



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

28 July 2004

APPLICATION FOR LICENCE FOR INTENTIONAL RELEASE OF GMOs INTO THE ENVIRONMENT: Application No. DIR 051/2004

SUMMARY INFORMATION

Project Title:	Field trial of genetically modified (GM) sugarcane expressing sucrose isomerase
Applicant:	The University of Queensland Brisbane QLD 4072
Common name of the parent organism:	Sugarcane
Scientific name of the parent organism:	<i>Saccharum officinarum</i> L. x <i>S. spontaneum</i> L.
Modified trait(s):	<ul style="list-style-type: none">• Altered sugar production• Antibiotic resistance
Identity of the genetic elements responsible for the modified trait(s):	<ul style="list-style-type: none">• <i>si</i> gene from the bacterium <i>Pantoea dispersa</i> 68J (altered sugar production)• <i>nptII</i> gene from the bacterium <i>E. coli</i> (antibiotic resistance)
Proposed Location(s)	Burdekin Shire Council in Queensland
Proposed Release Size:	Two sites covering an area of up to 3.55 hectares per year
Proposed Time of Release	Early 2005 – December 2010

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), 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 application and the proposed dealings

The OGTR has received an application from the University of Queensland (UQ) for a licence to intentionally release genetically modified (GM) sugarcane, on a limited scale and under controlled conditions. The genetic modification consists of a sucrose isomerase (*si*) gene that expresses a protein, the sucrose isomerase (SI) enzyme which converts sucrose into its structural isomer isomaltulose (an isomer is a molecule with the same kind and number of atoms but in a different arrangement). Isomaltulose is known to be an acariogenic sweetener (does not support the growth of plaque which can lead to dental disease and result in 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.

The proposed release would take place in the Burdekin Shire of Queensland at two sites, 'a' and 'b', covering a maximum area of 3.55 ha per year during the proposed release period 2005 to 2010. Over the six-year period UQ plans to release 120 lines of GM sugarcane.

The purpose of the trial is to determine the agronomic performance of the GM sugarcane lines under field conditions. Physiological characterisation of the modified lines over several years is required to determine:

- any direct effects of the modification, eg. concentration of different sugars in various tissues throughout the season;
- indirect effects including altered sensitivity to environment and biological stresses.

The GM sugarcane lines will be planted by hand. The planted material will be either cuttings of stems grown in a UQ Physical Containment Level 2 (PC2) greenhouse, or pre-germinated plants in peat pots grown either in a UQ PC2 greenhouse or on benches at release site 'b'. Stalks would be harvested at maturity for analysis and plants may be allowed to re-grow for further testing as ratoon plants. Non-viable material (juice, stalk material without viable buds) may also be taken to the other OGTR-approved facilities for analysis.

The applicant proposes to surround the field trial with guard rows of non-transgenic sugarcane. The proposed trial will also be separated from other experimental trials or commercial sugarcane by a 3 m isolation zone free of sugarcane. To further limit the possibility of spread of the introduced genes from the GM sugarcanes to other related species, UQ proposes to decapitate any GM sugarcane that commences floral development, to remove developing inflorescences before pollen release.

At the end of the trial, UQ proposes that sugarcane stools will be destroyed by a combination of herbicide treatment and mechanical means, and allowed to decompose by natural processes. Any volunteers that survive will be dug up and destroyed by burning on-site. Monitoring will be conducted for a period of at least 12 months to ensure the site is free from any volunteer sugarcane plants.

None of the GM sugarcanes from the trial, or its by-products will be used for human food or animal feed.

The UQ has applied for specific information relating to the gene constructs to be declared as confidential commercial information (CCI) under section 184 of the Act. The CCI application is currently being considered by the OGTR. However, it will be made available to the various prescribed expert groups that will be consulted on the preparation of the risk assessment and risk management plan.

Previous releases of the GMO

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

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

In addition, the Regulator granted licence DIR 019/2002 to the Bureau of Sugar Experimental Stations for the intentional release of another GM sugarcane during 2002-2004 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.

Parent organism

The parent organism is a commercial sugarcane hybrid, Q117, one of Australia's main commercial varieties derived from an interspecific cross between *Saccharum officinarum* L. and *Saccharum spontaneum* L. Sugarcane is exotic to Australia but has been grown commercially as an agricultural crop in Queensland and New South Wales since 1823 and more recently in the Ord district of Western Australia.

Genetic modification and its effect

The sucrose isomerase (*si*) gene was isolated from the bacterium *Pantoea dispersa* (isolate UQ68J). The *si* gene confers upon the sugarcane plant the ability to express the sucrose isomerase enzyme which converts sucrose into isomaltulose.

The GM sugarcane lines also contain neomycin phosphotransferase gene (*nptII*, also referred to as aminoglycoside phosphotransferase gene, *aphA*) used to select transgenic plants in the laboratory. The gene constructs used to modify the GM sugarcanes also contain another antibiotic resistance gene, the beta lactamase gene (*bla*). However, this gene is not expressed in plants as it is controlled by its bacterial promoter. Both these genes are derived from *E.coli*.

The *si* gene is regulated by promoters obtained either from sugarcane or maize. Other short sequences are also present that assist in expression of introduced genes obtained from tobacco, sweet potato or synthesised in the laboratory. The terminator sequences are obtained from *Agrobacterium tumefaciens*. Although *A. tumefaciens* is a plant pathogen, the regulatory sequences comprise only a small part of its total genome and are not capable of causing disease.

Different levels and locations of SI enzyme activity are expected to affect plant growth rates. Various combinations of the regulatory sequences will be tested for their ability to accumulate isomaltulose without stunting plant growth.

Method of gene transfer

The gene constructs containing the *si* or *nptII* gene were transferred into sugarcane cells by particle bombardment. This procedure involves coating the DNA containing the genes onto very small tungsten particles which are 'shot' into sugarcane tissue. This procedure has been widely used to introduce new genes into plants without causing any biosafety problems.

Consultation on preparation of the 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 and safety or the environment, in accordance with section 49 of the Act. Due to the low risk potential of the GMO and the control measures that will be imposed to limit the scale and scope of the dealings, **the Regulator has decided that the proposed release does not pose a significant risk to human health and safety or the environment.**

This means that the Regulator is **not required to seek public comment** on the assessment of this proposal until a risk assessment and risk management plan (RARMP) has been prepared. In the interim, copies of the application are available on request from the OGTR. Please quote application number DIR 051/2004.

In preparing the RARMP, the Regulator will seek input from a wide range of key stakeholders and expert groups comprising State and Territory Governments, relevant Australian Government agencies, the Minister for the Environment and Heritage, the Gene Technology Technical Advisory Committee and the relevant local council, as required by section 50 of the Act. In accordance with section 52 of the Act, the Regulator will again consult with these prescribed agencies and authorities, as well as the public, in finalising the RARMP.

At this stage, the consultation version of the RARMP is expected to be issued for an extended six-week consultation period in **October 2004**. 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. Summaries and copies of the RARMP 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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