



## DECISION

<b>Date</b>	24 December 2012
<b>Application code</b>	APP201556
<b>Application type</b>	To import into containment any new organism under section 40(1) of the Hazardous Substances and New Organisms Act 1996
<b>Applicant</b>	The New Zealand Institute for Plant and Food Research Limited
<b>Date application received</b>	16 November 2012
<b>Consideration date</b>	19 December 2012
<b>Considered by</b>	A decision-making Committee of the Environmental Protection Authority (the Committee) <sup>1</sup> : Kevin Thompson (Chair) Val Orchard Damian Stone
<b>Purpose of the application</b>	To import <i>Parakeelya</i> species into containment for the study of plant pigments
<b>The new organisms approved</b>	<i>Parakeelya</i> species

### 1. Summary of decision

- 1.1 The application to import *Parakeelya* species (APP201556) into containment was lodged under section 40(1) of the Hazardous Substances and New Organisms Act 1996 (the Act).
- 1.2 The application was considered in accordance with the relevant provisions of the Act and of the HSNO (Methodology) Order 1998 (the Methodology).
- 1.3 The Committee has **approved** the application to import *Parakeelya* species (as described in Appendix 1, Table 1) in accordance with section 45(1)(a) on the Act.

<sup>1</sup> 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

### Application Receipt

- 2.1 The application was formally received for processing on 16 November 2012.
- 2.2 The Committee considered that it had sufficient information to assess the application. To the extent the application may not meet any legislative information requirements, the EPA waives these requirements.

### 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 The Chief Executive has delegation to decide whether to publicly notify an application to import into containment any new organism. This application was not publicly notified because the Chief Executive did not identify any exceptional circumstances warranting public notification, or any significant public interest in this application.

### Comments from MPI and DOC

- 2.5 In accordance with section 53(4) of the Act, and the Methodology, EPA staff advised the Ministry for Primary Industries (MPI), and the Department of Conservation (DOC) of the application, and they were provided with the opportunity to comment.
- 2.6 MPI commented on the physical containment level at which the new organisms are proposed to be held, and suggested that research with *Parakeelya* should be conducted at a specified level of physical containment. Their comments were addressed by EPA staff in the Internal EPA staff advice. EPA staff advised that the applicant is required to document their physical containment procedures in their containment manual, and they must satisfy MPI that these procedures will be adequate to contain *Parakeelya* species before importation is permitted. MPI have indicated their support for the intent of the application.
- 2.7 DOC indicated that they had no significant concerns with the application, given it is an application for containment.

### Reports sought

- 2.8 Internal EPA staff advice was prepared, as provided for under section 58(1)(a) of the Act. EPA staff recommended that the application to import *Parakeelya* species into containment be approved.



## Information available for the consideration

2.9 The information available for the consideration comprised:

- the application form and references provided therein;
- Internal EPA staff advice memorandum; and
- Comments received from MPI.

## Sequence of the consideration

2.10 In its consideration of the application as per the requirements in the Act and the Methodology, the Committee considered;

- whether the application is for one of the purposes specified in the Act;
- whether the new organisms can be adequately contained;
- whether the set controls provide for matters specified in Schedule 3 (Part II) of the HSNO Act;
- whether the beneficial effects of allowing the new organisms in containment outweigh the adverse effects of allowing the new organisms in containment;
- the ability of the new organisms to escape from containment;
- the ability of the new organisms to establish undesirable self-sustaining populations; and
- the ease with which the new organisms could be eradicated if they established an undesirable self-sustaining population.

2.11 Each point is addressed in the following sections of this decision.

## 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 an application is a factor in the Committee's decision on that application.

3.2 The applicant (New Zealand Institute for Plant and Food Research Ltd) seeks to import *Parakeelya* species into containment for the study of plant pigments.

3.3 The Committee was 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*").

3.4 The Committee noted that the use of this approval is not limited to the applicant. Therefore, any person may use this approval provided that their intended imports comply with the approved organism description (control 1); meet the purpose of this approval (the study of plant pigments); and that the new organisms are maintained in accordance with the containment controls placed on this approval



(Appendix 1). Any persons using this approval must notify the EPA and MPI in writing prior to the first time they use the approval (control 22).

## 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 new organisms can be adequately contained in order to approve the application.
- 4.2 To evaluate the adequacy of containment, the Committee assessed the ability of the *Parakeelya* species to escape containment taking into consideration the:
- biological characteristics of *Parakeelya* species that relate to containment;
  - proposed containment regime; and
  - potential pathways for the escape of *Parakeelya* species from the containment facility.

### Biological characteristics of *Parakeelya* species that relate to containment

- 4.3 Members of the *Parakeelya* genus are small, hardy, annual flowering plants endemic to Australia. The normal habitat for *Parakeelya* spp. is the arid and semi-arid regions of Australia, of which New Zealand has limited comparison.
- 4.4 The Committee noted the following characteristics of *Parakeelya* species:
- Flowers of *Parakeelya* species are insect pollinated, and have limited self fertility (EPA Internal Staff Advice Memo, page 1).
  - *Parakeelya* species produce small, light seeds. The seeds have no specialised dispersal mechanisms, and are passively dispersed by wind or in soil.
  - Their natural habitat is the arid and semi-arid regions of Australia.
  - No inseparable organisms were identified.

### The containment regime

- 4.5 The Committee determined the set of controls to be imposed on this approval, and these are detailed in Appendix 1 of this decision.
- 4.6 The Committee was satisfied that the controls set out in Appendix 1 of this decision establish a containment regime that prevents the escape of *Parakeelya* species from containment. The Committee was satisfied that the containment regime provides for each of the applicable matters specified in Schedule 3 (Part 2) of the Act (Matters to be addressed by containment controls for new organisms excluding genetically modified organisms), as outlined in Table 1.



## Potential pathways of escape of *Parakeelya* species from containment

4.7 The Committee considered the potential pathways of escape from containment of the *Parakeelya* species proposed to be imported, and assessed these pathways against the requirements of the controls in Appendix 1, the biological characteristics of the organisms, and the containment regime imposed by this approval (Table 1).

Table 1 Assessment of potential pathways of escape

Potential pathways of escape	Assessment
Escape during transport to and from the containment facility.	<b>Highly improbable</b> as the containment regime includes specific requirements for moving new organisms ( <b>controls 1, 13, and 14</b> ).
Escape due to accidental or deliberate removal by staff or unauthorised persons.	<b>Highly improbable</b> as the containment regime specifically requires that procedures be established to prevent unauthorised access to the facility. It also requires that the facility is clearly identified as a containment facility, and that unauthorised persons be excluded from the facility ( <b>controls 8, 9, and 10</b> ).  The containment regime requires operational procedures be established to ensure that new organisms are contained and do not escape containment through incorrect handling or the disposal of wastes from the facility ( <b>controls 1, and 3 to 11</b> ).  Persons entering the containment facility are to be instructed on the containment practices relevant to that individual's responsibility ( <b>control 12</b> ).
Escape during or following fire, flood or natural disaster.	<b>Highly improbable</b> as the containment regime requires that containment facilities have contingency plans for these events (breaches of containment through an accident, deliberate action, natural disaster, fire, theft, sabotage, or any other event) ( <b>controls 4, and 17 to 21</b> ).

## Conclusion on adequacy of the containment regime

4.8 The Committee concluded that it is **highly improbable** that the *Parakeelya* species would be able to escape from containment.

4.9 Therefore, the Committee is satisfied that the new organisms can be adequately contained.

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



- 4.11 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.

## 5. Ability of the organisms to establish a self-sustaining population and ease of eradication

- 5.1 In accordance with sections 37 and 44 of the HSNO Act and clause 10(e)(f) of the Methodology, the Committee considered the ability of the *Parakeelya* species to form self-sustaining populations should they escape containment, and the ease of eradicating such populations should they establish.
- 5.2 The Committee considers that for a self-sustaining population to establish, the new organisms would need to escape containment, find a suitable location and suitable conditions to become established, and be capable of surviving in New Zealand's environment.
- 5.3 The Committee noted that as the *Parakeelya* species derive from arid and semi-arid regions of Australia and cannot survive low temperatures, they will be unlikely to survive in New Zealand's climate. However, the Committee considered that the organisms could potentially survive in the warmer climate of northern parts of New Zealand, in the **highly improbable** event that they escaped containment.
- 5.4 The Committee considered that in the **highly improbable** event that the new organisms escape containment and form a self-sustaining population, the probability of eradication would be high because the population is likely to be small, and confined to a localised area.
- 5.5 The Committee acknowledged that if a self-sustaining population was to form, the plants can be identified by visual searches by their fleshy succulent leaves and brightly coloured flowers. Eradication is then possible through the use of standard, readily available herbicides, and/or mechanical destruction.

## 6. Identification and assessment of potentially significant adverse and beneficial effects (risks, costs and benefits)

- 6.1 The Committee is required by section 45(1)(a)(ii) of the Act 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 (Table 2).



Table 2 Assessment of potentially significant adverse and beneficial effects from the new organisms

Potentially significant effect:	Significance	Discussion
Potential for the imported organisms to have an adverse effect on New Zealand's flora and fauna and valued introduced species:	Significance: <b>negligible</b>	Potential adverse effects could occur in the form of displacement of native or valued species in their natural environment.  Having considered the containment regime (Appendix 1) and likelihood of escape from containment, the Committee considered that the likelihood of this effect occurring is <b>highly improbable</b> . The Committee therefore considered this risk <b>negligible</b> .
Potentially significant adverse effect on human health and safety:	None identified	
Potentially significant adverse effect on Māori culture and traditions:	Significance: <b>negligible</b>	Adverse effects on Māori culture or traditions could only occur through an escape of the new organisms from containment, formation of a self-sustaining population, consequent effects on valued flora, fauna, and other taonga, environmental degradation and decline in the well being of communities.  Having considered the containment regime (Appendix 1) and the likelihood of the new organisms escaping containment is <b>highly improbable</b> , the Committee did not identify any potentially significant effects on Māori culture and traditions. The Committee therefore considered this risk <b>negligible</b> .
Potentially significant adverse effect on society and community:	None identified	
Potentially significant adverse effect on the market economy:	None identified	
Potentially significant beneficial effects on the environment, human health and safety and Māori culture and traditions:	None identified	
Potentially significant beneficial effects on human health and safety:	None identified	



Potentially significant beneficial effects on market economy:	None identified	
Potentially significant beneficial effects on society and community:  Benefits to the science community in understanding details of the development of plant pigmentation, and its evolutionary significance.	Significance: <b>non-negligible</b>	Key benefits of this application are the development of new scientific knowledge and expertise. Given the applicant's strong record of research output the likelihood of beneficial effects is <b>likely</b> . The benefits to be gained from this research are considered <b>minor</b> . The Committee therefore considered the benefits <b>non-negligible</b> .



### Conclusion on the risks, costs, and benefits

- 6.2 After considering the relevant information, the Committee did not identify any adverse effects from importing *Parakeelya* species into containment. Therefore, the Committee considered that any adverse effects would be **negligible**. Since the Committee did not identify any adverse effects, the Committee was not required to consider the probability of occurrence or magnitude of any adverse effects.
- 6.3 After considering the relevant information, the Committee identified beneficial effects on society and the community from importing *Parakeelya* species into containment, such as the development of new scientific knowledge and expertise. The Committee considered that these beneficial effects would be **non-negligible**.

## 7. Evaluation and weighing of positive and adverse effects

- 7.1 The Committee considered that they had sufficient information to weigh the effects of the new organisms in containment.
- 7.2 The Committee concluded that the potential adverse effects of importing the new organisms into containment were **negligible**, and that the benefits to society and the community were **non-negligible**.
- 7.3 Given that there were no adverse effects identified, consideration of whether the adverse effects may aggregate in order to assess any cumulative effects was not relevant.
- 7.4 The Committee took into account all the effects of the new organisms, and all the measures available for risk management, and concluded that it was evident that the positive effects outweigh the adverse effects of importing *Parakeelya* species into containment in New Zealand.
- 7.5 Section 6(f) of the Act requires the Committee to take into account New Zealand's international obligations when determining this application. New Zealand has no obligations which are relevant to this approval.
- 7.6 The Committee, having considered all the effects of the new organisms in containment and the effects of any inseparable organisms, and the matters outlined in section 45 of the Act, concluded that:
- the application is for one of the purposes specified in section 39(1) of the Act;
  - the beneficial effects outweigh the adverse effects of the new organisms and any inseparable organisms; and
  - the approved organism can be adequately contained.



## 8. Achieving the purpose of the Act

- 8.1 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).
- 8.2 In order to achieve the purpose of the Act, the Committee recognised and provided for the following principles of the Act (section 5 of the Act) when considering the application:
- the safeguarding of the life-supporting capacity of air, water, soil and ecosystems; and
  - 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.
- 8.3 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).
- 8.4 The Committee was 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.

## 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 new organisms and any inseparable organism;



- the matters in section 37, 44, and 45, and Schedule 3 (Part 2) 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 *Parakeelya* species, 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.

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**Kevin Thompson**  
**Chair, Decision Making Committee**  
**Environmental Protection Authority**

**Date 20 December 2012**

Approval code: *NOC100146*



Table 3 New organisms and approval numbers for organisms in application APP201556

<b>Organism</b>	<b>Approval code</b>
<i>Parakeelya</i> species	NOC100146



## Appendix 1: Controls required by this approval

Any person importing the approved organisms 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 organisms (*Parakeelya* species) must not escape containment.
2. This approval is limited to the importation into containment of the approved organisms.

### 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 organisms. The plan must:
  - describe the activities that will be implemented in the event that containment of an approved organisms is compromised or potentially compromised;
  - include a description of recapture and eradication protocols;
  - be able to be implemented for the approved organisms; and
  - be implemented if there is reason to believe that the approved organisms have escaped or been released from the containment facility.
5. The containment facility must be designed and constructed to contain the approved organisms held within it.
6. The containment facility must be maintained in order to contain the approved organisms held within it (i.e., preventing escape).
7. All measures must be taken to prevent the accidental or deliberate release of the approved organisms 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 organisms.

### 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 organisms during any movement within the containment facility or outside the containment facility.

14. Containers used for moving the approved organisms must clearly identify the contents and containment requirements. When the approved organisms are 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 organisms, or heritable material from the approved organisms, must be treated to ensure that the approved organisms and any heritable material are killed prior to disposal.

16. Subject to Control 13, any equipment that may harbour the approved organisms, or heritable material from the approved organisms must be treated to ensure that the approved organisms 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 organisms 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 (for example flood, earthquake etc), 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 organisms.

### **Requirements for notification**

22. Each approval holder must, prior to the first time it uses this approval at each containment facility, notify the EPA and the MPI inspector in writing that the approval will be used.



## 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:

**approval holder** means any person importing the approved organisms under the approval granted by this decision.

**approved organism** means the organisms described in Control 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).

