Environmental Protection Authority
Te Mana Rauhī Taiao

DECISION

Date	25 July 2012
Application code	ERMA200792
Application type	To import any new organism into containment under section 40(1) of the Hazardous Substances and New Organisms Act 1996
Applicant	University of Auckland, Massey University, University of Otago, Lincoln University, New Zealand Institute for Plant & Food Research Limited, Scion, AgResearch Limited, ViaLactia Biosciences New Zealand Limited, and the University of Canterbury.
Date application received	13 March 2012
Hearing and Consideration date	20 June 2012
Considered by	A decision-making Committee of the Environmental Protection Authority (the Committee)[1]: Helen Atkins (Chair) Shaun Ogilvie Richard Woods
Purpose of the application	To import genetically modified *Arabidopsis thaliana* into containment to investigate gene function and gene delivery systems, to develop new bioassays.

1. Summary of decision

1.1 The application to import genetically modified (GM) *Arabidopsis thaliana* into containment was lodged under section 40(1) of the Hazardous Substances and New Organisms Act 1996 (the Act).

1.2 The Committee has **approved** the application to import GM *Arabidopsis thaliana* (as described in Appendix 1, Table 1) in accordance with section 45(1)(a) of the Act.

[1] The Committee referred to in this decision is the subcommittee that has made the decision on this application under delegated authority in accordance with section 18A of the Act.

2. Application process

2.1. This application was considered together with the application to develop GM *Arabidopsis thaliana* in containment (ERMA200706).

Application Receipt

2.2. The application was formally received for processing on 13 March 2012.

Public notification

2.3. Section 53(2) of the Act provides that an application under section 40 of the Act may be publicly notified by the EPA if it considers that there is likely to be significant public interest.

2.4. This application was considered likely to be of significant public interest, so it was publicly notified by placing a notice on the EPA website on 19 March 2012.

2.5. In accordance with section 53(4) of the Act, EPA staff directly notified the Minister for the Environment, the Ministry for Primary Industries (MPI), the Department of Conservation (DOC), and other government departments, crown entities, and local authorities who have expressed an interest in applications for genetically modified organisms. Māori organisations, non-government organisations and stakeholders who have expressed an interest in applications for genetically modified organisms were also directly notified in writing. Those parties had an opportunity to provide written submissions on the application as per section 54(1) of the Act and clause 5 of the Hazardous Substances and New Organisms (Methodology) Order 1998 (Methodology).

2.6. Section 59(1)(c) of the Act requires an application to be open for the receipt of submissions for 30 working days from the date of public notification. The application was open for submissions for a period of 30 working days from 19 March 2012 until 3 May 2012.

2.7. Seven submissions were received: from Alan Willoughby, GE Free New Zealand, Nick Albert, Jared Fudge, Peter Dearden, the New Zealand Institute of Agricultural and Horticultural Science, and the New Zealand Society of Plant Biologists. Of these submissions, one opposed the application, five were in support, and one neither opposed nor supported the application. GE Free New Zealand requested to be heard in support of their submission.

Reports sought

2.8. Internal EPA staff advice was prepared, as provided for under section 58(1)(a) of the Act, and was published on the EPA website on 1 June 2012. The applicants and submitters were informed of the availability of the report.

Comments from MPI and DOC

2.9. MPI did not make a submission, but expressed specific comments on the details contained in the application as provided for in section 58(1)(c) of the Act. These comments were addressed in the EPA staff advice[2] presented at the hearing. MPI indicated their support for the intent of the application.

2.10. DOC had no comments on the application.

Hearing and consideration

2.11. Section 59(1)(d) of the Act requires a date for the commencement of the hearing of this application that is not more than 30 working days after the closing date for submissions. Many of the HSNO Committee[3] members had working relationships with one or more of the applicant organisations. The Chair of the HSNO Committee sought a time waiver to allow the formation of a suitable sub-committee to hear the application.

2.12. The hearing took place at the Town Hall in Wellington on 20 June 2012. The applicants and one submitter (GE Free New Zealand) presented at the hearing.

2.13. Dr Elspeth MacRae from Scion led the presentation for the applicants. She was supported by two expert witnesses: Mariette Komene – AgResearch Limited, and Dr Roger Hellens – New Zealand Institute for Plant & Food Research Limited. Mariette Komene was a member of a group of experts that produced a guidance document[4] detailing international best practice in the containment of *Arabidopsis thaliana*. Dr Hellens represented a group of experts that have reviewed the guidance document. In addition to the presentation team other members of the applicant organisations that were present at the hearing were: David Jenkins - University of Auckland; Dr Jasna Rakonjac - Massey University; Dr Richard McKnight - University of Otago; Angelene Holton - New Zealand Institute for Plant & Food Research Limited; Dr Tim Strabala – Scion; Professor Tony Conner – AgResearch Limited; Dr David Whittaker - ViaLactia Biosciences New Zealand Limited; and Dr David Collings - University of Canterbury. Claire Bleakley with support from Susie Lees spoke for GE Free New Zealand in support of their submission.

2.14. The Committee found all the information supplied by the applicants and the submitters to be valuable and informative in assisting them to make a decision. The Committee was very grateful for

[2] EPA staff advice on applications ERMA200706 and ERMA200792 The development and import of genetically modified *Arabidopsis thaliana* in containment released June 2012 http://www.epa.govt.nz/search-databases/HSNO%20Application%20Register%20Documents/ERMA200706_EPA%20Staff%20Advice%20Report.pdf

[3] The HSNO Committee is appointed by the EPA under clause 14, Schedule 5 of the Crown Entities Act 2004. As occurred with this application, the HSNO Committee may delegate its powers to hear and decide an application to a subcommittee in accordance with s 18A of the Act.

[4] Appendix 1; Appendices to the advice for applications ERMA200706 and ERMA200792, http://www.epa.govt.nz/search-databases/HSNO%20Application%20Register%20Documents/ERMA200706_EPA%20Staff%20Advice%20Report%20Appendices.pdf

these contributions from the applicants and submitters. These contributions are discussed in detail throughout this decision.

Information available for the consideration

2.15. The information available for the consideration comprised:

- The application;
- Internal EPA staff advice;
- Comments received from MPI;
- Public submissions; and
- Information obtained during the hearing.

Legislative criteria for application

2.16. The application was determined in accordance with section 45 of the Act, taking into account the matters specified in sections 39, 44, and 45, Schedule 3 (Part 1), and relevant matters in Part 2 of the Act, and the Methodology.

3. Purpose of the application

3.1. Section 45(1)(a)(i) of the Act requires that the application be for one of the purposes specified in section 39(1) of the Act. The purpose of the application is a factor in the Committee's decision on the application.

3.2. The Committee notes that GM *Arabidopsis thaliana* has been used for research purposes for more than 30 years in New Zealand. This application is in part to consolidate the plethora of containment approvals that are currently in existence.

3.3. The applicants seek approval to import GM *Arabidopsis thaliana* into containment to allow the genetic modification of *A. thaliana* for teaching and research purposes, to investigate gene function and gene delivery systems, to develop new bioassays, and to develop new plant varieties. The modifications will use genetic material from plant, animal, bacterial, fungal, viral or synthetic sources.

3.4. The Committee is satisfied that the purpose of this application is a fit and proper purpose and falls within the scope of section 39(1) (h) of the Act ("*such other purposes as the Authority thinks fit*").

4. Adequacy of containment and controls imposed

4.1. Section 45(1)(a)(iii) of the Act requires that the Committee be satisfied that the GM *Arabidopsis thaliana* can be adequately contained. This is one of the criteria for approving the application.

4.2. To evaluate the adequacy of containment, the Committee assessed the ability of GM *Arabidopsis thaliana* to escape from containment taking into account the:

- biological characteristics of the proposed GM *Arabidopsis thaliana* that relate to containment;
- containment regime; and
- potential pathways of escape of GM *Arabidopsis thaliana* from the containment facility.

Biological characteristics of *Arabidopsis thaliana* that relate to containment

4.3. *Arabidopsis thaliana* (L.) Heynh (thale cress) is a small flowering plant that is widely used as a model organism in plant biology.

4.4. The Committee notes the following characteristics of *Arabidopsis thaliana*[5]:

- It is an annual species that is self-pollinating (page 6 of application ERMA200792). The pollen is not known to have any specialised dispersal mechanisms to facilitate wind, insect or animal dispersal.
- It produces small, light seeds approximately 0.3 - 0.5 mm in length in fruits called siliques. The seeds have no specialised dispersal mechanism, but are released from ripe siliques and are passively dispersed by wind or in soil.
- It has a relatively short germination time, and fast growth rate.
- While it can grow in open disturbed sites, it does not colonise established habitats in New Zealand (page 6 of application ERMA200792).
- *Arabidopsis thaliana* is not known to be able to regenerate (i.e. grow) from plant material such as stems, roots, or leaves.
- *Arabidopsis thaliana* is not known to be able to regenerate (i.e. grow) from plant tissue culture or cell culture material.

4.5. As discussed in section 5 of the application, the proposed genetic modifications are to investigate gene function and gene delivery systems, to develop new bioassays.

The containment regime

4.6. As part of their application, the applicants proposed a set of outcome focused controls to prevent the escape of GM *Arabidopsis thaliana* from containment.

4.7. The Committee noted that EPA staff reviewed the applicants' proposed controls, and made modifications to improve their clarity and enforceability[6]. The Committee further modified the controls,

[5] Appendix 3; Appendices to the advice for applications ERMA200706 and ERMA200792, http://www.epa.govt.nz/search-databases/HSNO%20Application%20Register%20Documents/ERMA200706_EPA%20Staff%20Advice%20Report%20Appendices.pdf

[6] EPA staff advice on applications ERMA200706 and ERMA200792 The development and import of genetically modified *Arabidopsis thaliana* in containment June 2012 http://www.epa.govt.nz/search-databases/HSNO%20Application%20Register%20Documents/ERMA200706_EPA%20Staff%20Advice%20Report.pdf

having regard to the biological characteristics and potential pathways of escape of GM *Arabidopsis thaliana*.

4.8. The Committee determined the set of controls to be imposed by the EPA, as detailed in Appendix 1 of this decision.

4.9. The applicants also produced a guidance document outlining international best practise measures to ensure compliance with the controls proposed in the application. Included in this guidance document are policies and procedures for:

- staff training;
- containment facility design and maintenance;
- waste water handling; and
- other practical elements of containment.

4.10. These policies and procedures acknowledge the potential pathways of escape for GM *Arabidopsis thaliana* plants and seed, and propose measures and procedures to mitigate the risks of escape.

4.11. The Committee noted that this guidance document has been reviewed by a panel of experts in the containment of *Arabidopsis thaliana*, and it is considered to represent international best practice.

4.12. The Committee understands that the applicant organisations will use the guidance document as a reference when writing their own facility-specific containment manual. The operator of the facility is responsible for ensuring compliance with the controls imposed under this approval. The containment manual will be reviewed and used by MPI when approving, monitoring and auditing a containment facility.

4.13. The Committee noted that neither it nor the EPA has a role in approving or reviewing the guidance document.

4.14. The applicants noted at the hearing that they are "*committed to containment. Without containment we would be unable to perform the valuable research we do and to stay ahead, or at least abreast, internationally*".

4.15. Claire Bleakley, for GE Free New Zealand expressed concern over the accountability and integrity of the applicant organisations in maintaining containment. She was concerned "*not that scientists can or can't do stuff, but the honesty with which they do it. And if there is a problem, how honest is the reporting of that problem and how willing are they able to look at the risks and deal with the risks rather than push for research publications to make their name*."

4.16. In their written submission, GE Free New Zealand requested that a NGO (Non-Government Organisation) be involved in monitoring containment compliance. However, the Committee heard from Dr Barry Wards, Specialist Adviser (HSNO) of the Agency Technical Verification Services Directorate at MPI noted "*MPI is actually legislatively required to enforce the New Organism divisions of the HSNO Act. In terms of any follow up of non-compliance, we follow up all non-compliance and follow up all corrective actions."*

4.17. The Committee is satisfied that the controls it has imposed set out in Appendix 1 of the decision establish a containment regime that prevents the escape of GM *Arabidopsis thaliana* from containment. The Committee is satisfied that the containment regime provides for each of the applicable matters specified in Schedule 3 (Part 1) of the Act (Matters to be addressed by containment controls for importing, developing or field testing of genetically modified organisms).

Potential pathways of escape of GM *Arabidopsis thaliana* from containment

4.18. Controls 1-21, Appendix 1 of the decision have been imposed by the EPA to address containment.

4.19. The Committee agreed with the applicants and the EPA staff that the control of GM *Arabidopsis thaliana* seed dispersal is the most significant containment issue due to the small size of the seeds.

4.20. *The Committe*e noted that the applicants have restricted the proposed modifications to *Arabidopsis thaliana* to prohibit modifications that result in the modified organism having a greater ability to escape from containment than the unmodified host (Control 1, Table 1).

4.21. The potential pathways of escape and controls to address these are discussed in the following paragraphs.

Pathway: GM Arabidopsis thaliana seeds washed out of facility (eg, waste water overflowing and seeping through walls or floor or running under the facility entrance doorway, waste water flowing down drains).

4.22. The Committee notes this pathway and the potential it provides for seed to escape. To prevent escape the Committee imposed controls 1, 3, 4, 5, 6, 7, 12, 13, 15 and 16. For example, control 6 states: The containment facility must be maintained in order to contain the approved organism held within it (i.e., preventing escape).

4.23. The applicants noted in their guidance document that "*it is the seed that has the highest potential risk of escape, therefore we have highlighted structural elements designed to reduce the potential of seed to escape the facility*". Structural elements recommended by the applicants include:

- sealing the junction between the floor and wall in containment glasshouses/facilities;
- no gaps under doors;
- management of all waste water to ensure it contains no live approved organisms or heritable material; and
- smooth flooring, which is seamless and impervious, to allow easy seed capture.

4.24. The Committee considered that it would be highly improbable that GM *Arabidopsis thaliana* could escape from containment via this pathway taking into account the containment regime.

Pathway: GM Arabidopsis thaliana whole plants or seeds are inadvertently carried out of the facility by personnel (eg, in clothing or footwear).

4.25. The Committee notes this pathway and the potential for accidental release of seed or plants. The Committee imposes controls 1, 3, 5, 6, 7, 8, 11, 12, 13, 15 and 16, to prevent escape of *Arabidopsis thaliana* seeds or plants via this pathway. For example, control 8 states: 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.

4.26. The applicants noted in their guidance document that dedicated laboratory coats for use only in the plant house are required. The guidance document recommends that these laboratory coats are pocketless, to prevent inadvertent seed transfer and escape. The guidance material also recommends that disposable shoe covers or dedicated shoes be worn in the plant house to prevent the escape of seed in shoes, shoe treads, socks, etc. These recommendations are noted to be international best practises.

4.27. Claire Bleakley for GE Free New Zealand expressed concern over the nature and numbers of personnel permitted to enter containment facilities. She proposed that "*Only the people directly involved in an experiment should be able to enter those facilities. If you have a private partner like Monsanto or Seminis or whomever, you would have to video your experiment and send it to them through the cloud."* She noted that "*if you have a look at a lot of the training manuals at the end, I mean the audits, you'll just see this whole list of people who have been going in and out of the facility. We have no idea who they are, we don't know if they are dedicated to the team, if they are part of the organisations that are funding it, or whatever."*

4.28. In response to Ms Bleakley's concerns the Committee notes that control 11 states: Unauthorised persons must be excluded from the containment facility.

4.29. The Committee considered that it would be highly improbable that GM *Arabidopsis thaliana* could escape from containment via this pathway taking into account the containment regime.

Pathway: GM Arabidopsis thaliana whole plants or seeds escape during transit to another facility.

4.30. The Committee notes the potential for GM *Arabidopsis thaliana* plants or seed to escape containment during transit between containment facilities. The Committee imposes controls 13 and 14 that direct outcomes to prevent this pathway from occurring. For example, control 13 states : 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.

4.31. The applicant noted in their guidance document that any approved organism should be contained in at least two layers of closed containment (double containment) for transportation. It is suggested that these could include plastic microcentrifuge tubes, plastic screw-top centrifuge tubes, or air tight plastic boxes.

4.32. The Committee is satisfied that it would be highly improbable that GM *Arabidopsis thaliana* could escape from containment via this pathway taking into account the imposed containment regime.

Conclusion on adequacy of the containment regime

4.33. The Committee concluded that it is highly improbable that GM *Arabidopsis thaliana* would be able to escape from containment, taking into account the:

- biological characteristics of the proposed GM *Arabidopsis thaliana* that relate to containment;
- containment regime; and
- potential pathways of escape of the GM *Arabidopsis thaliana* from the containment facility.

4.34. Therefore, the Committee is satisfied *that GM Arabidopsis thaliana* can be adequately contained.

4.35. In particular, the Committee considers that the controls imposed in Appendix 1 provide for each of the applicable matters specified in Schedule 3 (Part 1) of the Act (as required under section 45(2) of the Act).

4.36. While section 45(2) also provides that an approval may include controls that provide for any other matters in order to give effect to the purpose of the Act, the Committee considered that no additional controls were required to achieve the purpose of the Act.

4.37. The Committee notes that it has taken into account the EPA staff advice, in particular Appendix 3 of the EPA staff advice which discusses how the controls imposed under this approval provide for the applicable matters in Schedule 3 (Part 1) of the Act.

5. Effects of the organism and any inseparable organism

5.1. The Committee is required by section 45(1)(a)(ii) to take into account all the effects of the organism and any inseparable organism, and consider whether the beneficial effects of having the organism in containment outweigh the adverse effects of the organism and any inseparable organism.

Effects of any inseparable organism

5.2. Based on the information provided, the Committee did not identify any inseparable organisms.

Effects on the matters in section 44 of the Act

The ability to establish an undesirable self-sustaining population and the ease of eradication

5.3. Sections 37 and 45(1)(a)(ii) of the Act require the Committee to have regard to the ability of the organism to establish an undesirable self-sustaining population and the ease with which the organism could be eradicated if it established such a population.

5.4. The Committee considered the ability of GM *Arabidopsis thaliana* to establish undesirable self-sustaining populations should the organism escape containment. The Committee noted that some biological characteristics of *Arabidopsis thaliana* are relevant to its ability to establish such a population and the ease with which it could be eradicated. These biological characteristics are mentioned in paragraph 4.4.

5.5. *Arabidopsis thaliana* is not known to be able to regenerate (i.e. grow) from plant material such as stems, roots, or leaves. Therefore, the escape of GM *Arabidopsis thaliana* plant material from a containment facility is not considered a feasible pathway of escape that would result in the establishment of GM *Arabidopsis thaliana* in the environment.

5.6. *Arabidopsis thaliana* is not known to be able to regenerate (i.e., grow) from plant tissue culture or cell culture material. Therefore, the escape of *Arabidopsis thaliana* cell or tissue culture material from a containment facility is not considered a feasible pathway of escape that would result in the establishment in the environment of GM *Arabidopsis thaliana*.

5.7. *Arabidopsis thaliana* plants are self-pollinating. They can produce up to 10,000 small seeds per plant, but in the native environment *Arabidopsis thaliana* seeds do not have specialised dispersal

mechanisms, and are passively dispersed by wind or in soil. As such *Arabidopsis thaliana* is not an invasive plant, and only grows in open areas of disturbed soil. This characteristic means that in the event of escape the plant is easily spotted. Since GM *Arabidopsis thaliana* is not herbicide resistant it can be easily eradicated through herbicide spray management systems.

5.8. *Arabidopsis thaliana* is self-pollinating, meaning pollen is transferred from an anther to the stigma of the same flower. The out crossing rate for *Arabidopsis thaliana* has been estimated to be less than 1%. The pollen is not known to have any specialised dispersal mechanisms to facilitate wind, insect or animal dispersal. There is no evidence to suggest that *Arabidopsis thaliana* will hybridise with any other plants in New Zealand[7].

5.9. The Committee considers that in the highly improbable event that the GM *Arabidopsis thaliana* escapes containment and forms self-sustaining populations, such populations would be easily eradicated.

The ability of the organism to escape from containment

5.10. Sections 44(b) and 45(1)(a)(ii) of the Act require the Committee to have regard to the ability of the organism to escape from containment.

5.11. As discussed in Section 4 of this decision (Adequacy of containment and controls imposed), the Committee considered that it is highly improbable that GM *Arabidopsis thaliana* would be able to escape from containment, taking into account the:

- biological characteristics of the proposed GM *Arabidopsis thaliana* that relate to containment;
- containment regime; and
- potential pathways of escape of the GM *Arabidopsis thaliana* from the containment facility.

Assessment of adverse effects[8]

5.12. The Committee considered the potential adverse effects of GM *Arabidopsis thaliana* on human health and safety, the environment, society and communities, Māori culture and traditions, the principles of the Treaty of Waitangi and the market economy.

5.13. In considering the adverse effects of GM *Arabidopsis thaliana* (and any inseparable organisms) the Committee took into account the adverse effects (if any) of having the organism and any inseparable organisms in containment, the probability that the organism may escape containment after considering

[7] Appendix 3; Appendices to the advice for applications ERMA200706 and ERMA200792, http://www.epa.govt.nz/search-databases/HSNO%20Application%20Register%20Documents/ERMA200706_EPA%20Staff%20Advice%20Report%20Appendices.pdf

[8] Adverse effects can include any risks and costs associated with having the organism in containment.

all the controls to which the organism would be subject to if the application was approved, and the effects of the organism if the organism were to escape (section 45(4) of the Act).

Effects on the environment

5.14. The Committee considered the information provided on potential effects on the environment, noting that all work with *Arabidopsis thaliana* will be conducted in containment facilities.

5.15. GE Free New Zealand commented that some of the potential negative effects of GMOs will likely manifest in the long term, and be diffuse in nature, remarking on events at past overseas outdoor field trials.

5.16. After assessing all the information and the containment measures imposed and the likelihood of escape from containment, the Committee did not identify any non-negligible adverse effects on the environment.

Effects on human health and safety

5.17. The Committee noted that *Arabidopsis thaliana* is considered one of the most widely studied plant species. No significant adverse effects on human health and safety have been identified.

5.18. After assessing all the information, the Committee did not identify any non-negligible adverse effects on human health and safety from the import into containment of GM *Arabidopsis thaliana*.

Effects on Māori and their culture and traditions and the principles of the Treaty of Waitangi (Te Tiriti o Waitangi)

5.19. The Committee took into account the effects on the relationship of Māori and their culture and traditions with their ancestral lands, water, sites, waahi tapu, valued flora and fauna, and other taonga, and the principles of the Treaty of Waitangi.

5.20. The Committee noted that the applicants have excluded from this application all genetic modifications to *Arabidopsis thaliana* which use genetic material from native flora and fauna, or from Māori sources. This exclusion is reflected in the scope of the approval as per the definition of the approved organism in Appendix 1 (Control 1, Table 1).

5.21. After assessing all the information, the Committee did not identify any non-negligible adverse effects on the relationship of Māori and their culture and traditions with their ancestral lands, water, sites, waahi tapu, valued flora and fauna, and other taonga.

5.22. Given the absence of identified effects to the outcomes of significance to iwi/Māori (as outlined in the Protocol 'Incorporating Māori perspectives in HSNO Act decision making') the Committee considered the application to be broadly consistent with the principles of the Treaty of Waitangi.

Effects on the market economy

5.23. The Committee took into account the effects of importing GM *Arabidopsis thaliana* into containment on the market economy. It also noted that *Arabidopsis thaliana* is not a crop plant, and is used for research purposes only within MPI approved containment facilities.

5.24. Claire Bleakley for GE Free New Zealand was concerned that if GM *Arabidopsis thaliana* were to escape from containment, this could have negative impacts on New Zealand's reputation as a primary producer.

5.25. The Committee considered that the containment regime proposed was sufficient to contain GM *Arabidopsis thaliana*, and considered the risk of escape is negligible.

5.26. After assessing all the information, the Committee did not identify any non-negligible adverse effects on the market economy.

Effects on society and community

5.27. The Committee took into account the effects of importing GM *Arabidopsis thaliana* into containment on society and the community. It also noted that the import of *Arabidopsis thaliana* is for research and teaching purposes, and the organism will be held within MPI approved containment facilities.

5.28. After assessing all the information, the Committee did not identify any non-negligible adverse effects on society and community from the import into containment of GM *Arabidopsis thaliana*.

Conclusion on assessment of adverse effects

5.29. After considering the information provided, the Committee did not identify any adverse effects from the import into containment of GM *Arabidopsis thaliana*. Therefore the Committee considered that any adverse effects would be negligible. Since the Committee did not identify any adverse effects from the import into containment of GM *Arabidopsis thaliana*, the Committee was not required to take into account the probability of occurrence or magnitude of any adverse effects.

Assessment of beneficial effects

5.30. The Committee considered the potential beneficial effects on human health and safety, the environment, society and community, Māori culture and traditions, and the market economy from the import into containment of GM *Arabidopsis thaliana*.

5.31. Dr Roger Hellens for the applicants noted that: "*Ultimately Arabidopsis is more than a model. It's actually a reference for all plant genomics. The genome was sequenced 10 years ago, and the gene models and gene structures in the Arabidopsis genome are a reference for work in all other plants, including crops. Physicists have SI units, and Chemists have the Periodic Table of Elements, and Plant Biologists have got the Arabidopsis genome."*

5.32. Dr Elspeth MacRae for the applicants explained that "*[Arabidopsis] is very important for teaching the next generation of plant biologists, and geneticists, and molecular biologists*."

5.33. Dr Roger Hellens for the applicants noted the value of GM *Arabidopsis thaliana* research in responding to New Zealand's recent *Pseudomonas syringae* pv. *actinidiae* (Psa) outbreak in kiwifruit. He explained: "*In kiwifruit research with Psa we have had to quickly go from having no work on Pseudomonas resistance to a sizable chunk of work going on. Two things have really helped that. For one, we've sequenced the kiwifruit genome, so we can find kiwifruit genes that may contribute to enhanced tolerance, or even ultimately resistance. But a lot of that work has relied on identifying genes and gene models based on work that has gone on with Arabidopsis*". He noted "*Certainly, the information from Arabidopsis is helping us better understand how we might in future develop resistant kiwifruit through the genes that exist in the germplasm that are not in our breeding programs yet, but which may have resistant loci."*

5.34. Claire Bleakley for GE Free New Zealand said "*there was a lack of results of what the last 10 years of GE experiments has added to New Zealand scientific knowledge."*

5.35. The applicants presented information showing that over the last 14 years New Zealand has produced multiple patents and publications arising from *Arabidopsis thaliana* research. A search found 34 patents[9] using *Arabidopsis thaliana,* and at least 102 peer reviewed scientific publications[10]. The applicants also spoke of multiple Masters and PhD. theses produced that used *Arabidopsis thaliana* as a scientific reference plant.

5.36. The Committee noted that research activities conducted by the applicant organisations require funding – much of which comes from New Zealand government sources – and this funding is subject to reporting on results.

[9] Searching the US Patent and Trade Office web site - July 2012 key words Arabidopsis and assignee country New Zealand.
[10] Searching Pubmed 1998 - July 2012 key words, Arabidopsis and New Zealand.

5.37. The Committee identified beneficial effects arising from the import into containment of GM *Arabidopsis thaliana*, including:

- knowledge benefits to the research community;
- benefits to students and tertiary education institutes as a result of GM *Arabidopsis thaliana* being used in teaching; and
- economic benefits as a flow on effect of research conducted with GM *Arabidopsis thaliana.*

5.38. After considering the information, the Committee identified multiple beneficial effects of the import into containment of GM *Arabidopsis thaliana*. The Committee considered that these beneficial effects would be non-negligible. Given that the Committee considered that any adverse effects from the import of GM *Arabidopsis thaliana* into containment would be negligible, the existence of non-negligible beneficial effects means that the beneficial effects of the import of GM *Arabidopsis thaliana* into containment will outweigh the adverse effects.

6. Overall evaluation and weighing of beneficial and adverse effects

6.1. The Committee considered that they had sufficient information to weight the effects of the GM *Arabidopsis thaliana* importation into containment.

6.2. Overall, the Committee did not identify any non-negligible adverse effects from the import into containment of GM *Arabidopsis thaliana*.

6.3. Given that there were no non-negligible adverse effects identified, consideration of whether the adverse effects may aggregate in order to assess any cumulative effects was not relevant.

6.4. The Committee concluded that the beneficial effects accruing from the import into containment of GM *Arabidopsis thaliana* are non-negligible.

6.5. The Committee, having considered all the effects of GM *Arabidopsis thaliana*, the effects of any inseparable organisms, and the matters outlined in section 45 of the Act, concluded that:

a) the application is for one of the purposes specified in section 39(1);
b) the beneficial effects of importing GM *Arabidopsis thaliana* into containment outweigh the adverse effects of the approved organism and any inseparable organisms; and
c) the approved organism can be adequately contained.

7. Achieving the purpose of the Act

7.1. The purpose of the Act is to protect the environment, and the health and safety of people and communities, by preventing or managing the adverse effects of hazardous substances and new organisms (section 4 of the Act).

7.2. In order to achieve the purpose of the Act, when considering the application the Committee recognised and provided for the following principles (section 5 of the Act):

a) the safeguarding of the life-supporting capacity of air, water, soil and ecosystems; and
b) the maintenance and enhancement of the capacity of people and communities to provide for their own economic, social and cultural well-being and for the reasonably foreseeable needs of future generations.

7.3. The Committee took into account the following matters when considering the application in order to achieve the purpose of the Act (sections 6, 7 and 8 of the Act):

- the sustainability of all native and valued introduced flora and fauna;
- the intrinsic value of ecosystems;
- public health;
- the relationship of Māori and their culture and traditions with their ancestral lands, water, sites, waahi tapu, valued flora and fauna, and other taonga;
- the economic and related benefits and costs of using a particular hazardous substance or new organism;
- New Zealand's international obligations;
- the need for caution in managing adverse effects where there is scientific and technical uncertainty about those effects; and
- the principles of the Treaty of Waitangi (Te Tiriti o Waitangi).

7.4. The Committee is satisfied that this decision is consistent with the purpose of the Act and the above principles and matters. Any substantive issues arising from the legislative criteria and issues raised by submitters have been discussed in the preceding sections of this decision.

8. Associated approvals

8.1. The Committee notes that the approval granted under this decision does not affect the requirements of the Biosecurity Act 1993, including any authorisations or approvals that may be required under that Act (such as approval of containment facilities by MPI).

9. Decision

9.1. After reviewing all of the information contained in the application, the Committee was satisfied that the application met the requirements of section 40 of the Act.

9.2. The Committee considered that the threshold for approval under section 45 of the Act has been met, it is satisfied that the organisms can be adequately contained and that the beneficial effects of the organisms outweigh the adverse effects of the organisms, taking into account all of the following:

- all the effects of the organisms and any inseparable organism;
- the matters in section 39, 44, and 45, and Schedule 3 (Part 1) of the Act;
- the relevant matters in Part 2 of the Act; and
- the Methodology.

9.3. The Committee decided to exercise its discretion and **approve** the import into containment of GM *Arabidopsis thaliana* under section 45(1)(a) of the Act. The Committee noted that in accordance with section 45(2) of the Act, the approval has been granted with controls.

9.4. The Committee wished to thank the applicants and the submitters for their presentations. It appreciated the time the presenters made to present in a frank and open manner that was very respectful to everyone's respective positions even when these were opposed.

Signed	**25 July 2012**
Helen Atkins **Chair, Decision Making Committee** **Environmental Protection Authority**	**Date**

Approval code: GMC100152

Approval number for the organism in application ERMA200792

Organism	Approval number
Arabidopsis thaliana (L.) Heynh.	**GMC100152**

Appendix 1: Controls required by this approval[11]

Any person importing the approved organism under the approval granted by this decision (each referred to as the approval holder) must ensure compliance with the controls set out below in respect of any activity 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.

Table 1: Approved organism 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.

[11] Compliance with the controls imposed under this decision does not affect the requirements of the Biosecurity Act 1993, including any authorisations or approvals that may be required under that Act (such as approval of containment facilities by MPI).

2. This approval is limited to the import of the approved organism into containment.

Requirements for containment facility

3. A management plan must be documented specifying procedures for implementing the controls imposed under this approval.

4. The management plan must contain contingency plans for the accidental release or escape of the 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 the approved organism; and
    - be implemented if there is reason to believe that the approved organism has escaped or been released from the containment facility.

5. The containment facility must be designed and constructed to contain the approved organism held within it.

6. The containment facility must be maintained in order to contain the approved organism held within it (i.e., preventing escape).

7. All measures must be taken to prevent the accidental or deliberate release of the approved organism from the containment facility.

Requirement for entering/exiting containment facility

8. 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 to limit access to the containment facility

9. All entrances must clearly identify the facility as being a containment facility.

10. All personnel entrances and other means of access into the containment facility must be specified in the management plan.

11. Unauthorised persons must be excluded from the containment facility.

Requirement for training of staff

12. 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 moving an approved organism

13. All measures must be taken to prevent the escape of the approved organism during any movement within the containment facility or outside the containment facility.

14. Containers used for moving the approved organism must clearly identify the contents and containment requirements. When the approved organism is being moved from one approval holder to another approval holder, the container used must also display details of the sender and receiver.

Requirements for removing equipment and waste from the containment facility

15. Subject to Control 13, 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 disposal.

16. Subject to Control 13, 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.

Requirements for audits, inspections and monitoring

17. 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.

18. The approval holder must grant MPI access to the containment facility and relevant documentation for the purpose of auditing and inspecting.

19. 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.

20. 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.

21. 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.

Requirements for Notification

22. Each approval holder must, the first time it uses this approval at each containment facility, notify EPA and the MPI Inspector in writing.

Interpretation

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

2. Unless the context otherwise requires:

approved organism means the organism(s) described in Table 1 of this Appendix 1.

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 the approved 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 for 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 is 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 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.

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