



Australian Government

Department of Health and Ageing

Office of the Gene Technology Regulator

APPLICATION FOR LICENCE FOR INTENTIONAL RELEASE OF GMOs INTO THE ENVIRONMENT: Application No. DIR 079/2007

SUMMARY INFORMATION

Project Title:	Limited and controlled release of banana genetically modified for disease resistance. ¹
Applicant:	Queensland University of Technology
Common name of the parent organism:	Banana
Scientific name of the parent organism:	<i>Musa acuminata</i> Colla cv. Grande Naine
Modified trait(s):	Enhanced disease resistance, reporter gene expression.
Identity of the gene(s) responsible for the modified trait(s):	<ul style="list-style-type: none">• <i>ced-9</i> from the nematode <i>Caenorhabditis elegans</i> (inhibition of apoptosis)• <i>GFP</i> (green fluorescent protein) from the jellyfish <i>Aequorea victoria</i> (reporter gene)• <i>nptII</i> (neomycin phosphotransferase type II) from the bacterium <i>Escherichia coli</i> (antibiotic resistance marker)
Proposed Location(s)	One site in the shire of Johnstone (QLD)
Proposed Release Size:	up to 1.4 ha
Proposed Release Dates:	April 2008 to April 2010

Introduction

The *Gene Technology Act 2000* (the Act) in conjunction with the *Gene Technology Regulations 2001*, an inter-governmental agreement and corresponding legislation that is being enacted in each State and Territory, comprise Australia's nationally consistent regulatory system for gene technology. Its objective is to protect the health and safety of people, and the environment, by identifying risks posed by or as a result of gene technology, and managing those risks by regulating certain dealings with genetically modified organisms (GMOs).

The Act establishes a statutory officer, the Gene Technology Regulator (the Regulator), to administer the legislation and make decisions under the legislation. The Regulator is supported by the Office of the Gene Technology Regulator (OGTR), an Australian Government regulatory agency located within the Health and Ageing portfolio.

The legislation sets out the requirements for considering applications for licences for dealings with GMOs and the matters that the Regulator must take into account before deciding whether, or not, to

¹ The title of the licence application submitted by the Queensland University of Technology is *Limited and Controlled Release of GM Disease Resistant Banana*.

issue a licence. The Regulator's *Risk Analysis Framework*² outlines the assessment process that will be followed.

The application and the proposed dealings

The Regulator has received a licence application from Queensland University of Technology (QUT) for a licence for dealings involving the intentional release of genetically modified (GM) banana (*Musa acuminata* Colla cv. Grande Naine) into the Australian environment on a limited scale under controlled conditions.

Up to 17 GM banana lines³ are proposed for release. One line contains a gene (a reporter gene) that expresses a protein which provides a visual indication (fluorescence) where successful transformation of plant tissues has occurred. The other lines contain a gene that is expected to provide protection from certain disease-causing (pathogenic) micro-organisms. The purpose of the proposed trial is to conduct proof of concept experiments with the GM banana lines to assess their development and disease response. The GM bananas will not be used for human food or animal feed.

The applicant proposes to limit the release to one site in the shire of Johnstone, Queensland (QLD) on a total area of up to 1.4 ha between April 2008 and April 2010.

The applicant has also proposed a number of controls to restrict the dissemination or persistence of the GM plants and their introduced genetic material, that will be considered in the assessment of this application, including:

- locating the proposed trial site on flat land 250 m away from, and 18 m above, the nearest natural waterway (South Johnstone River)
- utilising a parent plant that has been cultivated to the extent that it is essentially female and male sterile (see Parent organism)
- applying bunch covers to emerged inflorescences to prevent access to the developing fruit by birds and mammals that may feed on the fruit
- removing the immature male bud (bell) of inflorescences or bagging the bell to prevent access by pollinators
- complying with State Government legislation for banana disease control that would also aid in containment of GM plants
- destroying all (GM and non-GM) plant materials from the field trial by herbicide treatment and surface decomposition of non-propagative parts
- analysing GM plant materials from the trial in a certified PC2 facility and then destroying the materials by autoclaving
- post harvest monitoring of the trial site for 12 months and destroying any volunteers
- transporting GM plant materials to and from the proposed trial site in accordance with OGTR transportation guidelines
- not using the GMO in human food or animal feed.

² Available on the Office of the Gene Technology Regulator (OGTR) website at <<http://www.ogtr.gov.au/pubform/riskassessments.htm>>. Information on the assessment of licence applications is also available at <<http://www.ogtr.gov.au/ir/process.htm>> or Freecall 1800 181 030.

³ The term 'line' is used to denote plants derived from a single plant containing a specific genetic modification made by one transformation event.

Parent organism

The parent organism is a sweet banana (*Musa acuminata* Colla cv. Grande Naine), which is exotic to Australia. Bananas are grown commercially on the east coast of Australia from northern New South Wales to far north Queensland. They are also grown in Western Australia around Carnarvon, Kununurra and Broome and in the Northern Territory near Darwin. The 'Grande Naine' cultivar is one of several cultivars in the sub-group Cavendish that accounts for approximately 95% of the bananas on the Australian market. Members of the Cavendish subgroup set seed so rarely that they can be regarded as female sterile and produce so little viable pollen that they are effectively male sterile.

The genetic modifications and their effect

Up to 16 of the GM banana lines contain the *ced-9* gene, derived from the nematode *Caenorhabditis elegans*, which encodes a protein that is expected to confer disease resistance by preventing cells from undergoing programmed cell death (or apoptosis) in response to infection by certain pathogenic micro-organisms. The gene may also affect growth and development of the GM banana plants and confer enhanced tolerance to a range of biotic and abiotic stresses.

One GM banana line contains the *GFP* gene, derived from the jellyfish *Aequorea victoria*. It encodes a green fluorescent protein that enables visual identification of plant tissues in which the gene is expressed. GM banana plants containing the *GFP* gene will be used as controls to ascertain whether any observed disease response is as a result of the expression of the *ced-9* gene.

In addition, all of the GM banana lines contain the antibiotic resistance selectable marker gene, neomycin phosphotransferase type II (*nptII*). This gene, encoding the enzyme neomycin phosphotransferase, was derived from the common gut bacterium *Escherichia coli*, and confers kanamycin or neomycin resistance on GM plant cells. The *nptII* gene was used during initial development of the GM plants in the laboratory.

The GM banana lines also contain short regulatory sequences that control expression of the introduced genes. These are derived from plants (*Zea mays* – maize and *Ricinus communis* – castor bean), a soil bacterium (*Agrobacterium tumefaciens*) and two plant viruses (Cauliflower mosaic virus and Tobacco etch virus). Although *A. tumefaciens*, Cauliflower mosaic virus and Tobacco etch virus are plant pathogens, the regulatory sequences comprise only a small part of their respective total genomes, and are not in themselves capable of causing disease.

Method of genetic modification

The GM banana lines were produced by introducing gene constructs containing the gene(s) of interest, along with the *nptII* gene and regulatory sequences, into cells from the commercial banana cultivar 'Grande Naine'. The gene constructs were carried by *Agrobacterium tumefaciens*, which mediated the transformation of banana cells. These vectors are 'disarmed' since they lack the genes that encode the tumour-inducing functions of *A. tumefaciens*.

Transformed banana plants were grown in tissue culture in the laboratory and molecular analysis will be used to confirm the presence of the genes of interest. Each of the 17 GM banana lines proposed for release is the result of a separate genetic modification event.

Previous releases of the same or similar GMOs

There have been no previous releases of these GM banana lines in Australia or elsewhere.

Suitability of Applicant

Section 43(2)(f) of the Act requires the Regulator to be satisfied regarding the suitability of the applicant to hold a licence as a pre-requisite for considering DIR applications. The matters to be

considered are outlined in section 58 of the Act and include relevant convictions, revocation of a licence or permit relating to the health and safety of people, and capacity to meet the conditions of the licence.

The Regulator has determined that QUT currently meets the suitability requirements and will verify this continues to be the case prior to making any decision regarding the issuing of a licence.

Consultation process for this DIR application

The Regulator has made an assessment of whether the application should be considered as a limited and controlled release under section 50A of the Act. As its principal purpose is to enable the conduct of experiments, and the applicant has proposed limits on the size and duration of the release and controls to restrict the dissemination and persistence of both the GMO and its genetic material in the environment, **the Regulator has decided that the application qualifies as a limited and controlled release.**

This means that the Regulator is not required to consult on the assessment of this application until after a Risk Assessment and Risk Management Plan (RARMP) has been prepared in accordance with section 51 of the Act. In the interim, copies of the application are available on request from the OGTR. Please quote application number DIR 079/2007.

The Regulator will seek comment on the consultation RARMP from the public as well as a wide range of experts, agencies and authorities including the Gene Technology Technical Advisory Committee, State and Territory Governments, Australian Government agencies and the Minister for the Environment, Heritage and the Arts and relevant local councils. The RARMP will then be finalised, taking into account matters raised relating to risks to human health and safety and the environment, and form the basis of her decision whether or not to issue a licence.

At this stage, **the RARMP is expected to be released for comment in late April 2008.** The public will be invited to provide submissions on the RARMP via advertisements in the media and direct mail to anyone registered on the OGTR mailing list. The RARMP and other related documents will be available on the OGTR website, or in hard copy from the OGTR.

If you have any questions about the application or the assessment process, or wish to register on the mailing list, please contact the OGTR at:

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