



APPLICATION FOR LICENCE FOR INTENTIONAL RELEASE OF GMOs INTO THE ENVIRONMENT: Application No. DIR 078/2007

SUMMARY INFORMATION

Project Title:	Limited and controlled release of sugarcane genetically modified for altered sugar production ¹
Applicant:	University of Queensland (UQ)
Common name of the parent organism:	Sugarcane
Scientific name of the parent organism:	<i>Saccharum</i> (interspecific hybrid of <i>S. spontaneum</i> and <i>S. officinarum</i>)
Modified trait(s):	Altered sugar production, antibiotic resistance
Identity of the gene(s) responsible for the modified trait(s):	<ul style="list-style-type: none">• <i>SI</i> (sucrose isomerase) from the bacteria <i>Pantoea dispersa</i> UQ68J and <i>Pseudomonas mesoacidophila</i> MX-45• <i>nptII</i> (neomycin phosphotransferase type II) gene from the bacterium <i>Escherichia coli</i> (antibiotic resistance selectable marker)• <i>bla</i> (beta-lactamase) gene from the bacterium <i>Escherichia coli</i> (antibiotic resistance selectable marker)
Proposed Location(s):	Up to 15 sites in the local government areas of Burdekin, Moreton Bay, Hinchinbrook, Cairns, Bundaberg, Mackay (Qld)
Proposed Release Size:	Maximum total of 65 ha over 6 years
Proposed Release Dates:	September 2008 to December 2014

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

¹ The title of the licence application submitted by UQ is Field trial of sugarcane expressing sucrose isomerase

² More information on the assessment of licence applications is available from the Office of the Gene Technology Regulator (OGTR). Free call 1800 181 030 or at <<http://www.ogtr.gov.au/ir/process.htm>>.

The application and the proposed dealings

The Regulator has received a licence application from UQ for a licence for dealings involving the intentional release of genetically modified (GM) sugarcane (*Saccharum spp.*) into the Australian environment on a limited scale under controlled conditions.

Up to 3000 GM sugarcane lines³ are proposed for release. They contain a sucrose isomerase (*SI*) gene derived from the common bacteria *Pantoea dispersa* or *Pseudomonas mesoacidophila*. Expression of the introduced gene is expected to alter sugar production in the sugarcane plant. A number of regulatory and protein stabilising sequences are also being tested to identify those that allow for optimum expression of the *SI* gene in the various plant cellular compartments.

The proposed trial would involve experiments to assess the agronomic properties of the GM sugarcane lines under field conditions and to analyse sugar production and quality. Promising lines will be selected for propagation for possible future commercial development (subject to additional approvals) and some lines will also be crossed with non-GM sugarcane under controlled conditions to evaluate the feasibility of using them in future breeding programs.

The applicant proposes to limit the release to up to fifteen sites in the Queensland local government areas of Burdekin, Moreton Bay, Hinchinbrook, Cairns, Bundaberg and Mackay on a maximum total area of 65 ha over six years between September 2008 and December 2014.

The applicant has also proposed a number of control measures 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:

- separating GM sugarcane grown in the field from any adjacent sugarcane by an isolation zone of at least 3 metres that is maintained free of sugarcane or a corresponding width of two planted rows of non GM sugarcane;
- locating the trial sites on land that is not subject to flooding and located at least 50 metres away from the nearest natural waterway;
- separating GM sugarcane grown in pots from other sugarcane plants by one metre and covering flowering stalks with a pollen proof lantern;
- processing and storing GM sugarcane seeds separately from other sugarcane seeds;
- not using the GM sugarcane in food or feed;
- transporting GM plant materials to and from the proposed trial site in accordance with OGTR transportation guidelines;
- destroying all plant materials not required for further analysis or propagation;
- following harvest, clean the sites, monitoring zones and equipment used on the sites;
- post harvest monitoring of the trial site for at least 6 months and destroying any volunteers until the sites are clear of volunteers for a period of at least 60 days.

Confidential Commercial Information

Some details of the genetic constructs containing the *sucrose isomerase (SI)* gene from *Pantoea dispersa* UQ68J and *Pseudomonas mesoacidophila* MX-45 have been declared Confidential Commercial Information (CCI) under section 185 of the Act. The confidential information will be made available to the prescribed experts and agencies that will be consulted on the Risk Assessment and Risk Management Plan (RARMP) for this application.

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 cultivated sugarcane, *Saccharum spp.*, which is an interspecific hybrid of *S. spontaneum* and *S. officinarum* that is exotic to Australia. Sugarcane is grown commercially on the east coast of Australia from northern New South Wales to far north Queensland.

The genetic modifications and their effect

All GM sugarcane lines contain a sucrose isomerase (*SI*) gene, derived from the bacteria *Pantoea dispersa* or *Pseudomonas mesoacidophila*, which encodes the sucrose isomerase protein. Sucrose isomerase converts sucrose to the structural isomers⁴ isomaltulose or trehalulose. These sugars are produced in different ratios depending on the source gene. Expression of the *SI* gene from *Pantoea dispersa* is expected to produce predominantly isomaltulose whereas expression of the *SI* gene from *P. mesoacidophila* is expected to produce predominantly trehalulose in the GM sugarcane plant cells.

In addition, all of the GM sugarcane lines contain one of the antibiotic resistance selectable marker genes, beta-lactamase (*bla*) and neomycin phosphotransferase type II (*nptII*), which are derived from the common gut bacterium, *Escherichia coli*. The *bla* gene encodes the enzyme beta-lactamase and confers resistance to ampicillin. It was used to select for bacteria containing the plasmid in the laboratory prior to production of GM plants. The *nptII* gene encodes the enzyme neomycin phosphotransferase and confers kanamycin or neomycin resistance. It was used to identify transformed plants.

The GM sugarcane lines also contain short regulatory sequences that control expression of the introduced gene and stability of the expressed protein. These are derived from maize (*Zea mays*); rice (*Oryza sativa*); sugarcane (*Saccharum spp.*); sweet potato (*Ipomoea batatas*); tobacco (*Nicotinia tabacum*); bean (*Phaseolus vulgaris*); pea (*Pisum sativum*); sorghum (*Sorghum*); a soil bacterium (*Agrobacterium tumefaciens*) and plant viruses (banana bunchy top virus and banana streak virus). Although *A.tumefaciens*, banana bunchy top virus and banana streak 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

Biolistic transformation, also known as particle bombardment, was used to produce the GM sugarcane lines. This technique involves coating the expression cassette containing the gene constructs onto very small gold particles that are 'shot' into sugarcane embryos. Particle bombardment has been widely used in Australia and overseas and is not known to cause any adverse effects for people or the environment.

Transformed sugarcane plants are grown in tissue culture in the laboratory. Each of the 3000 GM sugarcane lines proposed for release is the result of a separate genetic transformation event.

Previous releases of the same or similar GMOs

The Regulator has previously issued Licence DIR051/2004 for the limited and controlled release of GM sugarcane containing the same SI genes.

In addition, the Regulator has issued two other licences for the limited and controlled release of GM sugarcane with different introduced traits. DIR019/2002 was issued to BSES Ltd for trials with GM sugarcane containing a green fluorescent reporter gene on 0.7ha. DIR070/2006 was issued to BSES Ltd for trials with GM sugarcane with altered plant architecture, enhanced water or improved nitrogen use efficiency on up to 18ha.

⁴ An isomer is a molecule with the same kind and number of atoms but in a different arrangement.

Seven field trials were authorised under the former voluntary system that was overseen by the Genetic Manipulation Advisory Committee (GMAC): PR-23 (UQ and BSES Ltd, 1993-1998) and PR-23X (UQ and BSES Ltd, 1993-1994) for GM sugarcane expressing reporter genes, PR-68 (UQ and BSES Ltd, 1996-2000) and PR-68X (UQ and BSES Ltd, 1998-2001) for GM sugarcane modified for increased leaf scald resistance, PR-72 (BSES Ltd, 1997-2000) for GM sugarcane modified for sugarcane mosaic virus resistance, PR-73 (CSIRO Tropical Agriculture, 1997-2000) and PR-136 (CSIRO Tropical Agriculture, 2000-2003) both for GM sugarcane modified for increased sugar yield and altered juice colour.

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 UQ 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 with 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 078/2007.

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, and the relevant local council(s). 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 June 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:

The Office of the Gene Technology Regulator, MDP54 GPO Box 9848 Canberra ACT 2601

Telephone: 1800 181 030 Facsimile: 02 6271 4202 E-mail: ogtr@health.gov.au

Website <http://www.ogtr.gov.au>