



24 July 2009

**EXECUTIVE SUMMARY OF THE RISK ASSESSMENT AND
RISK MANAGEMENT PLAN
FOR
APPLICATION NO. DIR 095
FROM
BSES**

Introduction

The Gene Technology Regulator (the Regulator) has made a decision to issue a licence in respect of licence application (DIR 095) from BSES Limited (BSES). The licence authorises dealings involving the limited and controlled release of up to 12,500 lines¹ 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 the *Risk Analysis Framework* and finalised following consultation with a wide range of experts, agencies and authorities and the public².

The application

BSES applied for a licence for dealings involving the intentional release of up to 12,500 lines of GM sugarcane on a limited scale and under controlled conditions. The sugarcane lines will be genetically modified to alter plant growth, enhance drought tolerance, enhance nitrogen use efficiency, alter sucrose accumulation or improve cellulosic ethanol production from sugarcane biomass. The trial will place at six BSES stations in the Queensland local government areas of Moreton Bay, Bundaberg, Mackay, Burdekin and Cairns, on a maximum total area of 21 ha, between August 2009 and August 2015.

The GM sugarcane lines will contain one or more genes or gene fragments from 22 genes derived from a range of plant and bacterial species. Some of the GM sugarcane lines will be modified to express proteins encoded by the introduced genes and some will contain genes or parts of genes designed to suppress the function of endogenous sugarcane genes. In addition, each GM sugarcane line will contain one or two genes encoding antibiotic resistance selectable marker genes used during their initial development in the laboratory.

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

² 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>>.

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 other GM sugarcane lines or 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 introduced genetic materials in the environment that were considered during the evaluation of the application.

Confidential Commercial Information

Some details, including the identities of several 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 took into account information in the application (including proposed containment measures), relevant previous approvals, current scientific knowledge and advice relating to risks to human health and safety and the environment provided in submissions received during consultation on the RARMP. No new risks to people or the environment were identified from the advice received on the consultation RARMP.

A **hazard** identification process was used in the first instance to determine potential pathways that might lead to harm to people or the environment as a result of gene technology.

Nine 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 advance in the risk assessment process.

The characterisation of the nine 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.

Any risks of harm to the health and safety of people, or the environment, from the proposed release of the GM sugarcane lines into the environment are considered to be **negligible**. Hence, the Regulator considers that the dealings involved in this limited and controlled 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 nine events characterised in the risk assessment are considered to give rise to an identified risk that requires further assessment, the level of risk from the proposed dealings 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 are 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 and locations requested by the applicant as these were important considerations in establishing the context for assessing the risks. The context for assessing the risks may change substantially over the 15 year period proposed by the applicant, potentially impacting upon the conclusions of the risk assessment. Therefore, the imposed licence conditions limit the duration of the release to six years.

The licence conditions require BSES to **limit** the release to a total area of 21 ha at six BSES stations between August 2009 and August 2015. The **control** measures include containment provisions at the trial site, preventing the use of GM plant materials in human food or animal feed; destroying GM plant materials not required for further studies; transporting GM plant materials in accordance with the Regulator's transportation guidelines; and conducting post-harvest monitoring at the trial site to ensure all GMOs are destroyed.

Conclusions of the RARMP

The risk assessment concluded that this limited and controlled release of up to 12,500 lines of GM sugarcane on a maximum total area of 21 ha over 15 years in the Queensland local government areas of Moreton Bay, Bundaberg, Mackay, Burdekin and Cairns 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 and locations requested by the applicant as these were important considerations in establishing the context for assessing the risks. The context for assessing the risks may change substantially over the 15 year period proposed by the applicant, potentially impacting upon the conclusions of the risk assessment. Therefore, the imposed licence conditions limit the release to six years, rather than the 15 years proposed by the applicant.