



18 February 2009

APPLICATION FOR LICENCE FOR INTENTIONAL RELEASE OF GMOs INTO THE ENVIRONMENT: Application No. DIR 095

SUMMARY INFORMATION

Project Title:	Limited and controlled release of sugarcane genetically modified for improved drought tolerance and nitrogen use efficiency, enhanced sucrose and fermentable sugars accumulation, and altered plant growth ¹
Applicant:	BSES Ltd
Common name of the parent organism:	Sugarcane
Scientific name of the parent organism:	<i>Saccharum spp.</i> hybrid
Modified trait(s):	drought tolerance, nitrogen use efficiency, sugar accumulation, shoot architecture, marker gene expression (antibiotic resistance and reporter genes)
Identity of the gene(s) responsible for the modified trait(s):	<ul style="list-style-type: none">• 3 genes² for enhanced drought tolerance from rice (<i>Oryza sativa</i>), as well as a common plant species and a common bacterium• 1 gene for improved nitrogen use efficiency from corn (<i>Zea mays</i>)• 10 genes² for sugar accumulation from various plant and bacterial species• 5 genes for altered plant architecture from rice (<i>Oryza sativa</i>), sugarcane (<i>Saccharum Spp.</i>), barley (<i>Hordeum vulgare subsp. vulgare</i>) and bean (<i>Phaseolus coccineus</i>)• <i>uidA</i> (beta-glucuronidase or GUS) from the bacterium <i>E. coli</i> (reporter gene)• <i>nptII</i> (neomycin phosphotransferase type II) and <i>bla</i> (beta-lactamase) genes from the bacterium <i>E. coli</i> (antibiotic resistance selectable markers)
Proposed Location(s):	Six sites per season in the shires of Bundaberg, Mackay, Burdekin, Moreton Bay and Cairns City Council (Qld)
Proposed Release Size:	Up to 21 hectares per season
Proposed Release Dates:	June 2009 - June 2024

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).

¹ The title of the licence application submitted by BSES is 'Limited and controlled release of genetically modified sugarcane clones and their progeny from crosses involving these clones, with improved drought tolerance, water and nitrogen use efficiency, enhanced sucrose and fermentable sugars accumulation and altered plant growth'.

² BSES has sought approval to declare the precise identity of some genes, their source and their precise functions as Confidential Commercial Information.

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*³ outlines the assessment process that will be followed.

The application and the proposed dealings

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

Twenty-four categories of GM sugarcane are proposed for release, with up to several hundred plants from each GM category. The GM sugarcane contains genes intended to improve drought tolerance and nitrogen use efficiency, enhance sucrose and fermentable sugars accumulation, and alter plant growth.

The purpose of the trial is to evaluate the GM sugarcane plants grown under field conditions for key changes to agronomic characteristics such as sugar and cane yield and the use of resources such as water and fertiliser.

The release is proposed to take place at six sites; Bundaberg Regional Council, Mackay Regional Council, Burdekin Shire Council, Moreton Bay Regional Council and Cairns City Council in Queensland (Qld) on a maximum area of 21 ha per year over fifteen years from June 2009 to June 2024.

The applicant has 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:

- surround the field trial sites by one guard row of non-GM sugarcane and an isolation zone of at least 6 metres
- locate the field trial sites at least 50 m away from natural waterways
- harvest and process sugarcane from the trial separately from any other commercial sugarcane
- analyse plant materials at the trial sites or in a PC2 laboratory
- destroy all plant materials not required for experimentation or propagation
- following cleaning of sites, monitor for and destroy any GM sugarcane that may grow for 12 months and thereafter until the site is free of volunteers for a continuous 6 month period
- transport of GM plant materials in accordance with OGTR transportation guidelines
- not allowing the GM plant material or products to be used for human food or animal feed.

Confidential Commercial Information

Some details, including the names of some genes and promoters, their source and their precise function are the subject of an application for declaration of Confidential Commercial Information

³ 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>>.

(CCI) under section 185 of the Act, which is currently under consideration. 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.

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

The applicant proposes to release 24 categories of GM sugarcane. The GM sugarcane categories, with the exception of two categories containing only the antibiotic resistance selectable marker gene (*nptII*) with or without the reporter gene (*uidA*), will contain genes that may affect water or nitrogen use efficiency, shoot architecture, or sugar accumulation. The applicant intends to cross a subset of the 24 GM sugarcane categories using conventional breeding to produce GM sugarcane plants with a combination of these traits.

Three categories of GM sugarcane will contain genes expected to confer improved drought tolerance. One gene is *OsDREB1* from rice and the other two genes are from a common plant and a common bacterium.

One category of GM sugarcane will contain the gene *ZmDof1* from rice and is expected to confer improved nitrogen use efficiency under low nitrogen conditions. This may lead to reduced suckering.

Twelve categories of GM sugarcane will contain partial or complete gene sequences expected to alter sucrose and fermentable sugars accumulation. Fragments of five genes from a common plant species are expected to alter the sucrose content via gene silencing. The other five genes derived from bacteria or a common plant species are expected to modify the plant cell wall chemical structure and improve efficacy of biomass as a feedstock.

Six categories of GM sugarcane will contain partial or complete gene sequences expected to alter plant architecture of the GM sugarcane plants such as decreased or increased height, decreased or increased tillering and thicker or narrower stalks. These genes are *PcGA2ox-1* derived from beans, *HvGA20ox-1* and *HvGA20ox-1* from barley, *OsTBI* from rice and *ShTBI* from sugarcane.

The reporter gene (*uidA*), will be present in one GM sugarcane category, encodes an enzyme (β -glucuronidase (GUS)) that enables visual identification of plant tissues in which this gene is being expressed. The tissue containing the GUS enzyme will turn a dark blue colour after adding a staining solution. This staining also provides an indication of the level of activity of the promoter (regulatory sequence) that is being used to control the expression of the reporter gene. The reporter gene was originally derived from the common gut bacterium *Escherichia coli*.

All the GM sugarcane categories will contain an antibiotic resistance selectable marker gene, neomycin phosphotransferase type II (*nptII*). The *nptII* gene encoding for the enzyme neomycin phosphotransferase was originally derived from the common gut bacterium *E. coli*, and confers kanamycin or neomycin resistance on the GM plant. The *nptII* gene was used only as a selective marker during early stages of development of the GM plants in the laboratory.

Additionally, 22 of the GM sugarcane categories will contain the marker gene, *bla*, from the bacterium *E. coli*, which encodes ampicillin resistance. It is linked to a bacterial promoter that does not function in plants, so the gene is not expressed in the GM sugarcane plants. The gene was used to select for bacteria containing the desired genes, in the laboratory, prior to the production of the genetically modified plants.

Short regulatory sequences that control expression of the genes will also be present in all the GM sugarcane categories. These are derived from plants (including maize and pea), a soil bacterium (*Agrobacterium tumefaciens*) and *E. coli*. Although *A. tumefaciens* is a plant pathogen and *E. coli* is a facultative human pathogen, the regulatory sequences comprise only a small part of their respective total genomes, and are not capable of causing disease.

Method of genetic modification

To generate the GM sugarcane plants proposed for release, independent transformation events are produced by two different methods. Particle bombardment involves ‘shooting’ sugarcane embryos with gold particles coated with plasmids. Particle bombardment has been widely used in Australia and overseas and is not known to cause any adverse effects for people or the environment. *Agrobacterium*-mediated transformation involves introducing a plasmid vector carried by *Agrobacterium tumefaciens* (a common soil bacterium) into sugarcane embryogenic callus. The vector is ‘disarmed’ since it lacks the genes that encode the tumorigenic functions of *A. tumefaciens*. GM sugarcane plants are regenerated from the embryos using tissue culture techniques.

The applicant intends to cross a subset of the 24 GM sugarcane categories using conventional breeding to produce GM sugarcane plants with a combination of traits.

Previous releases of the same or similar GMOs

The Regulator has previously issued a licence to BSES for the limited and controlled release of GM sugarcane (DIR 070/2006), which included the same constructs proposed for this release containing the *PcGA2ox-1*, *HvGA20ox-1*, *HvGA20ox-2*, *OsTB1*, *ShTB1* (also known as *SoTB1*) and *ZmDof1* genes. There have been no previous releases of the GM sugarcane plants containing the other genes in Australia.

The Regulator has issued licences for the limited and controlled release of other types of GM sugarcane: DIR 019/2002 to BSES in 2002 and DIR 051/2004 to the University of Queensland in 2005.

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

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 Acting Regulator has determined that BSES 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 Acting Regulator has made an assessment of whether the application should be considered as a limited and controlled release, under 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 GMOs and their genetic material in the environment, **the Acting Regulator has decided that the application qualifies as a limited and controlled release.**

This means that the Acting Regulator is not required to consult on the assessment of this application until after a 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 095.

The Acting 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, Heritage and the Arts. 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 May 2009**. 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:

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