



**Australian Government**  
**Department of Health and Ageing**  
**Office of the Gene Technology Regulator**

11 February 2005

**EXECUTIVE SUMMARY**  
of  
**THE RISK ASSESSMENT AND RISK MANAGEMENT PLAN**  
for  
**APPLICATION NO. DIR 051/2004**  
from  
**THE UNIVERSITY OF QUEENSLAND**

**EXECUTIVE SUMMARY**

**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 and the environment that can not be managed. As part of the evaluation process, 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.

Under section 52 of the Act, the Regulator is required to seek comment on the RARMP from those consulted in its preparation and to invite submissions from the public. Matters raised relating to the protection of human health and safety or the environment are taken into account in finalising the RARMP, which then forms the basis of the Regulator's decision on whether, or not, to issue a licence.

The Act is designed to operate in a cooperative legislative framework with other regulatory authorities that have complementary responsibilities and specialist expertise. As well as enhancing coordinated decision making, this arrangement avoids duplication. The OGTR liaises closely with other regulators to ensure the identification, evaluation and management of risks that may be associated with development and use of gene technology.

The Regulator has made decision to issue a licence in respect of application DIR 051/2004 from UQ.

**THE APPLICATION**

The University of Queensland (UQ) has applied for a licence (application number DIR 051/2004) for the intentional release, under limited and controlled conditions, of genetically modified (GM) sugarcane the expressing the enzyme sucrose isomerase. UQ proposes to trial up to 120 GM sugarcane lines<sup>1</sup> at two sites in the Burdekin Shire in Queensland over six years between February

---

<sup>1</sup> The term 'line' has been used throughout this RARMP to denote a group of sugarcane plants containing a particular set of genetic modifications that are descendants of a single transformation event.

2005 and December 2010 over a maximum total area of 3.55 ha/year. The plantings are proposed to occur in the autumn and spring growing seasons of 2005, 2006 and 2007. The main aim of the proposed release is to determine the agronomic performance of the GM sugarcane lines under Australian field conditions. The results of these preliminary trials will be used to further improve effectiveness of the gene constructs for future development of the GMOs (subject to future applications and their approval).

The introduced genes expressed in the GM sugarcane lines are sucrose isomerase (*si*) and neomycin phosphotransferase II (*nptII*) derived from the bacteria *Pantoea dispersa* and *Escherichia coli*, respectively. The *si* gene encodes the sucrose isomerase enzyme (SI) that converts sucrose to isomaltulose. The *nptII* gene confers resistance to the antibiotics kanamycin, neomycin and geneticin and was used as a selectable marker in the laboratory to identify transgenic sugarcane. The GM sugarcane lines also contain another selectable marker from *E. coli*, the beta lactamase (*bla*) gene, which confers ampicillin antibiotic resistance. However, this gene is not expressed in the GM sugarcane plants as it is controlled by its bacterial promoter which does not function in plants.

The gene constructs containing the genes of interest and associated regulatory sequences were introduced into the sugarcane hybrid cultivar 'Q117' by the particle bombardment method. Q117 is a modern hybrid cultivar of sugarcane derived from inter-specific hybridisation between *Saccharum officinarum* and *S. spontaneum*.

Isomaltulose is an isomer<sup>2</sup> of sucrose and is known to be an acariogenic sweetener (i.e. it does not support the growth of oral bacteria which can lead to tooth decay). It is digested more slowly than sucrose and thus has health benefits for diabetics and non-diabetics. Currently, isomaltulose is produced industrially from sucrose, using bacteria that naturally produce the SI enzyme. The cost of producing isomaltulose in sugarcane is expected to be much lower than the current industrial processes.

UQ has proposed a number of containment measures to minimise spread and persistence of the GMOs and the introduced genes from the trial sites. These include:

- surrounding the GM sugarcane lines at the main field trial site (site a<sup>3</sup>) by guard rows of non-GM sugarcane and an isolation zone;
- seedling propagation benches (site b)<sup>4</sup> will be surrounded by a lockable fence;
- harvesting the GM sugarcane plants before flowering or removing GM flower heads;
- destroying GM plant materials not required for subsequent research; and
- destroying any volunteer GM sugarcane plant that may occur in the release sites after completion of the trials.

None of the sugarcane plants from the release, or their products, will be used for human food or animal feed. Transport of the GM plant materials will be in accordance with the transport guidelines (Guidelines for Transport of GMOs available at [www.ogtr.gov.au](http://www.ogtr.gov.au)) issued by the Regulator.

There have been no previous releases of the proposed GMOs. However, there were seven field trials of other types of GM sugarcane in Queensland ranging from 0.1-1.0 hectare under the former voluntary system that was overseen by the Genetic Manipulation Advisory Committee (GMAC):

---

<sup>2</sup> An isomer is a molecule with the same kind and number of atoms but in a different arrangement.

<sup>3</sup> 'Site a' refers to the field trial site at CSR sugarcane field station adjacent to Kalamia Mill, Burdekin Shire covering maximum area of 3.55 ha.

<sup>4</sup> 'Site b' refers to seedling propagation benches at Kalamia Mill on CSR property used to generate material for planting at 'site a' and the adjacent laboratory.

- PR-23 (1993-1994), PR-23X (1993-1994) PR-68 (1996-2000) and PR-68X (1998-2001) conducted by UQ and Bureau of Sugar Experimental Stations (BSES);
- PR-72 (1997-2000) conducted by BSES;
- PR-73 (1997-2000) and PR-136 (2000-2003) conducted by CSIRO Tropical Agriculture.

In addition, the Regulator also granted a licence DIR 019/2002 to the Bureau of Sugar Experimental Stations (BSES) to trial other types of GM sugarcane for the period 2002-2006 on an area of 0.7 ha in the Cairns district of Queensland.

There have been no reports of adverse effects on human health or the environment resulting from these releases.

## THE EVALUATION PROCESS

A risk assessment and risk management plan (RARMP) has been prepared in relation to licence application DIR 051/2004 from UQ in accordance with the Act, the Regulations, and the Risk Analysis Framework. This framework was developed as part of the establishment of the regulatory arrangements in consultation with the public, State, Territory and Australian Government agencies, key stakeholders and the Gene Technology Technical Advisory Committee. The framework is currently under review, but a copy of the current version is available at [www.ogtr.gov.au/pdf/public/raffinal.pdf](http://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 she must consider in preparing a RARMP, are set out in Appendix 6 of the RARMP. The complete RARMP can be obtained from the OGTR by contacting the Office on 1800 181 030 or from its web site: [www.ogtr.gov.au](http://www.ogtr.gov.au) along with a reference document 'The Biology and Ecology of Sugarcane (*Saccharum* spp. L. hybrids) in Australia' that was prepared to inform this risk assessment.

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

Through this process, potential hazards to human health and safety or the environment that may be posed by the proposed release of the GM sugarcane lines were identified. These have been evaluated to determine whether risks might arise, based on the likelihood of each hazard occurring and the likely impact of the hazard, were it to be realised.

The identified potential hazards explored by this risk assessment relate to:

- **toxicity and allergenicity to humans and other organisms:** could these GM sugarcane lines be more toxic or allergenic than non-GM sugarcane to humans or harmful to other organisms as a result of the novel gene products or because of unintended effects?
- **weediness:** could the genetic modifications be harmful to the environment by increasing the potential for the GM sugarcane plants to establish as a problematic weed compared to non-GM sugarcane?; and
- **transfer of introduced genes to other organisms:** could there be adverse consequences from potential transfer of the introduced genes/genetic elements to non-GM sugarcane plants, closely related plants, or to other organisms?

## CONCLUSIONS OF THE RISK ASSESSMENT

As noted above, the applicant proposed a number of containment measures to minimise the spread and persistence of the GMOs or introduced genes. The Regulator has imposed additional licence conditions to minimise potential exposure of humans and other organisms and to further limit the spread and persistence of the GMOs or the introduced genes in the environment. The risk assessment of each potential hazard identified above is summarised under a separate heading below. The Regulator has concluded that the proposed limited and controlled release of the GM sugarcane lines does not pose significant risks to human health and safety and the environment as a result of the genetic modification.

Chapter 2 of the risk assessment and risk management plan provides a tabulated summary of assessment conclusions and corresponding management conditions. Full details of the licence conditions are provided in Appendix 5.

### **Toxicity or allergenicity to humans and other organisms**

Sugarcane is a well-established agricultural crop with a long history of safe use as human food. Commercial sugarcane is grown as a source of sugar (sucrose) and molasses. Possible exposure of people to the GM sugarcane plants or pollen would be through working with the plants while conducting field trials or post harvest analyses, and/or living near the area where the GM sugarcane plants are grown. In Australia, commercial sugarcane cultivars rarely flower or produce seed in the field, and exposure to non-GM sugarcane has not been associated with any reports of allergic responses in Australia. However, there have been literature reports from India of sugarcane pollen triggering allergic responses in cane farmers.

The GM sugarcane lines are unlikely to be more toxic or allergenic to humans via occupational exposure than non-GM sugarcane. Measures imposed to minimise exposure include harvesting the GM sugarcane plants before flowering or removing flower heads before anthesis<sup>5</sup>.

A range of feral animals such as feral pigs, wallabies and foxes have been reported as major pests of sugarcane in Australia. It is possible that these animals could be exposed by grazing the GM sugarcane plants during the field trials. To limit the exposure of the GM sugarcane plants to these pests, a range of control measures have been imposed such as guard rows of non-GM sugarcane and an isolation zone for the main field trial site (site a), and a lockable fence for the seedling propagation benches (site b).

The release sites are not prone to flooding. To further limit the GM sugarcane entering food-chain, exposure of aquatic organisms will be minimised by the licence condition, which requires that the GM sugarcane lines must not be grown within 50 metres of natural waterways.

Humans and other organisms are commonly exposed to the proteins produced by the introduced genes, as the introduced proteins and micro-organisms from which they are derived are naturally found in the environment. The SI and NPTII proteins expressed in the GM sugarcane lines are not known to be toxic or allergenic to animals (including humans) or toxic to other organisms. Hence, the risk that GM sugarcane lines are toxic or allergenic to humans or harmful to other organisms as a result of consumption is very low.

The applicant does not intend to use any sugarcane materials produced in the proposed release in human food or animal feed, thus limiting potential exposure. Food Standards Australia New Zealand (FSANZ) is responsible for human food safety assessment. FSANZ approval would be needed before these GMOs or their products could be used in human food.

---

<sup>5</sup> anthesis refers to a period of opening of a flower.

## **Weediness**

Modern sugarcane cultivars (*Saccharum* hybrids) are not recognised as weeds in Australia or anywhere in the world and the introduced modifications are not expected to increase the very low risk of the GM sugarcane establishing as a weed. Limitations on the establishment, spread and persistence of modern hybrid cultivars of sugarcane in the natural environment are likely to be due to complex interactions involving disease infection, pest infestation, moisture stress, poor soil fertility, grazing pressure and/or weed competition. Moreover, some patterns of expression of the *si* gene can result in reduced growth rate of sugarcane plants due to indirect effects on the metabolism of the GM plants. This would result in sugarcane plants that may have reduced competitive ability due to poor seedling establishment and would therefore be less likely to establish and spread in natural environment than non-GM sugarcane. However, information on the field performance of these GM sugarcane plants as to whether the risk of weediness potential is decreased by the genetic modification is not yet available.

Measures proposed by the applicant to minimise the spread and persistence of the GMOs in the environment have been incorporated into the licence conditions. The Regulator has also imposed additional containment measures and required data to be collected on the agronomic performance of the GM sugarcane lines.

## **Transfer of introduced genes to other organisms**

Sugarcane is a predominantly cross-pollinated plant and can produce fertile seed by both selfing and crossing. However, the parent sugarcane cultivar Q117 has been observed and recorded in the unpublished breeding programs at CSR sugarcane field station as an ineffective male parent due to its limited viable pollen.

Most commercial sugarcane is traditionally harvested before flowering. Sugarcane is propagated by stem cutting rather than seed production. Seed of sugarcane is only required in conventional breeding programs to improve cultivars. Breeding sugarcane is complicated due to non-synchronous flowering and low sexual seed viability. Although sugarcane pollen is windborne, its viability is known to be lost rapidly. If the genetic modifications do not change the viability of pollen, gene transfer would only be expected to occur to flowering non-GM sugarcane plants or other related species (*Saccharum officinarum*, *S. spontaneum* and species in *Saccharum* complex) growing in close proximity to the trial sites.

Reproductive fitness, including pollen viability, of the GM sugarcane lines in the field has not yet been measured. However, it is considered that the risks of transfer of the introduced genes from the GM sugarcane plants to other sugarcane are very low. To limit the likelihood of unforeseen adverse consequences from gene transfer, a number of containment measures have been imposed, particularly the removal of flowers, or harvesting the GM sugarcane plants before flowering.

These measures have been incorporated into the licence conditions to minimise the risks of gene transfer to other cultivated sugarcane and related species.

The risk of transfer of the introduced genes from the GM sugarcane plants to other organisms is negligible because of well-established genetic incompatibility. Even if such transfer occurred it would be unlikely to pose any hazard to human health and safety and the environment.

## **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 conclusions of the risk assessment, above). This

plan has been 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 which require the applicant to:

- limit the scale and duration of the release;
- surround the GM sugarcane lines at the main field trial site (site a) with guard rows of non-GM sugarcane and an isolation zone and surround the seedling propagation benches (site b) with a lockable fence;
- prevent GM plant materials from being used as human food or animal feed;
- isolate GM sugarcane plants from natural water ways;
- remove flower heads or harvest before flowering;
- destroy all GM plant materials not required for testing or future trials;
- securely transport and store retained GM plant materials; and
- report any adverse impacts on human health and safety.

### **Weediness and transfer of introduced genes to other organisms**

Licence conditions have been imposed which require the applicant to:

- limit the scale and duration of the release;
- remove flower heads or harvest before flowering;
- surround the GM sugarcane lines at the main field trial site (site a) with guard rows of non-GM sugarcane and an isolation zone and surround the seedling propagation benches (site b) with a lockable fence;
- prevent GM plant materials from being used as human food or animal feed;
- isolate the GM sugarcane plants from natural water ways;
- destroy all GM plant materials not required for testing or future trials;
- securely transport and store retained GM plant materials;
- clean equipment used at the release sites; and
- monitor release sites after the trials and destroy volunteers.

### **General 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 allows access to the release sites by the Regulator, or persons authorised by the Regulator, for the purpose 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.

## **Research requirements**

Licence conditions have been imposed that require the applicant, in consultation with the OGTR, to collect and provide to the Regulator further information regarding:

- data confirming the integration of the introduced genes into the sugarcane genome;
- expression levels of the SI protein and isomaltulose content in different parts of plants, under Australian field conditions;
- agronomic characteristics indicative of potential weediness of the GM sugarcane lines under Australian field conditions; and
- other indirect effects that may adversely impact humans or the environment from the genetic modification of the GM sugarcane plants during the trials.

A progress report on the research will be required to be submitted to the OGTR annually.

## **Identification of issues to be addressed for future releases**

The proposed limited and controlled release is part of early stage research being conducted at two sites to evaluate the GM sugarcane lines under field conditions. If the applicant makes any application for future larger scale or commercial releases of the GM sugarcane lines, more detailed information would be required, addressing:

- molecular characterisation and stability of the introduced genes;
- potential toxicity associated with the genetic modification, and compositional analysis;
- weediness of the GM sugarcane plants under Australian conditions including growth rate, reproductive capacities eg pollen viability and seed set;
- potential for gene transfer to non-GM sugarcane and other related species; and
- potential effects associated with the fate of the SI protein and isomaltulose from the GM sugarcane in 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 an applicant 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 the Regulator has authorised. At least 20% of all field trial sites are inspected each year, in accordance with a monitoring and compliance strategy based on risk profiling (which takes into account biological, seasonal, geographical and ecological risk factors), to determine whether applicants are complying with the licence conditions, or whether there are any unintended effects.