

APPLICATION FOR LICENCE FOR INTENTIONAL RELEASE OF A GMO INTO THE ENVIRONMENT: Application No. DIR 026/2002

SUMMARY INFORMATION

December 2002

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

Applicant: University of Queensland
St. Lucia
Brisbane QLD 4072

Common name of the parent organism: Papaya, or pawpaw

Scientific name of the parent organism *Carica papaya* L.

Modified trait(s): Delayed fruit ripening, reporter gene expression and antibiotic resistance

Identity of the gene(s) responsible for the modified trait(s):

- *capacs1* and *capacs2* genes from papaya (genes associated with ethylene production and fruit ripening);
- *etr1-1* gene from *Arabidopsis thaliana* (ethylene reception and fruit ripening);
- β -Glucuronidase gene (*uidA*) from *Escherichia coli* (reporter gene); and
- *nptII* gene from a bacterial Tn5 transposon, (antibiotic resistance)

Proposed Location Shire of Redlands (QLD)

Proposed Release Size: 1.07 hectares

Proposed Time of Release June 2003 – 2006. Continue evaluation of 1000 GM papayas planted since 1999 and release of 300 new GM papaya plants in August 2003

* Approval of this licence application would enable the continued evaluation of up to 1000 plants of GM papaya planted in an area of 1 hectare since 1999 that was authorised under the previous voluntary system and under 'deemed' licence PR-128, which expires in June 2003. The deemed licence was issued when the new regulatory system came into effect. Approval would also enable a new release of GM papaya, proposed for August 2003.

Introduction

The *Gene Technology Act 2000* (the Act) took effect on 21 June 2001. The Act, supported by the *Gene Technology Regulations 2001*, an inter-governmental agreement and corresponding legislation that is being enacted in each State and Territory, underpins 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), a Commonwealth 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 issue a licence.

The application and the proposed dealings

In accordance with section 190 of the Act, a 'deemed' licence (PR-128) for the release of genetically modified (GM) papaya plants into the environment was issued to the University of Queensland before the commencement of the Act on 21 June 2001, based on the approval issued under the previous voluntary system administered by the Genetic Manipulation Advisory Committee (GMAC). Deemed licence PR-128 is effective during the transition period, i.e. 2 years from the commencement of the Act. Therefore, the deemed approval for the release will expire in June 2003.

The OGTR has received an application from the University of Queensland (UQ) for a licence for the intentional release into the environment of GM papaya plants. Approval would enable the continued limited and controlled release of GM papayas that was approved under the former voluntary system administered by GMAC (PR-128). The release involves growing several lines of papaya plants that have been genetically modified to delay fruit ripening by down-regulation of the plant hormone, ethylene. In addition, UQ proposes to release some new lines of papaya that also have been genetically modified to delay fruit ripening, by a change in the ethylene receptor molecule (see below). Some plants have also been modified to express a reporter gene that can identify plants with the genetic modifications.

Papaya fruits have poor storage qualities. If fruit ripening is delayed over several days to weeks it may be possible to decrease spoilage due to over-ripening during transportation and storage. The release proposes to grow GM papaya plants under insect-proof netting in the field for fruit production and to monitor the rate of fruit ripening. The applicant aims to assess the rate of fruit ripening on the tree for a limited number of fruits but proposes to harvest most fruits before full ripening has occurred. Additionally, reporter gene expression will be evaluated to assess the effectiveness of the same promoter that drives expression of the fruit ripening genes. Other physiological, nutritional and quality attributes of the fruit will also be evaluated. None of the fruits that are produced during the trial will be used for human or animal consumption.

Previously under PR-128, the release involved transplantation of up to 1000 GM papaya plants from glasshouse to a field site covering an area of 1 hectare. UQ proposes to continue evaluation of these plants and conduct a limited and controlled release of up to 300 individual papaya plants at one site over a total area of 1.07 hectares in the Shire of Redlands (Qld). The release involves planting glasshouse-grown plants at the proposed release site in August 2003. All transport and storage of the GMOs or material derived from the GMOs would be in accordance with requirements of the OGTR.

Previous releases of the GMOs

Under the former voluntary system overseen by GMAC, there were two releases of GM papaya:

- PR-108 (Queensland Department of Primary Industries) comprised GM papaya plants resistant to Papaya Ring Spot Virus and involved 100 plants released in an area up to 0.15 hectares; and
- PR-128 (University of Queensland) comprised 1000 GM papaya plants modified for delayed fruit ripening released in an area up to 1 hectare.

As noted, the current application involves an extension of the release approved under PR-128, but includes two additional types of GM papaya.

Parent organism

The parent organism is papaya, or pawpaw (*Carica papaya* L, cultivar 'Solo', bred in Hawaii). This species is exotic to Australia but is grown in commercial plantations throughout coastal tropical and sub-tropical regions of the continent, from northern New South Wales to Western Australia.

Genetic modification and its effect

Plants that have been genetically modified to delay fruit ripening contain either additional copies of genes for the enzyme ACC (1-amino-cyclopropane-1-carboxylic acid) synthase (both sense and antisense versions of *capacs 1* or *capacs 2* from *Papaya carica*), or the gene encoding the modified ethylene receptor protein from *Arabidopsis thaliana* (*etr1-1*).

The *capacs 1* and *capacs 2* genes are associated with biosynthesis of ethylene. It is intended that production of ethylene will be decreased due to inhibition of production of ACC, a metabolic intermediate in the natural synthesis of ethylene in plants. One response of a lack of ethylene is to reduce the rate at which fruit ripen. In GM papaya plants containing *etr1-1*, the fruits are expected to be partially insensitive to ethylene, hence delaying or avoiding ripening.

Some plants proposed for release express the *uidA* gene from the bacterium, *Escherichia coli*. This gene codes for the enzyme β -glucuronidase (GUS). Its expression enables visual identification of plant tissues in which this enzyme is produced. The applicant proposes to release some papaya plants that have been modified by inserting the *uidA* gene, instead of the fruit ripening genes, as a means of confirming the effectiveness of regulatory sequence (promoter) that is used to drive the fruit ripening genes. GUS activity will be used to indicate the tissue(s) in which the gene is expressed (namely, papaya fruit).

The plants also contain a bacterial gene (*nptII*) conferring resistance to the antibiotics kanamycin and neomycin (*nptII* gene). This gene was used to select plants containing the desired fruit ripening and GUS genes, in the laboratory, prior to their transplantation to the field.

Short regulatory sequences that are required to control the functioning of the genes are also present in the GM papaya. These are derived from cauliflower mosaic virus, *Agrobacterium tumefaciens* (a common soil bacterium) and apple trees. Although the first two organisms are plant pathogens, the regulatory sequences comprise only a small part of their total genome and are not, in themselves, capable of causing disease.

Method of gene transfer

Each of the genes and their associated regulatory sequences were introduced into papaya by microprojectile bombardment. This technique involves coating the DNA containing the genes onto very small tungsten particles which are 'shot' into the papaya tissue. Particle bombardment has been widely used in Australia and overseas for introducing new genes into plants.

Consultation on risk assessment and risk management plan

The Regulator has made an initial assessment as to whether the proposed release may pose significant risks to human health or the environment, in accordance with section 49 of the Act. Due to the low risk potential of the GMO and the limited scale of the proposed field trial, **the Regulator has decided that the proposed release does not pose a significant risk to human health or the environment.**

This means that the Regulator is **not required to seek public comment** on the assessment of this proposal until the risk assessment and risk management plan has been prepared. At this stage, the plan is expected to be issued by **late February 2003**. In the interim, copies of the application are available on request from the OGTR. Please quote application number DIR 026/2002.

As required by section 50 of the Act, in preparing the risk assessment and risk management plan in relation to the licence application, the Regulator will seek input from a wide range of key stakeholders and expert groups comprising State and Territory Governments, relevant Commonwealth agencies, the Environment Minister, the Gene Technology Technical Advisory Committee and appropriate local councils. As required by section 52 of the Act, the Regulator will again consult with these prescribed agencies and authorities in finalising the plan.

The public will also be invited to provide comment on the risk assessment and risk management plan over a six week consultation period, via advertisements in the media and direct mail to anyone registered on the OGTR mailing list. Summaries and copies of the risk assessment and risk management plan will be available from the OGTR, or on the OGTR website.

If you have any questions about the application or the assessment process, please contact the OGTR at:

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