

**Office of the Gene Technology Regulator****EXECUTIVE SUMMARY****Risk Assessment and Risk Management Plan for
Application No. DIR 026/2002**

(Limited and controlled release of GM papaya)

INTRODUCTION

The *Gene Technology Act 2000* (the Act) and the *Gene Technology Regulations 2001* (the Regulations) set out requirements which the Gene Technology Regulator (the Regulator) must follow when considering an application for a licence to intentionally release a genetically modified organism (GMO) into the environment.

For a licence to be issued, the Regulator must be satisfied that the release will not pose any risks to human health and safety or the environment that can not be managed. To this end, Section 51 of the Act requires the Regulator to prepare a risk assessment and risk management plan (RARMP) for each licence application, in consultation with a wide range of expert groups and stakeholders.

THE APPLICATION

The University of Queensland (UQ) applied for a licence (application number DIR 026) for the limited and controlled release of genetically modified (GM) papaya in the Shire of Redlands, Queensland. Seven lines of GM papaya have been modified to delay the process of fruit ripening, while an eighth line contains a 'reporter' gene that will allow evaluation of the operation of the gene regulatory elements used in the other GM papayas. Up to 300 plants of these eight GM papaya lines will be grown in an area of one hectare, from June 2003 to December 2006.

Papaya fruits have poor storage qualities and delayed ripening may prevent spoilage during transportation and storage. Six of these GM papaya lines have modifications which are expected to decrease production of the plant hormone ethylene, which is the 'trigger' for initiation of the ripening process in papaya fruit. The seventh of these GM papayas has a modified ethylene receptor, expected to reduce sensitivity to ethylene. All seven GM papaya lines are expected to exhibit delayed fruit ripening.

All of the GM papayas also contain bacterial antibiotic resistance genes, which were used solely to aid in selection of genetically modified cells in the initial laboratory stages of development of the GM papayas.

The applicant will gather key information from the release about the effect of the genetic modification and the function of the inserted genes. The UQ indicated that these data could not be generated without a field release as fruit production is not possible in glasshouse-grown papaya trees, which can grow to several metres in height before reaching reproductive

maturity. However, the release will be strictly limited and controlled. The GM papaya plants in the release will be grown within a self-supporting ‘insect-proof’ enclosure[†], which will also prevent access by animals. None of the papaya plants from the release, or their by-products, will be used for human or animal feed. Fruit and some other plant tissues generated in the release will be analysed in the laboratory for physiological, nutritional and quality attributes and for expression of the inserted genes.

Two limited and controlled releases of GM papaya were approved in Australia under the previous voluntary system that was overseen by the Genetic Manipulation Advisory Committee. These releases received ‘deemed’ licences under the new regulatory system that are due to expire on 21 June 2003. There have been no reports of adverse effects on human health or the environment resulting from these releases of GM papaya.

Licence application DIR 026/2002 covers three of the lines that were previously authorised for release (PR-128) at this site. The issuing of a licence in respect of this application enables the continued evaluation of 20 plants of these three lines, as well as the release of up to five new lines of GM papaya.

THE EVALUATION PROCESS

Licence application DIR 026/2002 from the University of Queensland has been evaluated, and a risk assessment and risk management plan (RARMP) prepared, in accordance with the Act and the Regulations, using a Risk Analysis Framework. This framework was developed by the Regulator in consultation with the public and key State, Territory and Commonwealth government stakeholders and the Gene Technology Technical Advisory Committee, and is available at www.ogtr.gov.au/pdf/public/raffinal.pdf.

Details of the process that the Regulator must follow, including the prescribed consultation process on the application, and the matters that must be considered in preparing a RARMP, are set out in Appendix 6 of the RARMP. The complete RARMP can be obtained from the OGTR or from the OGTR’s web site at www.ogtr.gov.au.

The risk assessment considered information contained in the application (including information required by Act and the Regulations on the GMO, the parent organism, the proposed dealings and on potential impacts on human health and safety and the environment), submissions received during consultation and current scientific knowledge.

Through this process, potential hazards to human health and safety or the environment that may be posed by release of GM papayas were identified. These have been evaluated on the basis of the likelihood of each hazard occurring and the likely impact of the hazard were it to be realised. The identified potential hazards relate to:

- **toxicity or allergenicity to humans and other organisms:** could the GM papayas with delayed fruit ripening or reporter gene expression be more toxic or allergenic than non-GM papaya, as a result of the novel gene products or because of unforeseen or unintended effects;
- **weediness:** could the GM papayas be harmful to the environment because of inherent weediness or increased potential for weediness; and

[†] The term ‘insect-proof enclosure’ is used throughout the risk assessment and risk management plan and refers to an enclosure designed to prevent key pollinating insects from accessing the GM papayas and to exclude wildlife, particularly animals that may feed on or disperse papaya fruit and seeds, such as bats and possums.

- **transfer of introduced genes to other organisms:** could the new genes introduced into the GM papayas transfer to non-GM papaya or to other organisms, with adverse consequences.

CONCLUSIONS OF THE RISK ASSESSMENT

The Regulator considers that the limited and controlled release of GM papayas with delayed fruit ripening or reporter gene expression will not pose a significant risk to public health and safety, or to the Australian environment, that cannot be managed. The assessment of each potential hazard identified above is summarised under a separate heading below.

Toxicity or allergenicity to humans and other organisms

The GM papayas are unlikely to prove more toxic or allergenic to humans or other organisms than conventional papaya, because none of the introduced proteins, or the native proteins with modified expression in the GM papaya, have any known intrinsic toxicity or allergenicity. However, detailed toxicity and allergenicity studies have yet to be conducted. Food Standards Australia New Zealand (FSANZ) is responsible for human food safety assessment, and FSANZ approval would need to be obtained before these GM papayas could be used in human food. Currently, the applicant has not applied to FSANZ for evaluation of material from the GM papayas for use in human food.

Weediness

The risk of GM papayas establishing as a weed is low and not likely to be greater than that of conventional papaya. Papaya is not a problematic weed of either agriculture or of natural ecosystems and the genetic modifications are unlikely to alter those aspects of papaya's biology that may potentially affect its weediness. Other than human transportation of papaya fruit, the most likely means of *C. papaya* being dispersed in the environment is by flying foxes (*Ptilinopus* spp.), a known pest of papaya plantations. The use of an insect-proof enclosure, as proposed by the applicant, will prevent flying foxes and other animals from accessing the GM papayas.

Transfer of introduced genes to other organisms

Gene transfer from the GM papayas to non-GM papaya is possible by pollination. The most likely means by which pollen could be transferred to other plants is via hawkmoths (Lepidoptera: Sphingidae), which are the only significant pollinators of papaya in Queensland. The use of an insect-proof enclosure, as proposed by the applicant, will minimise the potential for pollen movement by pollinators. Thus, the risk of gene transfer from GM papayas to cultivated papayas is negligible.

The likelihood of transfer of the introduced genes to other organisms (including microorganisms) is negligible, but even if such transfer occurred, it would be unlikely to pose any hazard to human health and safety or the environment, as the introduced genes are naturally present in microorganisms or in papaya.

THE RISK MANAGEMENT PLAN (KEY LICENCE CONDITIONS)

As part of the evaluation process for this licence application, a risk management plan has been developed to address the risks identified (refer to Conclusion of the risk assessment, above). This plan is given effect by the licence conditions imposed. The key licence conditions are outlined below.

Toxicity or allergenicity to humans and other organisms

Licence conditions have been imposed to:

- restrict access to the site to authorised personnel;
- fully enclose the GM papaya plants in a self-supporting insect-proof enclosure that is secured at ground level (this condition has been imposed largely to manage the risks of weediness and gene flow (see below) but also limits the potential for realisation of any risk of toxicity or allergenicity);
- provide appropriate signage at the release site to indicate that GM papayas are being grown within the enclosure and that plants or other material (eg. fruit) must not be removed, except for laboratory analysis as expressly authorised by the licence;
- prohibit the use of the GM papayas and any of their by-products for human or animal food; and
- establish a system for accounting for all fruit produced by the GM papayas and record instances of damage or removal of such fruit.

Weediness

Licence conditions have been imposed to:

- enclose the release within a self-supporting insect-proof enclosure (which also excludes flying foxes or other animals which may otherwise disperse seed); and
- monitor the release site for 12 months after removal of the GM papaya, and remove any papaya plants that regrow on the site.

Transfer of introduced genes to other organisms

Licence conditions have been imposed which require the licence holder to:

- enclose the release within a self-supporting insect-proof enclosure (which excludes key pollinators);
- remove all male flowers before they open to prevent dispersal of pollen;
- immediately remove and destroy all flowers and fruits to prevent dispersal of pollen (or seeds), in the event that the insect-proof enclosure is damaged and cannot be repaired immediately; and
- install insect-light traps capable of attracting and trapping key potential pollinators within the enclosure, to monitor the efficacy with which the insect-proof netting excludes such insects.

General licence conditions

Any licence issued by the Regulator also contains a number of general conditions, which are also relevant to risk management. These include, for example:

- identification of the persons or classes of person covered by the licence;
- a requirement that the applicant allow access to the release sites by the Regulator, or persons authorised by the Regulator, for the purposes of monitoring or auditing; and
- a requirement to inform the Regulator if the applicant becomes aware of any additional information about risks to human health or safety or to the environment.

Monitoring and enforcement of compliance by the OGTR

As well as the legislative capacity to enforce compliance with licence conditions, the Regulator has additional options for risk management. The Regulator can direct a licence holder to take any steps the Regulator deems necessary to protect the health and safety of people or the environment. The OGTR also independently monitors releases that it has authorised. At least 20% of all release sites will be inspected each year, in accordance with a monitoring and compliance strategy based on risk profiling, to determine whether licence holders are complying with the licence conditions, or whether there are any unforeseen problems.

FURTHER INFORMATION

Detailed information on the evaluation of the application, including the licence conditions, is available in the risk assessment and risk management plan document for this application, which can be obtained from the web site of the Office of the Gene Technology Regulator (www.ogtr.gov.au), or by calling 1800 181 030 (please quote application number DIR 026/2002).