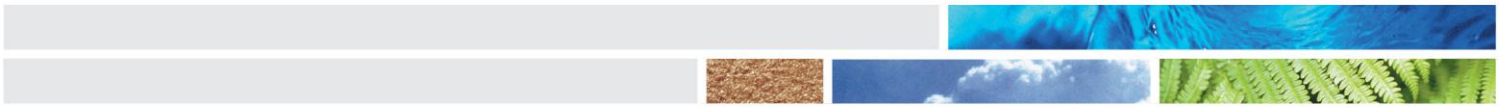
Environmental Protection Authority
Te Mana Rauhī Taiao

EPA staff advice on applications ERMA200706 and ERMA200792

The development and import of genetically modified *Arabidopsis thaliana* in containment

JUNE 2012



ADVICE TO THE DECISION MAKING COMMITTEE

New Zealand Government

Executive Summary

ERMA200706 and ERMA200792 are applications for the import and development in containment of genetically modified *Arabidopsis thaliana* – a model plant species used widely in the study of plant genetics and biology. Applications were received from the University of Auckland, Massey University, University of Otago, Lincoln University, Scion, AgResearch Limited, ViaLactia Biosciences New Zealand Limited, and Canterbury University.

The importation and development of genetically modified *A. thaliana,* has been considered and approved on numerous occasions. There are currently over one hundred approvals for developing and importing *A. thaliana* at the applicant institutions. These two applications aim to apply a consistent set of controls to the organism.

Our assessment identified significant beneficial effects associated with the ongoing import and development of genetically modified *A. thaliana* for research. Adverse effects were negligible, taking into consideration the stringent containment conditions proposed. Therefore we recommend that the HSNO Decision Making Committee approve the two applications *with controls*.

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1. Background

1.1. This document has been prepared by EPA staff to advise the HSNO decision making committee. The document discusses information provided in the applications and other readily available sources.

Applicants

1.2. These applications to import (ERMA200792) and develop (ERMA200706) genetically modified (GM) *Arabidopsis thaliana* in containment are jointly submitted by the University of Auckland, Massey University, University of Otago, Lincoln University, Scion, AgResearch Limited, ViaLactia Biosciences New Zealand Limited, and Canterbury University. Together they represent every organisation that currently holds an active Hazardous Substances and New Organsms Act 1996 (HSNO) approval to import or develop *A. thaliana* in containment.

1.3. This collective of New Zealand's universities, Crown Research Institutes, and independent research organisations have collaborated on a standardised set of working procedures to contain GM *A. thaliana*. They have proposed a set of containment controls to be imposed by the EPA, and have developed procedures to comply with these controls which are aligned with international best practice in the containment of GM *A. thaliana*.

Application descriptions

1.4. These applications to import (ERMA200792) and develop (ERMA200706) GM *A. thaliana* in containment aim to investigate gene function and gene delivery systems, and to develop new bioassays.

1.5. Both applications are made under section 40 of the HSNO Act. The applicants collectively sought for the applications to be publicly notified, and a full risk assessment made.

1.6. *Arabidopsis thaliana* is a model plant, widely used in the study of plant genetics and physiology. The approval of these applications will allow the continued research of this important model plant in New Zealand containment facilities.

1.7. Research using GM *A. thaliana* has been conducted in New Zealand since the 1980s. Since the establishment of the HSNO Act in 1996 all research projects to genetically modify *A. thaliana* or to import genetically modified *A. thaliana* have required regulatory approval from the Environmental Protection Authority (EPA) (previously the Environmental Risk Management Authority). Over the

past 15 years approvals have varied, and there is disparity in containment controls on approvals between organisations and even within the same organisation.

1.8. The aim of these applications is to allow continued research with *A. thaliana* in New Zealand laboratories, while streamlining external auditing processes and strengthening compliance procedures.

Organism description

1.9. *Arabidopsis thaliana*, also known as thale cress, is a small flowering plant widely used as a model organism in plant biology because:

- it is small in size;
- it has a short life cycle;
- there is extensive knowledge about the organism's biology; and
- it can be easily genetically modified.

1.10. Wild type, non-genetically modified *Arabidopsis thaliana* is native to Europe, Asia, and North West Africa, and is also present growing wild in New Zealand's environment.

1.11. *Arabidopsis thaliana* carries no known inseparable organisms.

1.12. The applicants have proposed a range of genetic modifications to the *Arabidopsis thaliana* host organism (Table 1). These include:

- the use of donor genetic material from plant, animal, bacterial, fungal, viral, and synthetic origin; and
- the use of genetic sequences that may code for genes, gene regulatory elements, transposable elements, and reporters or selectable markers (Table 1).

These modifications will be used in the study of:

- plant growth, metabolism, composition, differentiation and development;
- biological responses to environmental and chemical stress;
- host-pathogen and host-commensal interactions;
- the causation of disease; and
- health and nutrition.

1.13. The applicants have also detailed modifications that will not be permitted under these applications (Table 1). These applications will not involve genetic modifications that:

- result in the production of infectious particles;
- use genetic material derived from Māori;
- use genetic material derived from native flora and fauna;

- use genes encoding known or predicted vertebrate toxins;
- use uncharacterized sequences from pathogenic microorganisms;
- increase the pathogenicity, virulence, or infectivity of the host organism; or
- result in the modified organism having a greater ability to escape from containment than the unmodified host.

1.14. These exclusions are consistent with those found in the Hazardous Substance and New Organisms (Low-Risk Genetic Modification) Regulations 2003.

Table 1: Organism/host description

Host organism: *Arabidopsis thaliana* (L.) Heynh.
Modified using:
commercially available plant vectors.
Donor genetic material:
may include coding, non-coding or regulatory regions of genes from plant, animal, bacterial, fungal, viral or synthetic sources. The modifications will be used in the study of: • plant growth, metabolism, composition, differentiation and development; • biological responses to environmental and chemical stress; • host-pathogen and host-commensal interactions; • the causation of disease; and • health and nutrition. Donor genetic material that codes for gene regulatory elements, transposons, reporters or selectable markers may be from plant, animal, bacterial, fungal, viral or synthetic sources.
Regulatory elements, reporter and selectable marker genes and other features
Vectors will include fully characterised regulatory elements including promoters, regulatory element binding sites, transcriptional activators, enhancers, terminators, and multiple cloning sites, site directed recombination sequences, and origins of replication. The vectors may also contain selectable marker genes, reporter genes, transposons, protein targeting, localisation and secretory signals, solubility enhancement tags, protein purification tags and affinity tags including epitope tags.
Characteristics of the genetically modified organisms:
No infectious viral particles will be produced.
Exclusions:
- Genetic material derived from Māori; - Genetic material derived from native flora and fauna; - Genes encoding known or predicted vertebrate toxins; - Uncharacterized sequences from pathogenic microorganisms; - Genetic modifications that increase the pathogenicity, virulence, or infectivity of the host organism; and

- Genetic modifications that result in the modified organism having a greater ability to escape from containment than the unmodified host.

2. Information used in the risk assessment

2.1. An assessment of the adverse and beneficial effects of the importation and development of GM *Arabidopsis thaliana* was undertaken for five areas of impact: human health and safety, the environment, society and community, the relationship of Māori to the environment, and the market economy.

2.2. In assessing the adverse and beneficial effects associated with these applications, we considered *A. thaliana*'s role as a model organism in the study of plant biology, genetics, and physiology.

2.3. Our risk assessment also considered that these applications are for research that will be conducted in containment, within approved containment facilities. We evaluated the containment controls and procedures proposed by the applicants. Matters regarding the ability of *A. thaliana* to establish an undesirable self-sustaining population, and the ease with which it could be eradicated were also considered.

2.4. Information provided in the applications, and in submissions (Appendix 4) was included among the information used in the risk assessment.

3. Assessment of beneficial effects

3.1. There are a number of beneficial effects that will result from the importation and development of GM *A. thaliana* should it be approved.

3.2. We identified the following beneficial effects as being significant:

- Ongoing gains of scientific knowledge from the study of *A. thaliana*, a widely used model organism in the field of plant biology and genetics.
- Ability to conduct world class scientific research of plant biology, and to retain international class scientific talent in New Zealand.
- New Zealand scientists can continue to participate in international research programmes.
- Educational gains derived from the use of plants as a teaching tool at universities.

3.3. *Arabidopsis thaliana* has been extensively used worldwide as a model of plant biology since the early 20th century precisely because its biology so closely represents that of other flowering plants. Research into the genetics and physiology of *A. thaliana* provides valuable insight into the genetics

and physiology of other flowering plant species with intrinsic value to New Zealand - from pasture grasses, and forestry trees, to food species. *Arabidopsis thaliana* is favoured as an experimental organism because it is easy to grow, matures quickly, and has a relatively small genome.

3.4. We acknowledge the mandate of New Zealand's Crown Research Institutions to improve the inherent value of the country's agricultural and pastoral industries through the use of scientific research. We also acknowledge the role of universities to train young scientists to an international level. The number of applicants on both applications, representing five universities, three Crown Research Institutions and industry demonstrates how widely *A. thaliana* is used in scientific research in New Zealand. This is also reflected in the supporting submissions received, including that from Jared B. Fudge, who is using GM *A. thaliana* in his Masters research project.

3.5. New Zealand's plant biologists and researchers consider the continued use of *A. thaliana* to be critical for agricultural and horticultural plant research in New Zealand. We note that within the last three years more than 30 peer reviewed scientific journal articles have been published[1] by New Zealand research institutes, indicating research with *A. thaliana* continues to produce valuable scientific knowledge. Associate Professor Jon GH Hickford of the New Zealand Institute of Agricultural and Horticultural Science stated in his submission that New Zealand's plant scientists need access to GM *A. thaliana* to remain up to date with international plant science research. He noted that failure to support the applications could lead to our plant scientists leaving New Zealand permanently. We agree with the submitters, that the ability to conduct world class scientific research into plant biology, and to retain international class scientific talent in New Zealand must be preserved.

3.6. Dr Nick Albert stated in his submission that the use of GM *A. thaliana* in research is essential for answering fundamental questions about plant biology. He noted that GM-based research often results in important non-GM outcomes for New Zealand's agricultural and horticultural sectors. He stated that research and innovation would be severely stifled if New Zealand scientists were unable to use modified *A. thaliana* in research. He further explained that the use of GM *A.thaliana* allows our plant biologists to be part of the international research community aiming to understand the basic processes of flowering plants at the genetic and biochemical level. We agree that New Zealand scientists must continue to participate in international research programmes.

[1] Found by using search terms '*Arabidopsis'* and *'New Zealand'* on Pubmed-NCBI. Retrieved May 2012

3.7. Associate Professor Peter Dearden stated in his submission that fundamental research using *Arabidopsis thaliana* is the key to understanding how plant genes work to influence growth and development. He explained that *A. thaliana* research can lead to the development of better crops to mitigate the environmental effects of large-scale agriculture, and more efficiently feed the world's population.

3.8. GE Free New Zealand though has expressed a concern that '*There is little evidence that this research will benefit any body* [sic] *in New Zealand*'.

3.9. We consider the ongoing gains in scientific knowledge from the use of GM *A. thaliana* at New Zealand universities and research institutes as stated in section 3.3 to 3.8 demonstrate that there are many benefits to New Zealand over the long term (more than 5 years). It will lead to valuable innovation in New Zealand's agricultural and horticultural sectors, improved teaching in plant biology, and benefits to the local economy through the possible commercialisation of these innovations. The magnitude of the beneficial effects has been assessed as **major** based on their significance to New Zealand and New Zealanders[2].

3.10. As stated in the submission by the New Zealand Institute of Agricultural and Horticultural Science there are currently over 205,000 published scientific articles on research with *A. thaliana*. All of the applicant organisations have a strong record of research output and teaching excellence. Given the collective research output of the organisations that work with *A. thaliana* in New Zealand we have assessed the likelihood of the beneficial effects listed in section 3.2 as **highly likely** to occur.

3.11. In conclusion, the beneficial effects of the development and import of *Arabidopsis thaliana* described in section 3.2 have been assessed as **high**.

4. Assessment of adverse effects

4.1. Because of its role as a model plant, *Arabidopsis thaliana* is arguably the most well-studied and characterised plant species in the world. We feel there is ample information available to make a detailed assessment of the risks associated with the import and development of GM *A. thaliana*. Specific details of the genetic modifications, for example the exact vector used, transformation method, or precise genetic donor information are not needed for a risk assessment, as they do not hold any individual or cumulative risk. What is necessary to know for the evaluation is the end point - the characteristics or traits of the final modified organism, and whether these carry any risk.

[2] Qualitative descriptors for the assessment of beneficial and adverse effects are presented in Appendix 6.

4.2. The applicant has proposed restrictions on the traits that can be developed or imported under these applications. They exclude any genetic material derived from Māori, native flora and fauna, genes that code for known or predicted vertebrate toxins, or uncharacterised genetic sequences (Figure 1).

4.3. Strict containment measures have been proposed. If the containment system is complied with, then we are satisfied that the risks from this research to the environment, human health and safety, the relationship of Māori to the environment, society and the community, and the market economy are **negligible**.

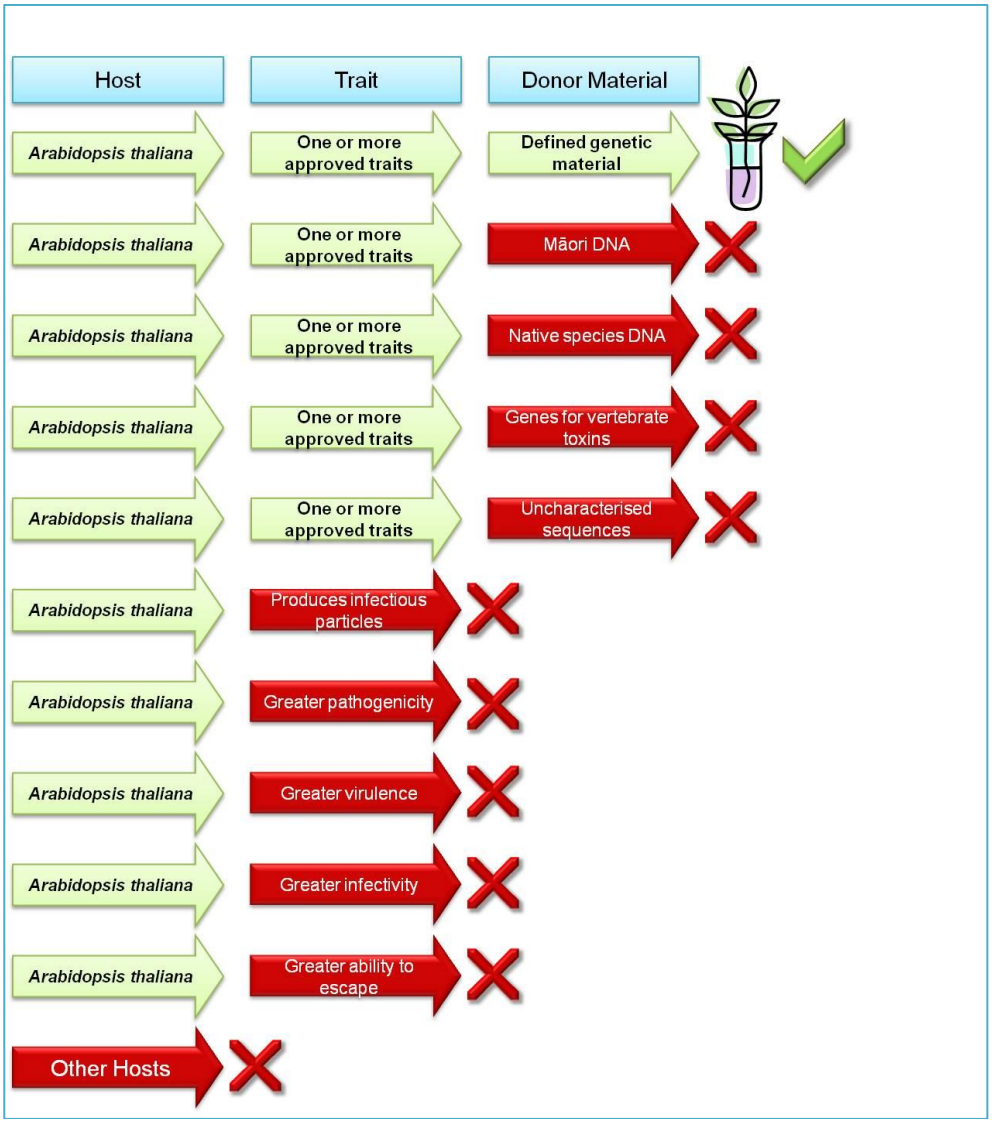

Figure 1: A graphical representation of the types of genetic modifications to *Arabidopsis thaliana* that are excluded by the applicants' restrictions.

5. Containment

5.1. The applicants propose that the import and development of *A. thaliana* will be undertaken in approved containment facilities designed and maintained to prevent the escape of *A. thaliana*.

5.2. *Arabidopsis thaliana* has been used in a laboratory setting for many decades. Its biology is well understood, and the potential pathways for its escape are well recognised. The applicants have developed procedures and protocols to minimise these potential pathways for escape, and have proposed a set of containment controls to be imposed by the EPA. The applicants consider that containment will be achieved by addressing these proposed controls.

5.3. The controls proposed by the applicants are outcome focussed, or results-based, instead of prescriptive. That is, instead of prescribing specific measures that must be adhered to, the controls direct that secure containment is required. The onus is then on the organisation to demonstrate that they can meet that outcome.

5.4. The applicants' proposed containment controls were reviewed and assessed by the EPA staff. The controls recommended by the EPA staff are presented in section 6 of this advice. We consider that the controls meet the requirements set out in Schedule 3 Part 1: Matters to be addressed by containment controls for importing, developing or field testing of genetically modified organisms in the HSNO Act (Appendix 2). Since the controls are outcome based, we do not recommend placing a time limit on the approval. How the applicant organisations may meet the controls may change as technology and accepted procedures change; however, the princlple outcome of containment will always be required.

5.5. The applicants have also produced a guidance document to ensure a high standard of compliance with the containment controls. This document is a result of collaboration between the Biological Safety and HSNO Compliance Officers from the applicant institutions, and was submitted with the applications for EPA expert staff to review. The EPA does not have a role in approving the guidance document, but has reviewed it and assisted the applicants by facilitating an expert review.

5.6. The applicants' containment protocols and guidance document address pathways of escape for *A. thaliana* plants and seed (Appendix 3). These include policies and procedures that deal with design, construction, and maintenance of the containment facility; waste water treatment; training of facility users; record keeping; regular reviews of containment protocols; contingency plans in case of an emergency, or in case of a containment breach; and transport and destruction of approved organisms.

5.7. The guidance document contains specific information on how best to comply with the containment controls, considering the biology of the organism and the potential pathways of escape. For example, *A. thaliana* seed is very small - approximately the size of this full stop. With this knowledge, the applicants have written containment protocols to address this issue, and the guidance document contains many specific provisions around seed containment. For example, it states that:

- *"Drains are screened with fine mesh (the size of which should reflect the size of A. thaliana seed), or a wad of filtration material (such as F6 air filtration matrix) that can be removed when clogged. This filtration material can be autoclaved, disposed of, and easily replaced. Regular checks of the mesh and/or filtration material should be carried out as part of routine maintenance.*
- *Bagging of seed heads (or growing in high sided containers) is an a important primary containment measure, but plants should also be on larger trays which act as secondary containment and prevent seed falling to the floor where is it less likely to be contained.*
- *It is preferable that lab coats should be pocketless, which prevents seed inadvertently escaping via the pockets. It is also recommended that disposable shoe covers or dedicated shoes should be worn in the plant house (option) to prevent the escape of seed.*
- *In the specific case of moving saved seeds to another containment facility for storage purposes they must be stored in another containment facility and transported inside double containers. When stored, seeds should be maintained in a spill-proof, labelled container. Seed containers must clearly identify the provenance of the seed and its genetic background."*

5.8. The guidance document will be used by each applicant institution to develop a facility-specific containment manual. The containment manual will detail such matters as the physical and procedural measures put in place to maintain compliance, requirements for staff training, and the appointment of staff members to oversee compliance with the controls. The manual will be required for Ministry for Primary Industries (MPI) inspectors to approve the containment facility under section 39 of the Biosecurity Act 1993. The manual will be regularly reviewed when monitoring the facility to ensure all protocols are being followed and containment of *A. thaliana* is maintained.

5.9. After review by EPA staff, we sent the guidance document to be reviewed by a panel of nationally and internationally recognised experts who work with *A. thaliana*. The expert panel included Dr Roger Hellens, Science Group Leader, Genomics, Plants and Food Research; Dr Tim Strabala, Senior Scientist and Project Leader (Molecular Forestry Programme), Scion; Associate Professor Joanna Putterill, University of Auckland; and Bruce Veit, Senior Scientist, AgResearch Grasslands. The guidance was also reviewed by an independent international expert, Dr Candice Sheldon,

Scientific Regulatory Affairs Manager, CSIRO Plant Industry and Food Health and Life Science Industries Group. Their feedback is presented in Appendix 5.

5.10. The expert panel were satisfied that the policies and protocols presented for the containment of *A. thaliana* represented international best practice. They made minor recommendations to strengthen the proposed guidance document, which we have reviewed and included in the *Arabidopsis thaliana* Containment Guidance Document ver. 2, presented in Appendix 1.

Conclusion

5.11. We consider that the containment controls and guidance documentation represents international best practice in the containment of *A. thaliana*. If the containment controls are complied with, then we are satisfied that the adverse effects from this research on the environment, human health and safety, the relationship of Māori to the environment, society and the community, and the market economy are **negligible**.

Additional matters that were considered

5.12. We considered the ability of *A. thaliana* to establish an undesirable self-sustaining population, and the ease of eradication.

5.13. Based on the containment controls (section 6) and the protocols proposed by the applicants to meet those controls (Appendix 1), we have assessed that the likelihood of escape from containment of any GM *A. thaliana*, as highly improbable. We do not consider that any of the proposed genetic modifications will enhance the ability of the organisms to escape from the containment regime.

5.14. *Arabidopsis thaliana* is already present in New Zealand, and grows wild in disturbed soil. In the highly improbable event that *A. thaliana* escaped from containment, the relevant consideration is whether GM *A. thaliana* could establish a self sustaining population.

5.15. In the highly improbable event that *A. thaliana* escaped from containment, the modified plants would need to survive in the environment undetected long enough to self fertilise and produce seeds. Any escaped plants would initially be highly localised around the exterior of the containment facility. Such plants would be quickly identified and could be easily eradicated with a standard commercially available herbicide, or by mechanical means.

5.16. Furthermore, in the highly improbable event that GM *A. thaliana* escaped from containment, and was able to persist in the environment long enough to self fertilise, the introduced traits will confer little or no selective advantage. Since a selective advantage is required for any given trait to spread

within a population, a self sustaining population of GM *A. thaliana* expressing the introduced trait is highly unlikely to form.

6. EPA staff recommended controls

6.1. We recommend that the applications to import (ERMA200792) and develop (ERMA200706) *Arabidopsis thaliana* in containment be approved, subject to the following controls:

Each of the applicant organisations granted approval under this decision (each referred to as the approval holder) must ensure compliance with the controls set out in respect of any work they carry out under this approval in a facility under their control.

Requirements for containment

1. The approved organism (Table 1) must not escape containment.
2. This approval is limited to the development in containment of the approved organism.

   [Alternative 2. This approval is limited to the importation of the approved organism into containment.]
3. A management plan must be documented specifying procedures for implementing the controls imposed under this approval.

Requirements for containment facility

4. The containment facility must be designed and constructed to contain the approved organism held within it.
5. The containment facility must be maintained in order to contain the approved organism held within it (i.e., preventing escape).
6. All measures must be taken to prevent the accidental or deliberate release of an approved organism from the containment facility.

Requirement for entering/exiting containment facility

7. All measures must be taken to ensure that persons entering and exiting the containment facility do so in a way that does not compromise the containment of the approved organism.

Requirements for moving an approved organism

8. All measures must be taken to prevent the escape of an approved organism during any movement within the containment facility or outside the containment facility.
9. Provided Control 8 is complied, with an approved organism may be moved from a containment facility to another containment facility for the purposes of laboratory based research, teaching, disposal, in case of an emergency, or any other necessary purpose.

10. Containment measures for an approved organism being transferred must require the container holding the approved organism to clearly identify the contents, containment requirements, and the details of the sender and receiver.

Requirements to limit access to the containment facility

11. All entrances must clearly identify the facility as being a containment facility.
12. All personnel entrances and other means of access into the containment facility must be specified in the management plan.
13. Unauthorised persons must be excluded from the containment facility.

Requirements for removing equipment and waste from the containment facility

14. Any waste (including biological material) that may harbour the approved organism, or heritable material from the approved organism, must be treated to ensure that the approved organism and any heritable material is killed prior to its removal from containment.
15. Any equipment that may harbour the approved organism, or heritable material from the approved organism must be treated to ensure that the approved organism and any heritable material is killed prior to being used for another purpose or removed from the containment facility.

Requirement for training of staff

16. All persons entering the containment facility (including contractors, staff, students, visitors and volunteers) must have received instruction on the containment practices of the containment facility relevant to the responsibility of the individual.

Requirements for contingency plans

17. The management plan must contain contingency plans for the accidental release or escape of an approved organism. The plan must:
    - describe the activities that will be implemented in the event that containment of an approved organism is compromised or potentially compromised;
    - include a description of recapture and eradication protocols;
    - be able to be implemented for each approved organism; and
    - be implemented if there is reason to believe that an approved organsm has escaped or been released from the containment facility.

Requirements for audits, inspections and monitoring

18. To ensure containment is being achieved and to identify any remedial maintenance requirements each containment facility must be inspected by the approval holder at reasonable intervals given the nature of the approved organism being contained.

19. The approval holder must grant MPI access to the containment facility and relevant documentation for the purpose of auditing and inspecting.
20. Each containment facility must be inspected by the approval holder as soon as possible after any event that could compromise the containment regime such as an Act of God (such as flood, earthquake), or any unauthorised attempt to enter the containment facility.
21. Remedial containment requirements identified by the approval holder or MPI (as applicable) must be completed as soon as possible, including such interim measures as are necessary to mitigate the risk of breach of containment.
22. Any structural modifications to a containment facility that may affect the integrity of containment must be approved by an MPI Inspector prior to being used to contain the approved organism.

Interpretation

1. In these controls, unless otherwise specified below, a word has the same meaning as it is defined in the HSNO Act (if any).
2. Unless the context otherwise requires:

approval holder means the organisation that has committed the resources and facilities to contain the approved organism for the purposes outlined in the application.

audit means a systematic documented review or examination and evaluation of evidence to determine the extent to which specific criteria are fulfilled.

authorised person is someone who has completed training relevant to the responsibility of that individual on the containment practises at the containment facility. Authorisation is given by the Operator (or delegated person) of the containment facility.

breach means the escape of organism(s), unauthorised entry to the containment facility, and/or the structural integrity of the facility being compromised.

contingency plan means a plan devised for a specific situation where things could go wrong. It contains information, tasks and procedures that are necessary for timely decision-making and response to an unexpected event, or situation where the preferred containment plan fails.

documentation means written or electronic records.

EPA means the Environmental Protection Authority, established under section 7 of the Environmental Protection Authority Act 2011.

MPI means Ministry of Primary Industries (former Ministry of Agriculture and Forestry).

maintenance means the process of maintaining (preserving or providing for the preservation of) or continuing a state of good repair.

operator the person who has overall responsibility for a containment facility, its maintenance and operation, in terms of section 40 of the Biosecurity Act 1993.

reasonable intervals means a period of time that MPI considers appropriate for that organisation depending on its history of compliance.

trained means individuals that undergo training or instruction in preparation for a particular role, in this case containment practices of the containment facility.

transferred means movement of an approved organsm between containment facilities subject to MPI approval.

waste unusable or unwanted substances or materials (including water or liquids, and solids).

7. Submissions

7.1. Seven submissions were received in response to public notification of the applications. Five submissions were in support, one neither supported nor opposed, and one was opposed to the applications. A summary of submissions is presented in Appendix 4.

Submissions in support of the applications

7.2. All five submissions in support of the applications highlighted the critical importance of continued research with *Arabidopsis thaliana* to New Zealand's plant science community. Many noted that GM *A. thaliana* is used by plant biologists and geneticists worldwide, and without access to this valuable research tool New Zealand's scientists cannot participate in world-leading research.

7.3. The New Zealand Institute of Agricultural and Horticultural Science supported the applications based on *Arabidopsis thaliana*'s importance as a model organism. They stated that GM *A. thaliana* will offer research opportunities with direct benefits to New Zealand's bio-economy, and noted the joint applications will enable bureaucratic and financial efficiencies.

7.4. Associate Professor Peter Dearden supported the applications because of the major benefits of GM *A. thaliana* research, and the low risks associated with using this plant in containment.

7.5. The New Zealand Society of Plant Biologists supported the applications because they believe they will standardise containment requirements for the use of *A. thaliana* in research institutes in New Zealand.

7.6. Dr Nick Albert supported the applications because he believes *A. thaliana* is an essential research tool to further agricultural and horticultural research in New Zealand. He believes that without the use of *A. thaliana* as a model plant system, plant research in New Zealand will grind to a halt.

7.7. Research with GM *A. thaliana* is important in the education sector, highlighted by Jared B. Fudge, who submitted that GM *A. thaliana* research is a necessary component of his Masters research project.

7.8. Alan Willoughby neither supported nor opposed the applications, but noted he hoped the EPA would approve the applications provided all plant material was securely contained.

Submissions in opposition to the applications

7.9. GE Free New Zealand provided a detailed submission in opposition to the applications.

7.10. GE Free New Zealand questioned whether non-GM methods can be used to achieve the same ends, citing section 44A of the HSNO Act.

7.11. The EPA notes that section 44A applies to field tests and applications to develop GM organisms in containment where the development does not take place within a containment structure. Since applications ERMA200792 and ERMA200706 are not for field tests, but for GM developments within a containment structure, this section of the HSNO Act does not apply.

7.12. GE Free New Zealand also asked how the import of viable seed will benefit New Zealand scientific expertise.

7.13. We note that scientific research is collaborative. The import of GM *A. thaliana* enables New Zealand scientists to participate in international research programmes.

7.14. GE Free New Zealand have expressed concerns that '*These applications have been submitted by multiple CRIs. This is not feasible. ...the lack of accountability that is the culture of all these applying CRIs does not provide confidence that they will follow the ERMA/EPA controls in future*'.

7.15. We acknowledge that these two applications are from multiple organisations. These organisations have purposefully collaborated to propose a standardised set of working procedures to contain GM *Arabidopsis thaliana* in New Zealand. MPI supports the intent of the applications and believes that, if these applications are approved, the enforcement of import and development approvals involving *A. thaliana* will be administered more effectively and consistently, removing some of the inconsistencies within the current range of approvals.

8. Recommendation

8.1. After reviewing the relevant information we consider that the beneficial effects arising from the import and development in containment of GM *A. thaliana* are **high**. Taking into consideration the proposed containment controls, we did not identify any non-negligible adverse effects. We consider that the beneficial effects of these applications are significantly greater than the adverse effects.

8.2. Therefore we recommend that the import and development in containment of *Arabidopsis thaliana* be approved *with controls* (section 6).

9. Impact on international obligations

9.1. We are not aware of any international obligations that may be impacted by the approval of these applications.

10. Declaration

This advice was produced by Asela Atapattu, Applications Manager New Organisms, and Seumas McCroskery, Senior EPA Advisor to assist the HSNO Decision Making Committee in deciding the applications ERMA200792 and ERMA200706 to import and develop genetically modified *Arabidopsis thaliana*. All information presented in this report is true and correct to the best of our knowledge.

Signature **1 June 2012**

Asela Atapattu
Applications Manager (New Organisms)
Environmental Protection Authority

Signature **1 June 2012**

Seumas McCroskery
Senior EPA Advisor
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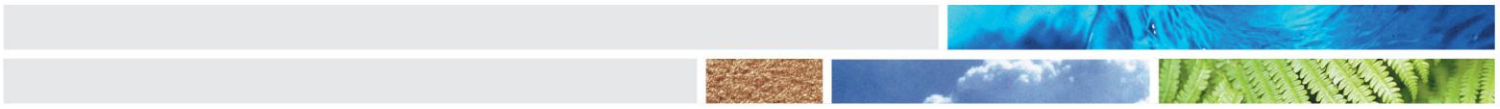

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