". Therefore DoC proposed that "the containment facility shall not have any opening other then what is absolutely necessary for air circulation and entry. Further, there shall be a monitoring control in place to observe the area surrounding openings of the herbarium to ensure that no new organisms have escaped the facility". In response to this, the applicant noted that "some containment facility will include offices, it is desirable that opening windows be permitted in these areas for ventilation". In terms of a monitoring requirement, the applicant stated that "when considering monitoring for each site we request that this is done of [sic] a per Facility basis – some herbaria are located in the middle of buildings".

3.26 The project team acknowledges that not all spore-producing organisms covered by this application require moisture to release their spores. However, the project team considers that the proposed containment regime is adequate to contain spores, without placing restrictions on openings such as windows. The project team considers that it would be difficult to specify appropriate conditions for a monitoring control that would effectively manage any risk and would be enforceable. Also, the project team notes that the proposed containment regime has been set such that escape of these

organisms from containment has been assessed as highly improbable (see section 3.34 below) and therefore a control on monitoring is not considered to be necessary.

3.27 The applicant stated that the mechanisms for seed dispersal (ie wind, animals, and water) are unavailable in the herbaria. The project team notes that Standard 155.04.09 requires an effective insect and rodent control programme to be in place, which would reduce the risk of seeds escaping via animals. DoC also noted the need for the herbaria to operate a vermin control strategy. In order to prevent insects entering areas where herbarium specimens are stored by being brought in with or being attracted by live plants, the project team has proposed an additional control stating that no growing or propagated plants are to be kept in rooms used for storing the specimens (proposed additional control 6.6, section 10). The project team considers that this control and the requirements of Standard 155.04.09 would make it highly improbable that the herbarium specimens would escape containment via a seed or spore dispersal vector.

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

3.28 As noted in the proposed containment manual (Appendix 1 of the application), the applicant wishes to be able to transfer herbarium specimens to non-containment facilities for public display and to conduct analyses (for example, scanning electron microscopy). The project team has therefore considered the potential for organisms to escape into the environment when they are being transported to or held in a non-containment facility.

3.29 According to the containment manual, material from herbarium specimens transferred for analysis usually consists of small amounts of dried, dead non-viable material, however in very rare instances the transfer may include viable material. Specimens are also rarely loaned to other New Zealand institutes without containment for public display. The containment manual states that specimens transferred for public display should not include mature seed or spores.

3.30 The applicant proposes that when material is transferred out of containment for analysis, it will be packaged according to the New Zealand National Herbarium Network Standard for the Transfer of Herbarium Specimens, provided in Appendix 2 of the application. The applicant also noted that any packages containing herbarium specimens to be transported for analysis would be accompanied by a staff member approved to use the Allan Herbarium Containment Facility. The project team considers that any transport of organisms (both into and out of the containment facility) imported in accordance with this approval should comply with packaging instruction No. 650 of the IATA Dangerous Goods Regulations as specified in Standard 155.04.09 (with the exception of the labelling requirements for the packages, which will be in accordance with additional control 6.3, as discussed in section 3.14 of this report). The project team notes that the applicant's proposed packaging standard presented in Appendix 2 of the application meets the packaging requirements specified in packaging instruction No. 650 of the IATA Dangerous Goods Regulations. The project team considers that compliance with the transport requirements specified in Standard 155.04.09 would make it highly improbable that the organisms would escape while being transported to a non-containment facility.

3.31 According to the containment manual, material transferred for analysis will be unpackaged upon arrival at the non-containment facility in a restricted, predetermined and prepared area immediately adjacent to the analysis equipment. After analysis the bench area will be cleaned, and all material, including cleaning and any waste material will be repackaged for transfer back to the containment facility. When queried by the project team on whether the process of analysis deviatlised the material, the applicant stated "all the material for analysis would usually be destroyed or rendered inviable by the treatments - if there was any 'extra' material it would be returned to the Herbarium for storage or disposal. The frequency of there being extra material would be extremely low as removing material from specimens is destructive so we try to ensure that only the material that is essential for an analysis is removed".

3.32 The project team considers that on arrival at the non-containment facility, the material should only be unpackaged in and kept within a contained area. Prior to transferring the organisms out of containment, the Biosecurity Inspector responsible for the supervision of the facility and MAF Biosecurity New Zealand should be notified and approve of the intention to transfer the material, the purpose of the transfer, the duration of the transfer, the proposed non-containment facility where the material will be held and the containment measures that will be in place to prevent escape. Any transfer out of containment will be temporary. Material that is transferred out of containment for analysis can only be handled by an approved user of the containment facility or by an appointed person under the supervision of an approved user of the containment facility, until the material is rendered non-viable. Material that is transferred out of containment for public display must be displayed in such a way that it cannot be accessed by the viewing public or animals (eg within a glass cabinet). Once the analysis or public display is completed, any remaining material must be packaged and transported back to the containment facility (in accordance with Standard 155.04.09), where it can either be disposed of in accordance with Standard 155.04.09 or stored within the facility. These requirements are detailed in proposed additional control 6.7 in section 10 of this report. Providing that these requirements are met, the project team considers that it is improbable that the organisms would escape into the environment when they are being held in a non-containment facility.

3.33 When commenting on the proposed additional controls, MAF raised a concern regarding transferring material out of containment for analysis. They considered that this could increase the risk of release of viable material or adventitious organisms and queried why such analyses could not take place within a containment facility. In response to this the applicant noted that most of the analyses would take place within a containment facility and most of the material would be rendered non-viable prior to being removed from containment for analysis. However, the applicant noted that some analyses require specialist equipment that is not available at all herbaria and is not always held within a containment facility. The applicant also noted that only small amounts of material would be removed for analysis, not whole specimens. The project team notes that a requirement of proposed control 6.7 is that MAF approval is gained prior to transferring any viable material from herbarium specimens out of containment. Therefore they can verify the adequacy of the proposed containment before the transfer occurs. The applicant noted that they would like the option of obtaining multiple movements within the transfer approval. The project team considers that this can be addressed on a case-by-case basis with MAF.

Summary of ability of herbarium specimens to escape from containment or into the environment

3.34 Taking into consideration the ability of the herbarium specimens to escape from containment, the proposed containment conditions, and the potential pathways for escape, the project team concludes that it is highly improbable that the organisms would be able to escape from containment. In the event that the organisms, or parts thereof, are transferred to a non-containment facility for public display or analysis, the project team considers that it is highly improbable that the organisms would escape during transportation and improbable that they would escape into the environment while being used for analysis or public display, provided that additional control 6.7 is adhered to.

4 Ability to form a self-sustaining population and ease of eradication

4.1 In accordance with section 37 of the Act, the project team has considered the ability of the herbarium specimens from the Kingdoms Plantae, Mycetae, Protista and Cyanobacteria to form self-sustaining populations outside containment and the ease of eradication of such populations.

4.2 The applicant contends that the only way that a self-sustaining population of herbarium specimens could establish is in the event of escape from containment and this is considered extremely unlikely in view of the containment and operational regime proposed.

4.3 The applicant also noted that even in the event of escape, the possibility of a self-sustaining population forming is further reduced by several factors, summarised below:

- The chance of the material being viable for germination is extremely low as conditions in herbaria are not ideal for maintaining the long term viability of spores and seed.
- Many spores and seeds require specific pre-treatments to induce germination (eg scarification[2], stratification[3] or leaching[4]) and these are unlikely to occur with an accidental release.
- Spores and seeds have to be released at a time when conditions are conducive for germination and find a suitable habitat in the area around the research centre (ie the seed or spore would need to be deposited in an environment with suitable temperature, light, moisture and substrate conditions).

4.4 The project team considers that it is possible that a self-sustaining population of herbarium specimens from the Kingdoms Plantae, Mycetae, Protista and

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[2] Abrasion or nicking of the seed coat to break dormancy.

[3] Chilling seeds for a period of time to break dormancy.

[4] Removal of germination inhibitors from the seed (by water) to break dormancy.

Cyanobacteria could establish, because the environmental conditions for growth of organisms within these Kingdoms occur in New Zealand. However, the project team also agrees with the applicant that the factors stated above (section 4.3) reduce the likelihood that a self-sustaining population could form in the event of an escape of material from herbarium specimens. The project team also notes that the viable material available from which a population could form is limited because the pre-import drying and post-import freezing requirements will render most material non-viable and the quantity of any given species imported is low.

4.5 The project team notes that in the event of escape, the organisms are likely to establish in the immediate vicinity of the containment facility. The applicant states that in the extremely unlikely event that a viable seed or spore escaped, germinated and established, it is highly likely to be observed because of the high density of expert scientists present at the sites, and would be rapidly and easily eradicated by physical and/or chemical destruction before it spread beyond the research centre.

4.6 The project team agrees with this assessment for macroscopic organisms. However, for microorganisms, such as those in the Kingdoms Protista and Cyanobacteria, a self-sustaining population may be difficult to detect and would be nearly impossible to eradicate. If eradication was attempted, determining the success of such an attempt would in practice be very difficult.

4.7 In conclusion, the project team considers that should an escape from containment occur, although it is theoretically possible that a self-sustaining population of herbarium specimens from the Kingdoms Plantae, Mycetae, Protista and Cyanobacteria could establish, it is very unlikely that this would occur because of the factors discussed above in sections 4.3 - 4.4. In the event that a population did establish, the ease of eradication would vary depending on they type of organism. For macroscopic organisms, eradication would be fairly easy, whereas microorganisms are likely to be difficult to detect and almost impossible eradicate. However, the project team notes that the proposed containment regime has been set such that escape of these organisms from containment or during transportation has been assessed as highly improbable and escape while the organisms are being used for analysis or public display as improbable (see section 3.34 of this report).

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

5.1 Adverse effects are those identified as potentially significant, having regard for those matters set out in clauses 9 and 10 of the Methodology.

5.2 In accordance with clause 9(c) of the Methodology, the project team has categorised potential adverse effects associated with the application into environmental, human health and safety, Māori culture, society and community and market economy categories.

5.3 Potential beneficial effects have also been identified by the project team in association with the applicant in accordance with clause 9(c) of the Methodology. A benefit is

defined as the value of a particular positive effect expressed in monetary or non-monetary terms.

5.4 The adverse and beneficial effects associated with the application have been considered in terms of the requirements of clauses 12 (risks), 13, and 14 (costs and benefits) of the Methodology, including the probability of occurrence and the magnitude of the 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 of the Methodology. Risks are assessed in terms of the likelihood of the effect occurring and the magnitude of the effect.

5.5 Appendix 4 of this report lists the qualitative scales used to describe the probability of occurrence and magnitude of effects for this application. The degree of uncertainty attached to evidence is taken into account, as required under clauses 25, 29 and 30 of the Methodology.

The environment

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

5.6 The project team notes that some members of the Kingdoms Plantae, Mycetae, Protista and Cyanobacteria in their living state may have attributes that are considered toxic or pathogenic. There is a large degree of uncertainty regarding the magnitude of any impact of such organisms on plants and animals in New Zealand should they be affected, which could range from **minimal** to **moderate**, depending on the level of pathogenicity or toxicity of the organism, what organisms were affected and how easily identifiable infected organisms were. However, it is considered **highly improbable** that this effect would occur. This assessment is based on the fact that the project team considers it highly improbable that the herbarium specimens would escape from containment and improbable that they would escape from non-containment facilities (see section 3.34 of this report) and in the event of escape, it is very unlikely that they would form self-sustaining populations (see section 4.7 of this report). Overall this risk is not considered to be significant.

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

5.7 The project team has considered the potential for herbarium specimens from the Kingdoms Plantae, Mycetae, Protista and Cyanobacteria to in the first instance escape from containment, establish in the environment, and then to cause disruption of New Zealand's flora and fauna through competition with and displacement of native species or through hybridisation. DoC also noted this as a potential risk. As discussed in section 4.7 of this report, the project team considers that it is very unlikely that the herbarium specimens would form self-sustaining populations in the event of an escape from containment. If this adverse effect were to occur, the magnitude could range from **minimal** to **moderate** depending on the nature of the organism and its competitive ability. However, the project team considers that it is **highly improbable** that this effect would occur because it is highly improbable that the organisms would escape containment (and improbable that they would escape from non-containment facilities) and very unlikely that they would form self-sustaining populations. Therefore the project team considers that this risk is not significant.

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

5.8 As discussed in sections 2.7 - 2.12 of this report, herbarium specimens are likely to include inseparable and associated organisms, and there is the potential for these associated organisms (such as viruses, fungi or insect pests) to adversely affect native or valued species. The project team notes that these associated organisms will be subject to the same drying and freezing treatments as the herbarium specimens, which is likely to render most material non-viable, and will be subject to the same containment regime. As discussed in section 2.11 of this report, the project team has also proposed an additional control requiring any user of the approval to have a contingency plan in their containment manual for use in the event that any adventitious organisms (other than the herbarium specimens) are detected as associates of the herbarium specimen and to notify MAF Biosecurity New Zealand in such an event (proposed additional control 6.5, section 10).

5.9 In the event that inseparable or associated organisms escaped containment and adversely affected native or valued species, the magnitude of their effect would depend upon the nature of the associated organisms, what organisms were affected and how easily identifiable infected organisms were. Thus there is a degree of uncertainty associated with the magnitude of this effect, which could range from **minimal** to **moderate**. However, the project team considers that the proposed containment regime is adequate to contain potentially associated organisms and therefore it is **highly improbable** that they would escape from containment and cause adverse effects on native or valued species. Overall this risk is not considered to be significant.

Human health and safety

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

5.10 Given the low likelihood of escape, the project team considers that the most likely exposure pathway for herbarium specimens or any associated organisms to have adverse effects on human health is through exposure of people working with the specimens. According to the applicant, there is no evidence to suggest that dried herbarium specimens have ever been the cause of a public health problem or had any effect on people working with them. The applicant also noted that no public health effects are likely to eventuate as the herbarium specimens will be kept in containment and only handled by personnel expert in handling such specimens.

5.11 The project team notes that the applicant's draft containment manual identifies two health hazards. Firstly, some old herbarium specimens were treated with mercuric chloride as protection against pest damage. Mercury has been recognised worldwide as a hazardous substance (EPA, 2005) and there is the potential for this substance to be absorbed through the skin or inhaled. Therefore the containment manual requires the use of gloves when handling such specimens and washing of hands afterwards. The second hazard identified is that some lichens may contain small amounts of the oxidised state of paraphenylenediamine (PPD). PPD is a substance that is widely used as a hair dye and may also be found in textile dyes. Reactions caused by the use of hair dye in mild cases usually only involve dermatitis to the upper eyelids or the rims

of the ears (DermNet NZ, 2005). Good herbarium practices should minimise these hazards and it is noted that the containment manual also specifies the use of gloves for handling these specimens.

5.12 The project team considers that the magnitude of any adverse effect to human health should it occur would be **minimal** to **minor**, depending on various factors such as the sensitivity of the person to the toxin/pathogen and the dose, route and duration of exposure (DermNet NZ, 2005; EPA, 2005). The project team considers that following good herbarium practices and using gloves to handle specimens with potential health hazards would make it **highly improbable** that any adverse effects would occur to human health resulting from handling herbarium specimens. Overall this risk is not considered to be significant.

Māori and their culture and traditions

5.13 The project team considered the potential Māori cultural effects of this application in accordance with clauses 9(b)(i) and 9(c)(iv) of the Methodology and sections 6(d) and 8 of the Act. In addition, the project team used the assessment framework contained in the ERMA New Zealand User Guide "Working with Māori under the HSNO Act 1996", and the ERMA New Zealand revised protocol "Incorporating Māori perspectives in Part V Decision-making", as guides in assessing the information contained in this application.

5.14 The project team recognises the value of the research that the applicant intends to conduct and can see positive spin-offs from having a better understanding of New Zealand's flora and their relationships to other flora from around the world.

5.15 In accordance with ERMA New Zealand policy and guidelines, the applicant was not required to consult with Māori regarding this application as the application does not directly involve nor pose significant risk to New Zealand native or valued species.

5.16 However, the applicant did consult with Ngāi Tahu, who do not envisage any adverse effects, given the containment measures outlined. Ngāi Tahu recommended that the Manager of the Herbarium contact Te Taumutu Runanga, the papatipu runanga that has manawhenua in the area in which Landcare Research's Allan Herbarium is located. The applicant notified Te Taumutu Runanga but they have made no comment.

5.17 ERMA New Zealand has no evidence to suggest that the introduction into containment of dried herbarium specimens from the Kingdoms Plantae, Mycenae, Protista and Cyanobacteria, including seeds, pollen and spores, or their use as reference material will breech the principles of the Treaty of Waitangi.

5.18 Taking into consideration the assessment of the potential adverse environmental effects associated with this application (see sections 5.6 - 5.9 of this report), the project team considers that this application presents no significant risk to Māori culture or traditional relationships with ancestral lands, water, sites, wāhi tapu, valued flora and fauna or other taonga. This assessment is made on the condition that the specimens are, transported, handled, stored, and used in accordance with the explicitly stated controls (in section 10 of this report), and any controls stipulated in other applicable Acts.

5.19 However, should inappropriate use or an accident result in the release of an organism into the environment, the project team encourages the herbaria to inform relevant local iwi authorities of the nature of the release and the measures taken to contain and remedy the situation.

Society and the community

5.20 Neither the applicant nor the project team identified any adverse effects to society and the community associated with the importation into containment of herbarium specimens.

The market economy

5.21 Neither the applicant nor the project team identified any adverse effects to the market economy associated with the importation into containment of herbarium specimens.

Identification of costs

5.22 The project team considers that any costs associated with the application are as a result of the adverse effects identified above. No further costs have been identified, other than the costs borne by the applicant. Therefore, no further assessment of costs has been conducted in this report.

Potential beneficial effects

5.23 The applicant identified the following potential direct benefits from approval of the application:

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

5.24 The applicant states that herbarium specimens are used for morphological, anatomical, chemical, palynological[5] and molecular analyses. Herbarium specimens are the primary resource used by scientists in determining the taxonomy and identification of the species that occur in New Zealand. In order to fully understand the New Zealand flora, specimens collected in New Zealand must be compared with specimens of species from overseas that have biogeographic or taxonomic links to New Zealand. DoC noted that "herbaria provide valuable services in identifying and monitoring the distribution flora [sic] within New Zealand".

5.25 According to the applicant, herbarium specimens from overseas are an essential tool for the identification of material that is intercepted at the border and for the verification of new naturalisations. Better knowledge of seeds, anatomy, and

[5] The scientific study of spores and pollen.

chromosome numbers produced by research using herbarium specimens provides tools useful in other research areas such as vegetation history, archaeology, and forensic science.

5.26 Biosystematic information is published in peer reviewed journals, making it available in the public domain. The applicant noted that currently herbarium specimens support databases and resulting research publications are used by a wide variety of people and organisations, including governmental agencies such as ERMA New Zealand, MAF, and DoC.

5.27 The applicant noted that if the application is unsuccessful, then it would be impossible to maintain the herbaria in their current form, which would curtail any research being carried out on defining the New Zealand flora.

5.28 The project team agrees with the applicant that there is some uncertainty regarding the magnitude of the benefits as they are difficult to quantify, however, they are potentially **moderate** to **major** in magnitude. The applicant considers that the likelihood of these benefits being realised is extremely high as the benefits are already tangible in the long history of scientific and educational publications. The project team agrees with this assessment and considers that it is **extremely likely** that these benefits would occur. These benefits will be shared by a wide variety of groups, including the science community and government agencies.

6 Previous similar applications

6.1 The project team notes that the Authority has previously approved, with controls, several applications to import organisms within the Kingdom Plantae, into containment facilities registered in accordance with Standard 155.04.09. For example, application NOC98009 was to import into containment eight species of Indonesian alpine moss and application NOC01006 was to import into containment *Wollemi nobilis*. The project team notes that for these applications, Physical Containment Level 2 (PC2) for plant house facilities was imposed, whereas PC1 for plant house facilities is proposed for the current application. The project team notes that the key difference between the current application and these previous applications is that for the current application, the organisms would be imported as dried herbarium specimens and would not be propagated. The proposed pre-import drying treatment and post-import freezing treatment would reduce the amount of viable material that is part of the herbarium specimens. The viability of the herbarium specimens would also decrease with the length of time they are stored. Taking this information into consideration, the project team considers that in this case, PC1 for plant house facilities is an appropriate level of containment.

6.2 The project team notes that the Authority has also previously approved, with controls, several applications with broad organism descriptions. For example, application NOC04016 was to import into containment unidentified microorganisms contained in water, soil, sediment and rock samples from Antartica.

6.3 Recent applications approved for the importation into containment of organisms have included an additional control requiring all users of the approval to notify ERMA

New Zealand and MAF when they first exercise the approval (for example applications NOC04017[6] and NOC04020[7]). The reasoning behind such a control is that in the event that new significant information about the effects of an approved organism becomes available the Authority has discretion to initiate a reassessment of an approval (section 62 of the Act). There are also provisions in the Act (section 67A) to make minor or technical amendments to approvals. In the event that a reassessment or amendment of an approval was warranted it would be essential to know who was using the relevant approval. The project team considers that the Authority might wish to consider imposing such a control on the current application if it is approved (proposed additional control 6.8, section 10).

7 Associated Approvals

7.1 The importation of herbarium specimens into containment is subject to the requirements of the Biosecurity Act 1993, including the issue of an import permit by MAF. As noted by the applicant, some herbarium specimens from the Kingdoms Plantae, Mycetae, Protista and Cyanobacteria may be listed in the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES) register. Any person exercising an approval to import species listed on CITES must comply with CITES requirements. According to the applicant, species listed on CITES are only sent from and received by CITES registered organisations and this is reported annually to DoC.

8 International Obligations

8.1 The project team is not aware of any international obligations that are relevant to this application in accordance with clause 9(c)(vi) of the Methodology and section 6(f) of the Act.

9 Overall Evaluation

9.1 The project team has evaluated the potential of the herbarium specimens to escape containment in accordance with section 44(b) of the Act. Having considered the proposed containment regime, the biological characteristics of the organisms and the potential pathways for escape from containment, the project team concluded that it is highly improbable that the herbarium specimens would escape from containment and improbable that they would escape from specified non-containment facilities.

9.2 The project team has evaluated the potential of the organisms to establish undesirable self-sustaining populations should they escape containment in accordance with section 37 of the Act. The project team considers that it is very unlikely that an undesirable self-sustaining population of the herbarium specimens could establish. Should an undesirable self-sustaining population establish, it is likely to be in the immediate vicinity of the containment facility and could range from being easily

[6] Application to import into containment phytoplasmas (NOC04017).

[7] Application to import into containment leopards (NOC04020).

detected and eradicated for macroscopic organisms to being very difficult to detect and almost impossible to eradicate for microscopic organisms.

9.3 The project team assessed the adverse and beneficial effects of significance related to approving this application. The potential adverse effects posed by the organisms to the environment, human health and safety and Māori culture and traditions were not considered to be significant by the project team. The potential beneficial effects associated with importing the herbarium specimens include increased scientific knowledge in New Zealand, the provision of a resource for teaching and creating keys to identify species and primarily the provision of a resource for research to understand the phylogenetic relationships of New Zealand flora. The project team assessed these benefits as being extremely likely to eventuate and moderate to major in value.

9.4 Overall the project team considers that the level of risk associated with this application is not significant.

9.5 A summary of all the major effects, the likelihood of the effect being realised, the magnitude of that effect should it occur, the uncertainty regarding that effect and its associated ranking is provided in Table 1.

Table 1: Summary of overall evaluation of risks, costs and benefits.

Description of Potential Effect	Magnitude	Likelihood	Level of uncertainty	Ranking	Qualitative statement of risk/benefit	Section reference
Adverse effects						
Potential for the herbarium specimens to be pathogenic or toxic to plants or animals in New Zealand	Minimal – moderate	Highly improbable	Some uncertainty regarding the magnitude, which can vary depending on the level of pathogenicity or toxicity of the organism, what organisms are affected and how easily identifiable infected organisms are	A-B	Not significant	5.6
Potential for disruption of New Zealand's flora and fauna environment	Minimal – moderate	Highly improbable	Some uncertainty regarding the magnitude, which can vary depending on the nature of the organism and its competitive ability	A-B	Not significant	5.7
Potential for inseparable or associated organisms to adversely affect native or valued plant or animal species	Minimal – moderate	Highly improbable	Some uncertainty regarding the magnitude, which can vary depending on the nature of the associated organisms, what organisms are affected and how easily identifiable infected organisms are	A-B	Not significant	5.8 - 5.9
Potential for herbarium specimens or inseparable or associated organisms to be pathogenic or toxic to humans	Minimal – minor	Highly improbable	Some uncertainty regarding the magnitude, which can vary depending on factors such as the sensitivity of the person to the toxin/pathogen and the dose, route and duration of exposure	A	Not significant	5.10 - 5.12
Beneficial effects						
Provision of a resource for research, teaching, and identifying specimens, new scientific knowledge in NZ	Moderate – major	Extremely likely	Some uncertainty regarding the magnitude as the benefits are difficult to quantify	F-G	Significant	5.23 - 5.28

10 Containment Controls

10.1 The containment controls proposed by the project team below are grouped in accordance with the Third Schedule of the Act (Part II): Matters to be addressed by containment controls for new organisms excluding genetically modified organisms. The Authority may also include controls that provide for any other matter in order to give effect to the purpose, as defined in section 4, of the Act. The project team did not consider that any additional controls were required to provide for any other matter. The Authority may wish to amend the proposed controls (in order to make them more or less 'strict') to achieve a level of probability of escape that is appropriate for the organisms.

Proposed containment controls

1 To limit the likelihood of any accidental release of any organism or any viable genetic material[8]:

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

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

a) Ministry of Agriculture and Forestry (MAF) Biosecurity Authority/ERMA New Zealand Standard 155.04.09[9]: *Containment Facilities for New Organisms (including genetically modified organisms) of Plant Species* (Standard 155.04.09).

b) Relevant sections of the Australian New Zealand Standard AS/NZS 2243:3 2002[9] *Safety in Laboratories: Part 3: (Microbiological aspects and containment facilities)*, excluding those deviations specified in Standard 155.04.09.

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

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

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

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

[9] Any reference to this standard in these controls refers to the current version or any subsequent updated version endorsed by ERMA New Zealand and MAF Biosecurity New Zealand.

2 To exclude unauthorised people from the facility:

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

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

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

3.2 If for any reason a breach of containment occurs the Biosecurity Inspector responsible for the supervision of the facility[10], MAF Biosecurity New Zealand and ERMA New Zealand shall be notified promptly as soon as is practicable after the event is noticed.

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

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

4 Inspection and monitoring requirements for containment facilities:

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

4.2 The operator of the containment facility shall provide access for inspection of the facilities at any reasonable time, in accordance with Standard 155.04.09.

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

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

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

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

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

[10] An inspector appointed under the Biosecurity Act.

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

6.3 All packages of herbarium specimens imported in accordance with this approval shall only be imported from herbaria registered on *Index Herbariorum*[11] or from government agencies. The packages shall be clearly labelled on the exterior with the ERMA New Zealand organism approval code and the direction that the package should not be opened at the border, and shall only be opened within the approved containment facility listed on the permit to import (or on the transfer request form for transfers). The package shall be accompanied by the appropriate documentation specifying this direction and attached to the package in such a way that the package does not have to be opened to access the documentation. The packaging of herbarium specimens shall be in accordance with the requirements of the IATA[12] Dangerous Goods Regulations packing instruction 650 as specified in Standard 155.04.09, however, the labelling of the package shall be in accordance with this control. All transfers of herbarium specimens will also comply with this control.

6.4 Packages containing herbarium specimens imported in accordance with this approval shall be frozen on arrival at the containment facility.

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

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

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

a) **Prior** to transporting the material out of containment, the Biosecurity Inspector responsible for the supervision of the facility[10] and MAF Biosecurity New Zealand shall be notified and **approve** of the intention to transfer the material, the purpose of the transfer, the duration of the transfer, the proposed non-containment facility where the material will be held and the containment measures that will be in place to prevent escape while the material is held in the non-containment facility.

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

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

[12] International Air Transport Association (IATA)

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

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

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

6.8 Any herbarium exercising this approval shall notify ERMA New Zealand, the Biosecurity Inspector responsible for the supervision of the facility[10] and MAF Biosecurity New Zealand in writing of their intention to do so prior to activating the use of the approval (ie a one-off requirement).

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

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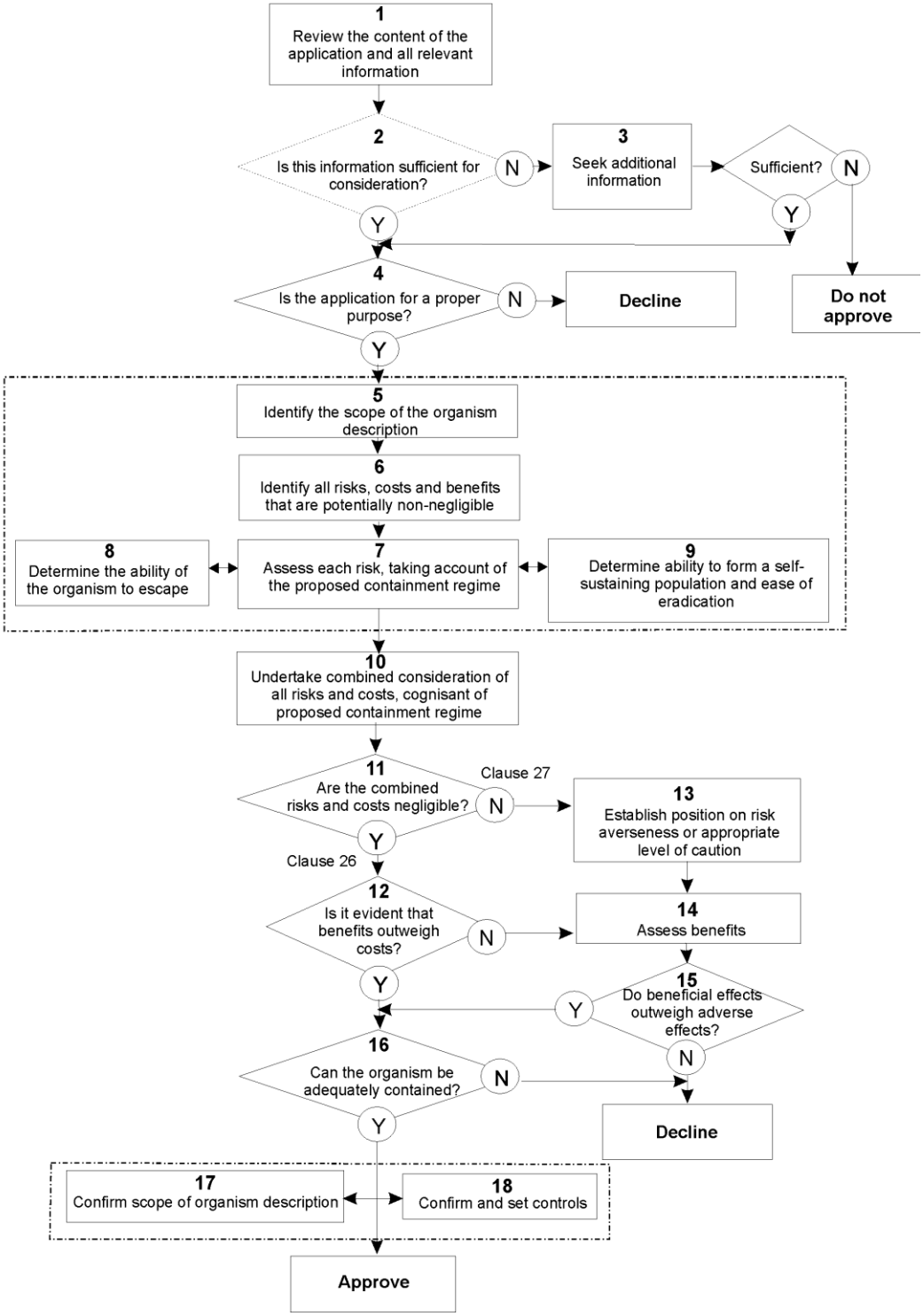
Appendices

Appendix 1: Decision path and explanatory notes

Figure 9: Decision path for applications to import into containment a new organism (non GMO) (application made under Section 40 of the Act and determined under Section 45 of the Act)

THE DECISION PATH MUST BE READ TOGETHER WITH THE ATTACHED NOTES



NOTES to Figure 9- Decision path for applications to import into containment a new organism (non GMO) (application made under Section 40 of the Act and determined under Section 45 of the Act)

An application may include a number of organisms or may be for a "generic" application. In both of these cases the organisms having similar risk profiles should be grouped into categories. Each category should be considered separately via the path below.

Items 1, 2 & 3: Information that should be reviewed includes that in the application, the E&R Report, from experts and in submissions (where relevant). Review should occur in terms of section 40(2) of the Act and clauses 8, 15, 16, 20 and 22 of the Methodology. Additional information may need to be sought under s58 of the Act.

If the applicant is not able to provide sufficient information for consideration then the application is not approved. In these circumstances the Authority may choose to decline the application, or the application may lapse.

Item 4: Acceptable purposes are set out in section 39 of the Act

Item 5: Clearly identify the scope of the organism description with particular reference to where the application is generic, or refers to a number of organisms.

Item 6: The range of risks, costs and benefits to be identified should be that covered by clauses 9, 10 and 11 of the Methodology. This is a two step process.

Step 1: Identify all possible risks, costs and benefits

Step 2: Eliminate those risks, costs and benefits that can be readily concluded to be negligible

Item 7: The assessment of risks and costs should be carried out in accordance with clauses 12 to 14, 22, 25, and 29 to 32 of the Methodology. The process of risk assessment includes the estimation of the likelihood and magnitude of each effect. The assessment is carried out with the controls proposed by the applicant and any controls required to meet the provisions of the 3rd Schedule of the Act in place.

The assessment also includes the following steps.

Step 1: Consideration of the extent to which the risk will be mitigated by the default controls.

Step 2: Consideration of how risk averse or cautious the Authority should be in giving weight to the residual risk (clause 33 of the Methodology), where residual risk is the risk remaining after the imposition of controls.

Note that only risks and costs are assessed at this stage, since assessment of benefits depends on whether the decision follows the clause 26 or clause 27 path.

The process of risk assessment is **not** linear. It is very iterative. In essence all of the steps (including the steps in items 8 & 9) must be repeated until a satisfactory conclusion is reached.

Item 8: Determine the ability of the organism to escape from containment and consider any addition controls that might be imposed that would reduce the likelihood of escape (Section 44).

Item 9: Determine the ability of the organism to form a self-sustaining population and ease of eradication of this occurred (Section 37)

Item Once the risks and costs have been assessed individually, consider all

10:	risks and costs together, taking account of the proposed controls (item 7) and any additional controls proposed in Item 8.
Item 11:	Consider whether any residual risks are negligible. An holistic perspective should be adopted, taking into account the particular characteristics of the substance and the feasibility of the proposed controls. (if necessary, review the controls).
Item 12:	This item constitutes a decision made under clause 26 of the Methodology. If risks are negligible and there are no external costs (costs accrue only to the applicant), then the fact that the application has been submitted is deemed to demonstrate existence of benefit, and no further benefits need be considered. However, if external costs exist then all benefits need to be assessed.
Item 13:	Although 'risk averseness' is considered as a part of the assessment of individual risks, it is good practice to consolidate the view on this if risks are non-negligible. Clause 33 of the Methodology applies, as does section 7 of the Act dealing with caution in the face of scientific and technical uncertainty.
Item 14:	Assess benefits in terms of clause 13 of the Methodology.
Item 15:	In weighing up adverse and beneficial effects, clause 34 of the Methodology applies. Where this item is taken in sequence from items 13 and 14 (i.e. risks are not negligible) it constitutes a decision made under clause 27 of the Methodology, and adverse effects comprise risks and costs. Where this item is taken in sequence from items 12 and 14 (i.e. risks are negligible, and costs do not accrue only to the applicant) it constitutes a decision made under clause 26 of the Methodology, and adverse effects comprise costs only.

At this step the scope of the organism description for generic application should be reviewed. If changes are made to the organism description, items 6 to 14 above should be repeated for the revised organism description. Then the weighing up process in this item for the revised organism description should also be repeated.

Item 16: The meaning of the phrase "adequacy of containment" needs to be extended so that it covers both the satisfactory biological and/or physical containment of the organisms. If the organism description was revised in item 15, the considerations in this item should relate to the revised organism description.

If, as a result of this consideration, further revision of the organism description is required, the determination as to whether the organisms can be adequately contained should be repeated for the new organism description.

Item 17: The scope of the organism description has been identified in item 5. This step in the decision-making process confirms the scope of the organism description in such a way that the risk boundaries are defined.

Item 18: Controls have been considered at the earlier stages of the process (items 7, 8, 10 and 16). However, this step confirms and sets the controls. Controls flow from, but are considered in conjunction with, the organism description. If controls are changed at this point, the previous steps need to be repeated.

Appendix 2: DoC's comments

APPLICATION FOR APPROVAL TO IMPORT INTO CONTAINMENT ANY THAT IS NOT GENETICALY MODIFIED UNDER SECTION 40 OF THE HSNO ACT

APPLICATION: NOC04018

APPLICANT: Herbarium Network

PURPOSE: To import into containment herbarium specimens

The Department of Conservation (the Department) would like to thank the Environmental Risk Management Authority (ERMA) New Zealand (the Authority) for the opportunity to comment on this application.

The Department's mission is to conserve New Zealand's natural and historic heritage for all to enjoy now and in the future. Therefore, the Department has carried out a risk assessment on this application to identify and assess adverse effects that can impact on the Department's mission.

Assumptions

The Department notes that this application is to cover the possibility of importing into New Zealand viable material in herbarium specimens that are new organisms.

Spores

The Applicant notes that "many spore baring organisms release their spores through moisture induced rupturing of cells or moisture induce movements which cannot operate in the dry conditions of the herbaria". The Department agrees with the applicant that many of the species that are the subject of this application require water for release of spores. However, the Department notes that is not true for all species that are the subject of this application. In fact there are many species that releases spores upon drying. Therefore, the Department considers that the dry conditions within the herbarium are not sufficient to prevent the release of spores from all the organisms that are the subject of this application.

Hazard Identification

The Department notes that there is a potential for the introduction of an organism that is invasive in the New Zealand environment

Further, the Department notes that there is a potential for the introduction of an organism that is capable of hybridising with a native or a valued species.

The Department consider that for these hazards to be realised viable material must be present in the herbarium specimens, that material must escape containment and establish a self-sustaining population.

Escape from containment

The Department notes that herbarium specimens despite the undergone treatments may contain viable material. Therefore, the Department has identified the following pathways of escape for such material from the proposed containment system:

- Escape while in transit;
- Escape via vermin;
- Inadvertent or deliberate removal from the facility;
- Escape of air borne spores;
- Escape via waste; and
- Escape on clothing.

The Department notes that the applicant has not proposed a mechanism to contain herbarium specimens while in transit. Therefore, the Department recommends that transport of all herbarium specimens shall be within a sealed container.

The Department notes that all herbaria operate a vermin control strategy to preserve herbarium specimens. The Department consider this to be effective in preventing the entry of vermin to the facility. Therefore, the Department recommends that the facility shall operate a vermin control strategy.

The applicant notes that there is a security system in place to restrict access to the facility. Further, the applicant has indicated that they shall at no time remove any new organisms from the facility for propagation. The Department considers that the above security system and intention is adequate to reduce the likelihood of intentional removal of material from facility. The Department notes that the applicant has not proposed a strategy to reduce the likelihood of the inadvertent removal of viable material from the facility. Therefore, the Department recommends that the applicant develop a standard operating procedure (SOP) to handle herbarium specimens.

The Department notes that some of the herbarium specimens may contain viable microscopic spore. Though, as discussed above some of these specimens require water to disperse spores however there are others that are dispersed when dry. The Department recognise that the amount of spores in herbarium specimens are low and that older the herbarium specimen it is lower still. However, it is impossible to rule out the possibility of a viable specimen escaping containment. Therefore, the Department proposes that the containment facility shall not have any opening other then what is absolutely necessary for air circulation and entry. Further, there shall be a monitoring control in place to observe the area surrounding openings of the herbarium to ensure that no new organisms have escaped the facility.

The Department notes that there is a potential for viable material to escape the facility via waste. Therefore, the Department propose that all waste within the facility shall be appropriately treated to inactivate viable material, all cleaning equipment used within the facility shall be kept exclusively for use within it and any material leaving the facility shall be treated as above. For example, a separate vacuum cleaner shall be kept for the facility and all vacuum cleaner bags should be carried in a sealed container and autoclaved or incinerated.

Finally, the Department notes that there is a potential for viable material to be carried out on clothing or shoes. Therefore, the Department recommends that facility personnel shall wear an overcoat that is kept within the facility and appropriately decontaminated before washing and that there shall be SOP to ensure that the shoes are clean before leaving the facility.

Ability to establish a self-sustaining population

The Department notes that if a viable particle does escape containment the probability of forming a self-sustaining population is low as the escaped organism would need to find specific conditions for activation and growth. However, the Department notes that it cannot be ruled out.

Identification of Beneficial effects

The Department notes that the herbaria provide valuable services in identifying and monitoring the distribution flora within New Zealand.

Conclusion

The Department considers the risk of this application to be low if any approval contains similar controls to those underlined above. Further, we consider that the benefits of the application are significant. Therefore, the Department support this application.

Asela Atapattu Biosecurity Technical Officer (key contact)

Appendix 3: Applicant's response to DoC's comments

21 November 2005

Sarah McLean
ERMA New Zealand
PO Box 131
Wellington

Dear Sarah McLean

Application NOC04018: Response to Department of Conservation Comments

Thank you for the opportunity to respond to some of the comments made by the Department of Conservation (included here in quote marks) to our application.

"transport of all herbarium specimens shall be within a sealed container."

A proposed standard for the transportation of specimens was included with the application. The proposed standard is based on international best practice for shipping specimens, and to our understanding complies with IATA Packing standard No. 650.

"applicant develop a standard operating procedure (SOP) to handle herbarium specimens."

The Kew Handbook provides a procedure for handling specimens on pages 104-105. However, there are minor differences between herbaria in handling specimens due to the physical storage at each herbarium.

If required, we suggest that the following points be include in the Containment Manuals to cover the handling of specimens (modified from the Kew Handbook):

- Specimens should always be handled with great care
- Hold specimens by both sides
- Keep sheets flat and fully supported
- Never shuffle specimens so that the edges of the sheet cut the underlying specimens
- Never align specimens to a vertical position
- Never turn specimens as though they are pages of a book
- Aligning specimens prior to returning them to storage to prevent parts protruding as these are liable to be bent
- Never bend a specimen to examine part of it
- Never rest books or heavy objects on specimens
- Place loose fragments in a packet (or similar) and attach to the sheet or place inside specimen packet
- Do not force too many specimens into a folder or storage space

- Always make sure storage containers (e.g., boxes or cabinets) are firmly shut when not in use
- Never keep specimens out of storage for longer than necessary
- Always keep a look out for insect damage

"containment facility shall not have any opening other then what is absolutely necessary for air circulation and entry."

Some containment facility will include offices, it is desirable that opening windows be permitted in these areas for ventilation.

"Further, there shall be a monitoring control in place to observe the area surrounding openings of the herbarium to ensure that no new organisms have escaped the facility."

When considering monitoring for each site we request that this is done of a per Facility basis – some herbaria are located in the middle of buildings.

"waste within the facility shall be appropriately treated to inactivate viable material, all cleaning equipment used within the facility shall be kept exclusively for use within it and any material leaving the facility shall be treated as above"

When considering waste disposal from herbaria, we suggest that any control that is imposed permit the separation of waste into different risk categories (e.g., non-hazardous office waste vs. material from a foreign specimen or vacuum waste from floor). An example of this separation is included in the draft containment manuals for the Allan Herbarium.

Any controls also need to consider that the service for disposal of risk waste may be provided by a commercial contractor. The above comments implies that material is inviable prior to leaving the facility, this would not be possible with a commercial contractor.

"facility personnel shall wear an overcoat that is kept within the facility and appropriately decontaminated before washing and that there shall be SOP to ensure that the shoes are clean before leaving the facility."

We consider that this exceeds the PC1 for Plants requirements and that dry seeds and spores are unlikely to adhere to clothing.

As a concession, if overcoats are regarded as necessary, we propose that use of overcoats be limited to work involving the handling of foreign specimens.

Aaron Wilton

Manager, Allan Herbarium

Landcare Research

Appendix 4: Qualitative scales for describing adverse effects

Qualitative Risk Assessment

Risks and benefits are assessed by estimating the magnitude of the possible effects and the likelihood of their occurrence. For each effect, the combination of these two components determines the level of that effect, which is a two dimensional concept. Risk assessment may be qualitative or quantitative. Qualitative assessment is informed by quantitative data where this is available.

Qualitative matrices are used to prioritise risks (and benefits), and to identify any risks that are unacceptable. The measure of the level of risk (combination of magnitude and likelihood) is specific to the application therefore measures of level of risk should not be compared between applications. However, the measures (descriptors) for different types of risk (human health, ecological etc) should be established so that they represent relative orders of magnitude.

Magnitude of effect

The magnitude must be a measure of the endpoint (specified by the Act and the Methodology), and is described in terms of the element that might be affected. The magnitude of the effect is not the same as the effect itself. The qualitative descriptors for magnitude of effect are surrogate measures that should be used to gauge the end effect or the 'what if' element.

Tables 1 and 2 contain generic descriptors for magnitude of adverse effects (risks and costs) and beneficial effects (benefits). These descriptors are examples only, and their generic nature means that it may be difficult to use them in some particular circumstances. They are included here simply to illustrate how qualitative tables may be used to represent levels of risk.

Table 1 Magnitude of adverse effect

Descriptor	Examples of descriptions
Minimal	Mild reversible short term adverse health effects to individuals in highly localised area Highly localised and contained environmental impact, affecting a few (less than ten) individuals members of communities of flora or fauna, no discernible ecosystem impact Low dollar cost of containment/cleanup/repair (<$5,000) No social disruption[13]
Minor	Mild reversible short term adverse health effects to identified and isolated groups[14] Localised and contained reversible environmental impact, some local plant or animal communities temporarily damaged, no discernible ecosystem impact or species damage Dollar cost of containment/cleanup/repair in order of $5,000-$50,000 Potential social disruption (community placed on alert)
Moderate	Minor irreversible health effects to individuals and/or reversible medium term adverse health effects to larger (but surrounding) community (requiring hospitalisation) Measurable long term damage to local plant and animal communities, but no obvious spread beyond defined boundaries, medium term individual ecosystem damage, no species damage Dollar cost of containment/cleanup/repair in order of $50,000-$500,000, Some social disruption (e.g. people delayed)
Major	Significant irreversible adverse health effects affecting individuals and requiring hospitalisation and/or reversible adverse health effects reaching beyond the immediate community Long term/irreversible damage to localised ecosystem but no species loss Dollar cost of containment/cleanup/repair in order of $500,000-$5,000,000 Social disruption to surrounding community, including some evacuations
Massive	Significant irreversible adverse health effects reaching beyond the immediate community and/or deaths Extensive irreversible ecosystem damage, including species loss

[13] The concept of social disruption includes both physical disruption, and perceptions leading to psychological disruption. For example, some chemicals may have nuisance effects (through odour) that result in communities feeling threatened.

[14] Note that the reference to 'groups' and 'communities' in the context of human health effects includes the notion of groups defined by health status.

	Dollar cost of containment/cleanup/repair greater than $5,000,000 Major social disruption with entire surrounding area evacuated and impacts on wider community

The economic effects category has been given a surrogate magnitude. This is for demonstration as a means of illustrating the type of magnitudes that might be encountered.

Table 2 Magnitude of beneficial effect

Descriptor	Examples of descriptions
Minimal	Mild short term positive health effects to individuals in highly localised area Highly localised and contained environmental impact, affecting a few (less than ten) individuals members of communities of flora or fauna, no discernible ecosystem impact Low dollar benefit (<$5,000) No social effect
Minor	Mild short term beneficial health effects to identified and isolated groups Localised and contained beneficial environmental impact, no discernible ecosystem impact or species damage Dollar benefit in order of $5,000-$50,000 Minor localised community benefit
Moderate	Minor health benefits to individuals and/or medium term health impacts on larger (but surrounding) community and health status groups Measurable benefit to localised plant and animal communities expected to pertain to medium term. Dollar benefit in order of $50,000-$500,000, Local community and some individuals beyond immediate community receive social benefit.
Major	Significant beneficial health effects to localised community and specific groups in wider community Long term benefit to localised ecosystem(s) Dollar benefit in order of $500,000-$5,000,000 Substantial social benefit to surrounding community, and individuals in wider community.
Massive	Significant long term beneficial health effects to the wider community Long term, wide spread benefits to species and/or ecosystems Dollar benefit greater than $5,000,000 Major social benefit affecting wider community

Likelihood of effect occurring

Likelihood in this context applies to the composite likelihood of the end effect, and not either to the initiating event, or any one of the intermediary events. It includes:

- the concept of an initiating event (triggering the hazard), and

- the exposure pathway that links the source (hazard) and the area of impact (public health, environment, economy, or community).

The likelihood term applies specifically to the resulting effect or the final event in the chain, and will be a combination of the likelihood of the initiating event and several intermediary likelihoods[15]. The frequency or probability solely of the initial incident or hazard event should not be used (as it sometimes is in the safety discipline).

The best way to determine the likelihood is to specify and analyse the complete pathway of the "chain of events" from source to the final environmental impact or effect. Each event in the chain is dependent upon the previous event occurring in the first place.

Likelihood may be expressed as a frequency or a probability. While frequency is often expressed as a number of events within a given time period, it may also be expressed as the number of events per head of (exposed) population. As a probability the likelihood is dimensionless and refers to the number of events of interest divided by the total number of events (range 0-1).

Table 3 Likelihood (adverse effect)

	Descriptor	Description
1	Highly improbable	Almost certainly not occurring but cannot be totally ruled out
2	Improbable (remote)	Only occurring in very exceptional circumstances.
3	Very unlikely	Considered only to occur in very unusual circumstances
4	Unlikely (occasional)	Could occur, but is not expected to occur under normal operating conditions.
5	Likely	A good chance that it may occur under normal operating conditions.
6	Very likely	Expected to occur if all conditions met
7	Extremely likely	Almost certain

Table 3 provides an example of a set of generic likelihood descriptors for adverse and beneficial effect. Note that when estimating these likelihoods, the impact of default controls should be taken into account.

The table is not symmetrical. This is to allow for classification of very low probability adverse effects.

In practical terms, where the exposure pathway is complex, it may be conceptually difficult to condense all the information into a single likelihood. For any risk where the likelihood is other than 'highly improbable' or 'improbable', then an analysis of the pathway should include identifying the 'critical points'; the aspects that are the most vulnerable, and the elements where controls might be used to 'cut' the pathway.

[15] Qualitative event tree analysis may be a useful way of ensuring that all aspects are included.

Calculating the level of risk

Using these qualitative descriptors for magnitude of effect and likelihood of the event occurring, an additional two-way table representing a level of risk (combined likelihood and measure of effect) can be constructed as shown in Table 4, where six levels of effect are allocated: A, B, C, D, E and F. These terms have been used to emphasise that the matrix is a device for determining which risks (benefits) require further analysis to determine their significance in the decision making process. Avoiding labels such as 'low', 'medium', and 'high' removes the aspect of perception.

The lowest level (A) may be deemed to be equivalent to 'insignificant'. In this table 'A' is given to three combinations; minimal impact and an occurrence of improbable or highly improbable, and minor impact with a highly improbable occurrence. In some cases where there is high uncertainty it may be preferable to split this category into A1 and A2, where only A1 is deemed to equate to insignificant.

For negative effects, the levels are used to show how risks can be reduced by the application of additional controls. Where the table is used for positive effects it may also be possible for controls to be applied to ensure that a particular level of benefit is achieved, but this is not a common approach.

Table 4 Calculating the level of risk (benefit)

	Magnitude of effect				
Likelihood	**Minimal**	**Minor**	**Moderate**	**Major**	**Massive**
Highly improbable	A	A	B	C	D
Improbable	A	B	C	D	E
Very unlikely	B	C	D	E	E
Unlikely	C	D	E	E	F
Likely	D	E	E	F	F
Very likely	E	E	F	F	G
Extremely likely	E	F	F	G	G

The table presented here is symmetric around an axis from highly improbable and minimal to massive and extremely likely, however, this will not necessarily be the case in all applications.

Impact of uncertainty in estimates

Uncertainty may be taken into account in two ways. Firstly, when describing a risk a range of descriptors may be used. For example, a risk may be allocated a range of very unlikely-improbable, and minor-major. This would put the range of the risk as B through E. Alternatively, the level of risk (or benefit) may be adjusted *after* it has been estimated on the grounds of uncertainty.