



10 June 2009

APPLICATION FOR LICENCE FOR INTENTIONAL RELEASE OF GMOs INTO THE ENVIRONMENT: Application No. DIR 096

SUMMARY INFORMATION

Project Title:	Limited and controlled release of sugarcane genetically modified for herbicide tolerance 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):	Herbicide tolerance, marker gene (antibiotic resistance) and reporter genes expression
Identity of the gene(s) responsible for the modified trait(s):	<ul style="list-style-type: none">• 2 genes² for herbicide tolerance from a plant species and a bacterium• <i>nptII</i> (neomycin phosphotransferase type II) and <i>bla</i> (beta-lactamase) genes from the bacterium <i>Escherichia coli</i> (antibiotic resistance selectable markers)• <i>gfp</i> (green fluorescent protein) from jelly fish (<i>Aequorea victoria</i>)
Proposed Location(s):	Six BSES stations per season in the shires of Bundaberg, Mackay, Burdekin, Moreton Bay and Cairns (Qld)
Proposed Release Size:	Up to 26 hectares per season
Proposed Release Dates:	November 2009 - November 2015

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,

¹ The title of the licence application submitted by BSES is 'Limited and controlled release of herbicide tolerant sugarcane clones and the progeny from crosses involving these clones'.

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

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 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.

The GM sugarcane lines proposed for release contain genes to confer herbicide tolerance. The purpose of the trial is to evaluate up to 6,000 GM sugarcane lines grown under field conditions for key changes to agronomic characteristics such as sugar and cane yield, and herbicide tolerance.

The release is proposed to take place at six BSES stations in the shires of Bundaberg, Mackay, Burdekin, Moreton Bay and Cairns in Queensland on a maximum area of 26 ha per year over six years from November 2009 to November 2015.

The applicant has proposed a number of control measures to restrict the dissemination and 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 Regulator's 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, their source and their precise function are the subject of an application for declaration of Confidential Commercial Information (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.

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>>.

The genetic modifications and their effect

The applicant proposes to release GM sugarcane lines containing two genes for herbicide tolerance. The genes conferring herbicide tolerance were derived from a bacterium and a common plant species. In addition to the herbicide tolerance genes, some of the GM sugarcane lines will also contain the antibiotic resistance selectable marker genes, *nptII* and *bla*, and a reporter gene (*gfp*). For comparative purposes some of the GM sugarcane lines would only contain the *nptII* and *bla* genes with or without *gfp*.

The antibiotic resistance selectable marker genes, *nptII* and *bla*, were originally derived from the common gut bacterium *Escherichia coli*. The *nptII* gene encodes the enzyme neomycin phosphotransferase and confers kanamycin or neomycin resistance on the GM plant. The *nptII* gene was used as a selective marker during early stages of development of the GM plants in the laboratory. The *bla* gene encodes β -lactamase which confers resistance to ampicillin. The *bla* gene 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 GM plants.

The reporter gene (*gfp*) encodes a green fluorescent protein (GFP). Expression of this gene in the GM sugarcane plant will enable visual identification of plant tissues in which this gene is being expressed, through fluorescence of GFP when exposed to ultraviolet or blue light. The level of fluorescence may provide an indication of the level of activity of the promoter (regulatory sequence) used to control the expression of the *gfp* gene. The *gfp* gene was originally derived from jelly fish (*Aequorea victoria*).

Short regulatory sequences that control expression of the genes will also be present in the all the GM sugarcane lines. These are derived from common plants (including maize and potato), a soil bacterium (*Agrobacterium tumefaciens*) and a plant virus (Cauliflower mosaic virus; CaMV). Although some of these sequences are derived from plant pathogens (*A. tumefaciens* and CaMV), the regulatory sequences comprise only a small part of the pathogen's total genome, and are not in themselves capable of causing disease.

Method of genetic modification

To generate the GM sugarcane plants proposed for release, independent transformation events are produced by particle bombardment which 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. GM sugarcane plants are regenerated from the embryos using tissue culture techniques.

The applicant intends to perform up to 20 crosses with selected GM sugarcane lines each year using conventional breeding.

Previous releases of the same or similar GMOs

There has been no previous release of the herbicide tolerant GM sugarcane lines in Australia or overseas.

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 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 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 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 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 096.

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, 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 September 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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