



13 February 2006

**TECHNICAL SUMMARY OF THE
RISK ASSESSMENT AND RISK MANAGEMENT PLAN**
for
APPLICATION NO. DIR 070/2006
from **BSES LIMITED**

INTRODUCTION

The Gene Technology Regulator (the Regulator) has decided to issue a licence (DIR 070/2006) to BSES Limited for dealings involving the intentional release of genetically modified (GM) sugarcane lines into the environment, on a limited scale and under controlled conditions.

The DIR 070/2006 licence permits the limited and controlled release of up to 2500 GM sugarcane lines. The release will occur at up to 3 sites per cropping cycle between February 2007 to November 2010 in the local government areas of Bundaberg, Caboolture and/or Cairns, Queensland. Each site would be a maximum 2 ha in area, with a total maximum area for the trial of 18 ha.

The *Gene Technology Act 2000* (the Act), the *Gene Technology Regulations 2001* (the Regulations) and corresponding State and Territory law govern the comprehensive and highly consultative process undertaken by the Regulator before making a decision whether to issue a licence to deal with a GMO.

The Regulator's *Risk Analysis Framework* explains the approach used to evaluate licence applications and to develop the Risk Assessment and Risk Management Plans (RARMPs) that form the basis of her decisions¹.

This RARMP for DIR 070/2006 has been finalised in accordance with the gene technology legislation. Matters raised in the consultation process regarding risks to the health and safety of people and the environment from the proposed dealings were taken into account by the Regulator in deciding to issue a licence and the licence conditions that have been imposed.

¹ More information on the assessment of licence applications and copies of the *Risk Analysis Framework* are 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>> and <<http://www.ogtr.gov.au/pdf/public/raffinal2.2.pdf>>, respectively.

APPLICATION

Title:	Limited and controlled release of GM sugarcane with altered plant architecture, enhanced water or improved nitrogen use efficiency*
Applicant:	BSES Limited
Common name of the parent organism:	Sugarcane
Scientific name of the parent organism:	<i>Saccharum</i> spp. hybrid
Modified traits:	Plant architecture (shoot number, stalk size and height), water use efficiency, nitrogen use efficiency, and marker gene expression (antibiotic resistance and reporter genes)
Identity of the genes responsible for the modified traits:	<ul style="list-style-type: none"> • 14 genes for altered plant architecture from the plants <i>Hordeum vulgare</i> subsp. <i>vulgare</i>, <i>Oryza sativa</i>, <i>Phaseolus coccineus</i> and <i>Saccharum</i> spp. • 3 genes for enhanced water use efficiency from the bacterium <i>Escherichia coli</i>, and plants <i>Arabidopsis thaliana</i>, <i>Malus x domestica</i>. • 1 gene for improved nitrogen use efficiency from <i>Zea mays</i> • <i>uidA</i> gene (β-glucuronidase reporter gene) from the bacterium <i>E. coli</i> • <i>nptII</i> gene (antibiotic resistance selectable marker) from the bacterium <i>E. coli</i> • <i>bla</i> gene (antibiotic resistance selectable marker) from the bacterium <i>E. coli</i>.
Proposed locations:	Local government areas of Bundaberg, Caboolture and/or Cairns (Qld)
Proposed release size:	Maximum total area 18 ha, comprising up to 3 sites of no more than 2 ha per cropping cycle
Proposed time of release:	February 2007 to November 2010

* The original title of licence application submitted by BSES was *GM sugarcane field trial – testing the effect on sugar yield of transformation methods*.

BSES applied for a licence to release up to 2500 GM sugarcane lines into the environment under limited and controlled conditions. Up to 1900 of the GM sugarcane lines have been modified to alter plant architecture (shoot number, stalk size and height), enhance water use efficiency (WUE)², or improve nitrogen use efficiency (NUE)³. Up to 600 of the GM sugarcane lines contain only introduced selectable antibiotic resistance marker and/or visual marker genes. The trial is intended to take place at up to 3 sites per cropping cycle between February 2007 to November 2010 in the local government areas of Bundaberg, Caboolture and/or Cairns, Queensland. Each site would be a maximum 2 ha in area, with a total maximum area for the trial of 18 ha.

The GM sugarcane lines for release were derived by transforming plants of the commercially grown *Saccharum* spp. hybrid Q117. Up to 1900 of the GM sugarcane lines contain either individual or combinations of 18 different introduced genes intended to improve agronomic characteristics and sucrose yields by either altering plant architecture, or enhancing WUE or improving NUE.

The 14 genes for altered plant architecture are derived from the plants *Oryza sativa* (rice), *Saccharum* spp. (sugarcane), *Hordeum vulgare* subsp. *vulgare* (barley) and *Phaseolus coccineus* (bean). The 3 genes for enhanced WUE are derived from the plants *Arabidopsis thaliana* (thale cress), *Malus x domestica* (apple) and the gut bacterium *Escherichia coli*. The one gene for enhanced NUE is derived from *Zea mays* (maize). The introduced genes encode proteins or double-stranded RNAs (dsRNAs) that are intended to alter plant architecture, enhance WUE or improve NUE, by modulating biochemical pathways, either through direct participation (proteins) or regulation of endogenous gene expression (dsRNA) in the sugarcane plants, which in turn may result in increased sugar yield.

The GM sugarcane lines modified to alter plant architecture, enhance WUE or improve NUE also contain the *E. coli* derived *nptII* marker gene, which confers resistance to some

² WUE is defined as the measure of total yield (sugar) produced per unit of water supplied to the sugarcane crop.

³ NUE is a term used to describe how effectively plants acquire and utilise nitrogen.

aminoglycoside antibiotics (eg neomycin, paromomycin, geneticin). The *nptII* gene enabled the identification and selection of GM plant tissues during the initial development of the GM sugarcane lines in the laboratory.

All except 100 of the 1900 lines contain the *E.coli bla* gene (conferring ampicillin resistance). However, this gene is not expressed in the GM sugarcane lines as it is linked to a bacterial promoter that does not function in plants. The *bla* gene was used to select bacteria carrying the gene construct of interest that were used in the initial plant transformations.

In addition to these 1900 GM sugarcane lines, up to 600 more lines contain only the *nptII* gene (100 lines), or the *nptII* gene with the *bla* bacterial marker gene (100 lines), or the *nptII* gene with the visual reporter gene *uidA* (400 lines). These lines will be compared during the trial to determine the best transformation technique for generating GM sugarcane lines.

The purpose of the trial is to conduct early stage ('proof of concept') research to assess the agronomic performance of GM sugarcane lines in the field, including some under different irrigation and fertilizer treatments, and to collect data to assist in optimising the transformation process.

The applicant proposed measures to limit the spread and persistence of the GM sugarcane lines in the environment. These were taken into account in establishing the risk assessment context for the release, and their suitability for limiting the release to the locations, size and duration proposed by the applicant was considered as part of the risk assessment process. No material from the GM sugarcane plants will be used for human food, animal feed or other sugarcane products.

RISK ASSESSMENT

The risk assessment considered information contained in the application, current scientific knowledge, and issues relating to risks to human health and safety and the environment raised in submissions received from consultation with a wide range of prescribed experts, agencies and authorities on the application (summarised in Appendix B of the RARMP). No new risks to people or the environment were identified from the advice received on the consultation RARMP. However, feedback on some previously raised issues has enabled their clarification in the final RARMP.

Two submissions from the public on the application and how they were considered are summarised in Appendix C of the RARMP. No submissions were received from the public on the consultation RARMP.

A reference document, *The Biology and Ecology of Sugarcane (Saccharum spp. hybrids) in Australia*, was produced to inform the risk assessment process for licence applications involving GM sugarcane plants. The document is available from the OGTR or from the website <<http://www.ogtr.gov.au>>.

The hazard identification process considered the circumstances or events by which people or the environment may be adversely affected by exposure to the GMOs, GM plant materials, GM plant by-products, the introduced genes, or products of the introduced genes.

A hazard (source of potential harm) may be an event, substance or organism. A risk is identified when a hazard is considered to have some chance of causing harm. Those events that do not lead to an adverse outcome, or could not reasonably occur, do not advance in the risk assessment process.

Sixteen events were identified and assessed whereby the release of the GM sugarcane lines might give rise to harm to people or the environment.

These 16 events included consideration of whether expression of the introduced genes could result in products that are toxic or allergenic to people or other organisms, alter characteristics that may impact on the spread and persistence of the GM plants, or produce unintended changes in their biochemistry or physiology. In addition, consideration was given to the opportunity for gene flow to other organisms, and its effects if this occurred.

All events were characterised in relation to both the magnitude and probability of harm in the context of the controls proposed by the applicant to limit the spread and persistence of the GMOs in both time and space. This detailed consideration concluded that none of the sixteen events gave rise to an identified risk that required further assessment. The principle reasons comprise:

- small scale of the trial is limited in both area and duration
- suitability of containment and disposal measures to limit the spread and persistence of the GM plants
- none of the GM plant materials will be used for any other purpose
- widespread presence of the same or similar proteins and enzymatic products in the environment and lack of evidence of harm from these proteins and their products
- the lack of known toxicity or allergenicity of the proteins (and enzymatic products) encoded by the introduced genes
- limited capacity of the GM sugarcane lines to spread and persist outside the areas for release
- limited ability and opportunity for the GM sugarcane lines to transfer the introduced genes to commercial sugarcane crops or other sexually compatible species.

Therefore, as no risks to the health and safety of people, or the environment were identified from the limited and controlled release of the GM sugarcane lines into the environment, the level of risk is considered to be **negligible**.

RISK MANAGEMENT

A risk management plan builds upon the risk assessment to consider whether any action is required to mitigate the identified risks, and what can be done to protect the health and safety of people and the environment.

As none of the 16 events that were characterised in the risk assessment process are considered to give rise to an identified risk that requires further assessment, the level of risk to human health and safety and the environment from the release of GM sugarcane lines is considered to be **negligible**.

The Regulators *Risk Analysis Framework* defines negligible risks as insubstantial with no present need to invoke actions for their mitigation. However, containment measures have been imposed to restrict the release to the locations, size and duration requested by the applicant, as these were important parameters in establishing the context for assessing the risks.

Licence conditions to manage this limited and controlled release

A number of licence conditions have been imposed to limit and control the release, including requirements to:

- surround the trial sites by one guard row of non-GM sugarcane and an isolation zone of at least 6 metres
- locate the trial sites at least 50 m away from natural waterways
- harvest and process sugarcane from the trial separately from any commercial sugarcane
- destroy all plant materials not required for experimentation or new plantings
- following cleaning of sites, monitor for and destroy any GM sugarcane that may grow for at least 12 months until the site is clear of volunteers for a continuous 6 month period.

Other regulatory considerations

Australia's gene technology regulatory system operates as part of an integrated legislative framework. The Regulator sought input on the preparation of the RARMP from other agencies that also regulate GMOs or GM products including Food Standards Australia New Zealand (FSANZ), Australian Pesticides and Veterinary Medicines Authority (APVMA), Therapeutic Goods Administration (TGA), National Industrial Chemicals Notification and Assessment Scheme (NICNAS), National Health and Medical Research Council (NHMRC) and Australian Quarantine Inspection Service (AQIS). Dealings conducted under a licence issued by the Regulator may also be subject to regulation by one or more of these agencies⁴.

FSANZ is responsible for human food safety assessment, including GM food. As the trial involves early stage research the applicant does not intend any material from the GM sugarcane lines to be used in human food. Accordingly the applicant has not applied to FSANZ to evaluate any of the GM sugarcane lines. FSANZ approval would need to be obtained before they could be used in human food.

Identification of issues to be addressed for future releases

The risk assessment identified additional information that may be required to assess an application for a larger scale trial, reduced containment conditions or commercial release of any of these GM sugarcane lines. These include:

- molecular characterisation of GM sugarcane lines selected for possible future releases
- additional data on the potential toxicity or allergenicity of proteins encoded by the introduced genes for altered plant architecture, enhanced WUE and improved NUE, and of plant materials from the GM sugarcane lines selected for further research
- altered biochemical, physiological and agronomic characteristics indicative of weediness in the selected GM sugarcane lines including measurement of tolerance to environmental stresses and reproductive capacity

CONCLUSIONS OF THE RARMP

The risk assessment concludes that this proposed limited and controlled release of up to 2500 GM sugarcane lines into the local government areas of Bundaberg, Caboolture and/or Cairns

⁴ More information on Australia's integrated regulatory framework for gene technology is contained in the *Risk Analysis Framework* available from the Office of the Gene Technology Regulator (OGTR). Free call 1800 181 030 or at <<http://www.ogtr.gov.au/pdf/public/raffinal2.2.pdf>>.

in Queensland poses **negligible** risks to the health and safety of people and the environment posed by, or as a result of, gene technology.

The risk management plan concludes that these **negligible** risks do not require specific risk treatment measures. However, licence conditions have been imposed to limit the release to the locations, size and duration requested by the applicant, as these were important parameters in establishing the context for assessing the risks.