



11 November 2009

**TECHNICAL SUMMARY OF THE RISK ASSESSMENT AND RISK  
MANAGEMENT PLAN  
FOR  
APPLICATION NO. DIR 096  
FROM  
BSES**

***Introduction***

The Gene Technology Regulator (the Regulator) has made a decision to issue a licence in respect of application (DIR 096) from BSES Limited (BSES). The licence authorises dealings involving the limited and controlled release of up to 6,000 lines<sup>1</sup> of genetically modified (GM) sugarcane into the environment.

The *Gene Technology Act 2000* (the Act), the Gene Technology Regulations 2001 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 genetically modified organism (GMO). The decision is based upon a Risk Assessment and Risk Management Plan (RARMP) prepared by the Regulator in accordance with requirements of the legislation. RARMPs apply the *Risk Analysis Framework* and are finalised following consultation with a wide range of experts, agencies and authorities, and the public<sup>2</sup>.

***The application***

BSES has applied for a licence for dealings involving the intentional release of up to 6,000 lines of GM sugarcane on a limited scale and under controlled conditions. The GM sugarcane lines have been genetically modified for herbicide tolerance. The trial will take place at six sites in the Queensland shires of Moreton Bay, Bundaberg, Mackay, Burdekin and Cairns, on a maximum area of 26 ha, between November 2009 and November 2015.

The applicant will release three categories of GM sugarcane with two herbicide tolerance genes, two marker genes and a reporter gene. One category will only contain antibiotic resistance selectable marker genes with or without a reporter gene and regulatory elements. Category two will contain gene sequences conferring herbicide tolerance, which would be combined with different regulatory elements, the two antibiotic resistance marker genes and a

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<sup>1</sup> The term 'line' is used to denote plants derived from a single plant containing a specific genetic modification made by one transformation event.

<sup>2</sup> More information on the process for assessment of licence applications to release a genetically modified organism (GMO) into the environment is available from the Office of the Gene Technology Regulator (OGTR) (Free call 1800 181 030 or at <<http://www.ogtr.gov.au/>>), and in the Regulator's *Risk Analysis Framework* (OGTR 2007) at <<http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/riskassessments-1>>.

reporter gene. The third category will only contain gene sequences conferring herbicide tolerance in combination with different regulatory elements.

The genes conferring herbicide tolerance have been obtained from a common bacterium and a plant species which has been consumed safely by humans and animals for centuries.

The reporter gene (*gfp*), which will be present in two GM sugarcane categories, encodes 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 exposing these plant tissues to ultraviolet or blue light. Those plant tissues containing the GFP enzyme will emit a green fluorescence. The GFP may also provide 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 jelly fish (*Aequorea victoria*).

The first two GM sugarcane categories will contain the antibiotic resistance selectable marker genes, *nptII* and *bla*, which 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 only as a selective marker during early stages of development of the GM plants in the laboratory. The *bla* gene encodes  $\beta$ -lactamase which confers resistance to ampicillin. This 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 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 potato), a soil bacterium (*Agrobacterium tumefaciens*) and a plant virus (Cauliflower mosaic virus; CaMV).

The purpose of the trial is to evaluate agronomic properties of the GM sugarcane lines grown under field conditions. Promising lines will be selected for crossing under controlled conditions to non-GM sugarcane cultivars for possible future commercial development (subject to additional approvals). The GM sugarcane will not be used for human food or animal feed.

BSES proposed a number of controls to restrict the dissemination and persistence of the GM sugarcane lines and their genetic material into the environment. These controls were considered during the evaluation of the application.

### **Confidential Commercial Information**

Some details, including the identities of some of the genes and regulatory sequences, have been declared Confidential Commercial Information (CCI) under section 185 of the Act. The confidential information was made available to the prescribed experts and agencies that were consulted on the RARMP for this application.

### **Risk assessment**

The risk assessment considered information in the application, relevant previous approvals, 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 (included in Appendix B of the RARMP) as well as the public (included in Appendix C of the RARMP).

A reference document, *The Biology of the Saccharum spp. (Sugarcane)*, 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 risk assessment begins with a hazard identification process to consider what harm to the health and safety of people or the environment could arise during this release of GMOs due to gene technology, and how it could happen, in comparison to the non-GM parent organism and in the context of the proposed receiving environment.

Eight events were identified whereby the proposed dealings might give rise to harm to people or the environment. This included consideration of whether or not 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. The opportunity for gene flow to other organisms and its effects if this occurred was also assessed.

A **risk** is only identified when a hazard is considered to have some chance of causing harm. Events that do not lead to an adverse outcome, or could not reasonably occur, do not represent an identified risk and do not advance any further in the risk assessment process.

The characterisation of the eight events in relation to both the magnitude and probability of harm, in the context of the control measures proposed by the applicant, did not give rise to any identified risks that required further assessment. The principal reasons for this include:

- limits on the size, locations and duration of the release proposed by BSES
- suitability of controls proposed by BSES to restrict the dissemination and persistence of the GM sugarcane plants and their genetic material
- limited ability and opportunity for the GM sugarcane to transfer the introduced genes to other sugarcane plants or other sexually related species
- none of the GM plant materials or products will be used for human food or animal feed
- widespread presence of the same or similar proteins encoded by the introduced genes in the environment and lack of known toxicity or evidence of harm from them.

Any risks of harm to the health and safety of people, or the environment, from the proposed release of the GM sugarcane into the environment are considered to be **negligible**. Hence, the Regulator considers that the dealings involved in this release **do not pose a significant risk** to either people or the environment.

### ***Risk management***

The risk management process builds upon the risk assessment to determine whether measures are required in order to protect people and/or the environment. As none of the eight events characterised in the risk assessment are considered to give rise to an identified risk that requires further assessment, the level of risk is considered to be **negligible**.

The Regulator's *Risk Analysis Framework* defines negligible risks as insubstantial, with no present need to invoke actions for their mitigation in the risk management plan. However, conditions have been imposed to restrict the dissemination and persistence of the GMOs and their genetic material in the environment and to limit the release to the size, locations and duration requested by the applicant as these were important considerations in establishing the context for assessing the risk.

## ***Licence conditions***

The Regulator has imposed a number of licence conditions including requirements to:

- limit the release to a total area of 26 ha at six BSES stations between November 2009 and November 2015
- locate the field trial sites at least 50 m away from natural waterways
- surround the field trial locations by one guard row of non-GM sugarcane and a further isolation zone of at least 6 m
- separate GM sugarcane material from non-GM material when propagating seedlings or setts on seedling benches, and clearly identifying GM material
- separate GM from non-GM sugarcane in crossing facilities by at least 1 m (glasshouses, pot holding areas, photoperiod facility and crossing shed)
- monitor GM sugarcane in photoperiod facilities for spikelet opening, enclose inflorescences in pollen lanterns prior to spikelet opening and destroy any open spikelets not enclosed in pollen lanterns
- harvest and process the GM sugarcane separately from any other sugarcane
- carry out analysis of plant materials at the BSES stations or in PC2 laboratories
- destroy all plant materials not required for experimentation or propagation (through methods such as mulching, burning and herbicide treatment)
- after cleaning of sites, monitor for and destroy any GM sugarcane that may grow for at least 12 months, and until no volunteers are observed for a continuous six month period
- transport the GM plant materials in accordance with Regulator's transportation guidelines or as specified in the licence
- not allow the GM plant material or products to be used for human food or animal feed.

The Regulator has issued guidelines and policies for the transport, supply and storage of GMOs (*Guidelines for the transport of GMOs, Policy on transport and supply of GMOs*). Licence conditions based on these guidelines and policies have also been imposed to control possession, use or disposal of the GMOs for the purposes of, or in the course of, the authorised dealings.

## ***Other regulatory considerations***

Australia's gene technology regulatory system operates as an integrated legislative framework involving the Regulator and other regulatory agencies that avoids duplication and enhances coordinated decision making. Dealings conducted under a licence issued by the Regulator may also be subject to regulation by other agencies that also regulate GMOs or GM products including Food Standard Australia New Zealand (FSANZ), Australian Pesticides and Veterinary Medicines Authority (APVMA), Therapeutic Goods Administration (TGA), National Industrial Chemicals Notification and Assessment Scheme (NICNAS) and Australian Quarantine Inspection Service (AQIS)<sup>3</sup>.

APVMA has regulatory responsibility for agricultural chemicals in Australia, including herbicides and insecticidal products. The GM sugarcane has been modified to be tolerant to

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<sup>3</sup> 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/internet/ogtr/publishing.nsf/Content/riskassessments-1>>.

selected herbicides and the applicant intends to apply these herbicides during the trial. The application of these herbicides is subject to regulation by the APVMA.

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 proposed for release to be used for human food. Accordingly, the applicant has not applied to FSANZ to evaluate the GM sugarcane lines. FSANZ approval would need to be obtained before they could be sold for human food in Australia.

### ***Identification of issues to be addressed for future releases***

Additional information has been identified that may be required to assess an application for a large scale or commercial release of these GM sugarcane lines, or to justify a reduction in containment conditions. This would include:

- additional data on the potential toxicity and allergenicity of plant materials from the GM sugarcane lines
- phenotypic characterisation of the GM sugarcane lines, in particular of traits which may contribute to weediness, persistence, and ability to disperse in the environment
- molecular and biochemical characterisation of the GM sugarcane lines
- compositional analysis of the GM sugarcane lines
- additional information on potential pollen flow from sugarcane to sexually compatible species.

### ***Suitability of the applicant***

The Regulator determined, at the commencement of the assessment process for this application, that BSES was suitable to hold a DIR licence under the requirements of section 58 of the Act. The Regulator is satisfied that BSES remains suitable as no relevant convictions have been recorded, and no licences or permits have been cancelled or suspended under laws relating to the health and safety of people or the environment.

### ***Conclusions of the RARMP***

The risk assessment concluded that this proposed limited and controlled release of up to 6,000 GM sugarcane lines on a maximum total area of 26 ha over six years in the Queensland shires of Moreton Bay Regional Council, Bundaberg Regional Council, Mackay Regional Council, Burdekin Shire Council and Cairns Regional Council, poses **negligible** risks to the health and safety of people or the environment as a result of gene technology.

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