



Australian Government

Department of Health and Ageing

Office of the Gene Technology Regulator

Licence for Dealings Involving an Intentional Release of GMOs into the Environment

Licence No.: DIR 026/2002

Licence holder: University of Queensland

**Title: The limited and controlled release of
genetically modified papaya**

Issued: 17 June 2003

Varied: 29 October 2004

Varied: 9 June 2006

Varied: 17 September 2010

Varied: 12 September 2011

More information about this licence is contained in the Risk Assessment and Risk Management Plan prepared in connection with this licence. This document can be obtained from the Office of the Gene Technology Regulator website at <http://www.ogtr.gov.au>, or by telephoning the Office on 1800 181 030.

Note in relation to the approval of genetically modified foods for human consumption

Food Standards Australia New Zealand (FSANZ, formerly the Australia New Zealand Food Authority, ANZFA), is responsible for human food safety assessment. Currently, the University of Queensland has not applied to FSANZ for evaluation of material from the GM papayas for use in human food. FSANZ approval would need to be obtained before any parts of the GM papayas, including the fruits, could be used as human food.

PART 1

Duration of Licence

- 1 This licence remains in force until it is suspended, cancelled or surrendered. No dealings with GMOs are authorised during any period of suspension.

Holder of Licence

- 2 The holder of this licence ('the licence holder') is the University of Queensland.

Details of Project Supervisor

- 3.1 The Project Supervisor in respect of this Licence is identified at Attachment A.
- 3.2 The licence holder must immediately notify the Regulator in writing if any of the contact details of the Project Supervisor change.

No dealings with GMO except as authorised by this licence

- 4 Persons authorised by this licence must not deal with the GMO except as expressly authorised or contemplated by this licence.

Permitted dealings

- 5 The permitted dealings with the GMOs are to, plant, grow and conduct experiments with the GMOs, and the possession, supply, use, transport and disposal of the GMOs for the purpose of any of the permitted dealings, or in the course of any of these dealings.

Persons covered by this GMO licence

- 6.1 The persons covered by this licence are the licence holder and employees, agents or contractors of the licence holder and other persons who are, or have been, engaged to undertake any activity in connection with a GMO grown in a Location pursuant to this Licence.
- 6.2 The licence holder must not allow a person to deal with the GMO unless the person is listed.

***Explanatory Note:** People named in the list are persons covered by a licence for purposes of the Gene Technology Act 2000. It may be an offence, or a breach of this licence, if a person not on the list deals with a GMO covered by this licence.*

Informing people of their obligations

- 7.1 The licence holder must inform each person covered by this licence of the obligations imposed on them as a result of the conditions in this licence.
- 7.2 The licence holder must provide the Regulator, on the Regulator's written request, with a signed statement from each person covered by this licence that the licence holder has informed the person of the conditions of this licence that apply to that person.

Applicant to notify of circumstances that might affect suitability

- 8 The licence holder must immediately, by notice in writing, inform the Regulator of:
- (a) any relevant conviction of the licence holder occurring after the commencement of this licence;
 - (b) any revocation or suspension of a licence or permit held by the licence holder under a law of the Commonwealth, a State or a foreign country, being a law relating to the health and safety of people or the environment; or
 - (c) any event or circumstances occurring after the commencement of this licence that would affect the capacity of the licence holder to meet the conditions in it.

Additional information to be given to the Regulator

- 9 The licence holder must inform the Regulator if he or she:
- (a) becomes aware of additional information as to any risks to the health and safety of people, or to the environment, associated with the dealings authorised by the licence; or
 - (b) becomes aware of any contraventions of the licence by a person covered by the licence; or
 - (c) becomes aware of any unintended effects of the dealings authorised by the licence.

People dealing with GMO must allow auditing and monitoring of the dealing

- 10 If a person is authorised by this licence to deal with a GMO and a particular condition of this licence applies to the dealing by that person, the person must allow the Regulator, or a person authorised by the Regulator, to enter premises where the dealing is being undertaken, for the purposes of auditing or monitoring the dealing.

Remaining an accredited organisation

- 11 The licence holder must at all times remain an accredited organisation and comply with conditions of accreditation set out in the OGTR guidelines for accreditation of organisations.

PART 2

Interpretation and Definitions

Words and phrases used in this licence have the same meanings as they do in the *Gene Technology Act 2000* (the Act) and the *Gene Technology Regulations 2001*.

Words importing a gender include any other gender.

Words in the singular include the plural and words in the plural include the singular.

Words importing persons include a partnership and a body whether corporate or otherwise.

References to any statute or other legislation (whether primary or subordinate) are a reference to a statute or other legislation of the Commonwealth of Australia as amended or replaced from time to time unless the contrary intention appears.

Where any word or phrase is given a defined meaning, any other part of speech or other grammatical form in respect of that word or phrase has a corresponding meaning.

In this licence:

‘Cage’ means a self-supporting enclosure designed to eliminate key pollinating insects, comprising transparent nylon netting no greater than 2.0 mm² pore size, sealed to the ground.

‘Clean’ (or **‘Cleaned’** or **‘Cleaning’**) means, as the case requires:

- (a) in relation to a Location or an area, the Destruction of the GMOs or Material from the GMOs to the reasonable satisfaction of the Regulator; or
- (b) in relation to Equipment, the removal and Destruction of the GMOs, and Material from the GMOs, to the reasonable satisfaction of the Regulator.

‘Destroy’, (or **‘Destroyed’**, or **‘Destruction’**) means, as the case requires, killed by autoclaving, incineration or burial under at least 1 metre of soil, which must remain undisturbed for at least 12 months.

‘Equipment’ includes planting equipment, harvesting equipment, storage equipment, transport equipment (eg. bags, containers, trucks), clothing and tools.

‘GM’ means genetically modified.

‘GMOs’ mean the genetically modified organisms covered by this licence.

‘Location’ means the location referred to in Clause 1.1 of Part 3 of this licence.

‘Material from the GMOs’ means stem sections, leaves, pollen or any other genetically modified material (including parts of GMOs) that are derived from or produced by the GMOs.

‘OGTR’ means the Office of the Gene Technology Regulator.

‘QDPIRRS’ means Queensland Department of Primary Industry Redlands Research Station.

‘Regulator’ means the Gene Technology Regulator.

‘Waterways’ includes streams, rivers and open irrigation channels.

PART 3 CONDITIONS OF LICENCE

Location and size of release

- 1.1 Planting of GMOs must be confined to a single planting area ('the Location') within the QDPIRRS in the Shire of Redlands.
- 1.2 The QDPIRRS must be secured against public access by fencing with a lockable gate.
- 1.3 The Location must have appropriate signage to indicate that GM papayas are being grown in it and that the GMOs and Material from the GMOs (eg. fruit) must not be removed from the Location except as expressly authorised by the Licence.
- 1.4 The total area of the Location must not exceed one hectare.
- 1.5 No more than 800 GMOs in total may be planted under this Licence.
- 1.6 The perimeter of the Location must be at least 100 metres from the nearest Waterway and the licence holder must not allow Material from the GMOs to enter any Waterway.

Release site location details

Total area of release site: 1.00 hectare

Street address of release: Queensland Department of Primary Industry Redlands Research Station, De Lancey Street, Cleveland, Queensland, 4163

GPS coordinates of release site:

Area (hectares) of site: 1.00 ha

Local Government Area: Shire of Redlands, Queensland

GPS Coordinates:

Limits	Coordinates	
North East	27° 31.62 S	153° 14.93 E
South East	27° 31.66 S	153° 14.93 E
South West	27° 31.65 S	153° 14.88 E
North West	27° 31.62 S	153° 14.88 E

Cage

- 2.1 The GMOs must be grown under a Cage that prevents key pollinating insects and vertebrate animals (other than humans) from accessing the GMOs. The Cage must remain in place, and be inspected and maintained in accordance with condition 2.2, until cleanup of the Location has been completed according to conditions 13.1 and 13.2.
- 2.2 The integrity of the Cage must be inspected at least 4 days a week but no more than 2 days are to expire between inspections. Any damage to the Cage must be repaired immediately.
- 2.3 If the Cage cannot be repaired immediately, all inflorescences and fruit must be removed from the GMOs immediately and Destroyed.
- 2.4 Subject to the condition immediately following, within 30 days of issuing this Licence, the licence holder must install in the Cage at least two insect light traps able to collect hawkmoths in the family Sphingidae (Lepidoptera). The light traps must be located in opposite corners of the Cage and must be inspected at least once every week until the Location is cleaned for the presence of sphingid moths.

- 2.5 One of the insect light traps referred to in the immediately preceding condition may be placed outside of and within 50 metres of the cage for a period of up to eight weeks.
- 2.6 The presence (or absence) of sphingid hawkmoths in the light traps must be determined by someone able to recognise moths in the family Sphingidae (Lepidoptera).
- 2.7 A log book must be maintained recording each date and time of inspection of the Cage, the results of the inspection, the nature and location of any repairs to the Cage that may have been required under Part 3, condition 2.2, and the GMOs from which inflorescences or fruit may have been removed, as required under Part 3, condition 2.3. The log book must also record each date on which the insect light traps were inspected and the total number sphingid hawkmoths present at each inspection. The log book must be available on request for examination or photocopying by OGTR inspectors or authorised officers.

***Explanatory note:** As insects often accumulate in corners of insect-proof enclosures, it is advisable to concentrate inspections for damage to the cage in the uppermost corners of the Cage. Regarding the insect light traps, it would be advisable to verify the effectiveness with which the traps collect hawkmoths, by positioning one trap outside, and about 50 m from, the Cage. These considerations are not required by the Licence but may assist the licence holder to fulfil its obligations under the Licence.*

Access and control of the Location

- 3 The licence holder must be able to access and control the Location to the extent necessary to comply with this licence, for the duration of the life of the licence.

GMOs must not be eaten

- 4 The licence holder must ensure that any fruit or other Material from the GMOs is not used as food for humans or other vertebrate animals.

Notification of commencement of planting

- 5 The licence holder must notify the OGTR at least 7 days, but not more than 20 days, in advance of each day on which the GMO is planted.

Notification of commencement of flowering

- 6 The licence holder must notify the OGTR at least 7 days, but not more than 20 days, in advance of the expected commencement of each flowering season of the GMOs that is to occur.

Management of Flowers

- 7 All male flowers must be removed prior to anthesis.

***Explanatory Note:** Conditions 2.3 and 8.2 of Part 3 of this Licence describe further actions that must be taken to manage flowers and fruit, including their removal and destruction, in the event that the Cage is damaged and cannot be repaired immediately.*

Notification of commencement of fruiting and harvesting

- 8.1 The licence holder must notify the OGTR at least 30 days, but not more than 60 days, in advance of the expected commencement of harvest of fruit in each fruiting season.
- 8.2 All fruit must be harvested before they fall to the ground and either:
- (a) removed from the Location and destroyed; or
 - (b) transported to a laboratory certified by the Regulator to at least physical containment level 2 (PC2) for analysis; or
 - (c) only if the fruit are green with flowers still attached, buried to a minimum depth of 20cm within the location.
- 8.3 If harvested, the GMOs or Material from the GMOs must be harvested and stored separately from any other papaya fruit or material from papaya plants.
- 8.4 A log book must be kept by the licence holder recording, for each season, the following information:
- (a) the number of fruit set on each tree;
 - (b) the number of fruit on each tree that sustain damage consistent with being eaten by fruit-eating vertebrate animals;
 - (c) the number of fruit removed from each tree and transported to a laboratory for further experiments;
 - (d) the number of fruit removed from the tree and destroyed; and
 - (e) the number of fruit missing without explanation.
- 8.5 The log book must be available on request for examination or photocopying by OGTR inspectors or authorised officers.
- 8.6 The findings recorded in the log book must be included in the licence holder's annual report to the OGTR.

Reporting of toxic and allergenic responses

- 9.1 All persons exposed to the GMOs must be notified by the licence holder (eg. by signage at doors into the Location and laboratories) that they should report to the licence holder any unusual allergenic responses that could be attributed to contact with the GMOs.
- 9.2 Any such reports (to the Licence holder) must be provided to the OGTR immediately.

Reporting of plant disease incidence

- 10.1 GMOs must be inspected every month for disease. A record of all inspections must be entered in a log book. The log book must be available on request for examination or photocopying by OGTR inspectors or authorised officers. The log book must record the date of inspections, reports of any disease symptoms, (eg. foliar chlorosis or necrosis, dieback, root rot, loss of fruit set), severity of symptoms, disease control measures, if any, carried out and which GMO shows which disease symptoms.
- 10.2 The results of findings with respect to disease and disease control measures must be included in the licence holder's annual report to the OGTR.

Cleaning

- 11 All Equipment used in the planting, growing and harvesting of GMOs must be Cleaned immediately after use, within the Cage.

Storage and Transportation

- 12.1 Any Plant Material transported outside a location must be transported in accordance with the Regulator's *Guidelines for the Transport of GMOs* as current at the time of transportation, and routes, methods and procedures used for this transportation in accordance with this licence must be documented and provided to the Regulator on request.
- 12.2 Material from the GMOs (including fruit) may only be stored in a facility that is certified by the Regulator.

Clean-up of location

- 13.1 Before 15 November 2011:
- (a) all flowers and fruit of the GMOs must be removed from the GMOs and destroyed.
 - (b) after flowers and fruit from the GMOs have been removed, the GMO must be cut off at ground level and raked into piles together with any other Material from the GMOs.
 - (c) cut stumps must be immediately treated with herbicide to kill them.
- 13.2 The GM plant material from 13.1(b) and 13.1(c) must be left within the caged area for at least two months after which a mechanical rotor must be used to dig up and mulch the GM plant material by 15 February 2012.

Note: the mechanical rotor can access the cage by temporarily lifting part of the netting.

Inspection

- 14.1 Following the clean up of the location, the Location must be inspected to establish whether any GMOs or Materials from the GMOs have survived at the Location (whether by regrowth of herbicide-treated stumps or some other regrowth). Inspection must be carried out until the Regulator has issued a sign-off notice under condition 14.11.
- 14.2 The destruction burial site must be inspected to establish whether it has been disturbed. If disturbed, the Regulator must be notified in a log book or paper file.
- 14.3 Inspection must take place at least every 3 months.
- 14.4 Any GMOs or Material from the GMOs found to have survived at the Location must be killed by herbicide treatment, incineration, hand weeding or autoclaving.
- 14.5 The results of inspection activities must be recorded in a logbook or paper file. The findings of the inspections as recorded in the logbook or paper file must be forwarded to the Regulator within 14 days of inspection taking place and must also be included in the licence holder's Annual Report to the Regulator. The logbook or paper file must contain at least the following:

- (a) details of the areas inspected;
 - (b) details of the date of inspection;
 - (c) the names of the person or persons who undertook the monitoring and details of the experience, training or qualification that enabled them to recognise Volunteer Plants;
 - (d) the means of inspection used;
 - (e) the number of Volunteer Plants observed, if any;
 - (f) details of the development stages reached by the Volunteer Plants, if any; and
 - (g) details of methods used to Destroy Volunteer Plants, if any.
- 14.6 The findings of the log book kept under the above clause must be included in the licence holder's annual report to the OGTR.
- 14.7 Inspections must be carried out by a person qualified to identify GMO seedlings, the GMO and Material from the GMOs.
- 14.8 The Location must not be planted with any other papaya plants while the inspections are continuing. The Location may be planted to a legume crop while the inspections are continuing.
- 14.9 If:
- (a) inspections have been routinely completed in a place for a period of at least 1 year; and
 - (b) inspection records for that place show that no Volunteers have been observed in the most recent 6 month inspection period;
- the licence holder may make written application to the Regulator that these inspection conditions no longer apply in respect of that place.
- 14.10 These inspection conditions do not apply in respect of a place if the licence holder has been issued with a notice from the Regulator that these inspection conditions do not apply in respect of that place. (These notices are called 'sign-offs'.)

Testing Methodology

- 15 The licence holder must provide a written instrument to the Regulator describing an experimental method that is capable of reliably detecting the presence of GMOs and the presence of the genetic modifications described in Attachment B in a recipient organism. The instrument must be provided within 24 months of the issuing of the licence.

Contingency Plan

- 16.1 Within 30 days of the date of the commencement of this licence, a written Contingency Plan must be submitted to the Regulator detailing measures to be taken in the event of:
- (a) damage to the enclosure that cannot be repaired immediately;

- (b) the unintended presence of the GMO or Material from the GMO at places not contemplated by this licence.
- 16.2 The Contingency Plan must include details of procedures to:
- (a) ensure the Regulator is notified immediately if the licence holder becomes aware of an event;
 - (b) remove flowers and fruits from the GMOs and prevent potential gene transfer from the Location; and
 - (c) eradicate the GMOs or Material from the GMOs from places not contemplated by the licence.
- 16.3 The Contingency Plan must be implemented in the event that the unintended presence of the GMO, or Material from the GMOs is discovered.

Compliance

- 17 A written Compliance Management Plan must be provided to the Regulator within 30 days of the date of commencement of this licence. The Compliance Management Plan must describe in detail how the licence holder intends to ensure compliance with these conditions and document that compliance.

Research Requirements

- 18.1 The licence holder must, in consultation with the OGTR, develop an agreed research program that includes, but need not be limited to, confirming the genes that have been introduced into the GMOs.
- 18.2 The results of the research program must be included in the licence holder's annual report to the OGTR.

Annual Report

- 19 The licence holder must provide an annual report within 90 days of each anniversary of this licence to the OGTR containing all the information required by these conditions to be reported.

ATTACHMENT A

to the Licence for dealings involving an intentional release of GMOs (papaya with delayed fruit ripening) into the environment

DIR No: 026/2002

***Full Title:** Field trial for evaluation of GM papaya to delay fruit ripening and test the expression of the introduced genes

Organisation Details

Postal address: University of Queensland
St Lucia QLD 4072

Phone No: (07) 3365 1857

Fax No: (07) 3365 1577

Project Supervisor Details

Surname: *[Personal Information Redacted]*

First Name: *[Personal Information Redacted]*

Title: *[Personal Information Redacted]*

Phone No: *[Personal Information Redacted]*

Fax: *[Personal Information Redacted]*

Email Address: *[Personal Information Redacted]*

Position: *[Personal Information Redacted]*

Organisation: Department of Botany, University of Queensland

Postal Address: Department of Botany
University of Queensland, St Lucia QLD 4027

IBC Details

IBC Name: University of Queensland

*** Information that must be included in the Record of GM Products and GMOs Dealings.**

ATTACHMENT B

*GMO covered by this licence:

Carica papaya spp. genetically modified by introduction of only the genetic elements listed below.

*Parent Organism(s) Common Name: Papaya (pawpaw)

*Parent Organism(s) Scientific Name: *Carica papaya* L.

Modified Trait(s):

*Category: Delayed fruit ripening, reporter gene expression and antibiotic resistance.

*Description: *Carica papaya* has been genetically modified to produce various 'lines' that contain either additional copies of endogenous *C. papaya* genes involved in ethylene production and fruit ripening (6 lines), a gene from *Arabidopsis thaliana* involved in ethylene perception and fruit ripening (1 line), or the *uidA* reporter gene (1 line). Each of the eight lines also expresses resistance to aminoglycoside antibiotics (e.g. kanamycin and neomycin).

*Gene(s) Responsible for Conferring the Modified Trait(s):

- *capacs 1* and *capacs 2* genes from papaya (genes associated with ethylene production and fruit ripening)
- *etr1-1* gene from *Arabidopsis thaliana* (ethylene perception and fruit ripening)
- β -glucuronidase gene (*uidA*) from *Escherichia coli* (reporter gene)
- *nptII* gene from bacterial Tn5 transposon (antibiotic resistance gene)

Purpose of the Dealing with the GMO:

To evaluate modified fruit ripening characteristics.

*** Information that must be included in the Record of GM Products and GMOs Dealings.**

