



11 November 2009

**EXECUTIVE 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 licence application (DIR 096) from BSES Limited (BSES). The licence authorises dealings involving the limited and controlled release of up to 6,000 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 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 public².

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 will be

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>>.

combined with different regulatory elements, the two antibiotic resistance marker genes and a 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 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 proposes a number of controls to restrict the dissemination and persistence of the GM sugarcane lines and the introduced genetic materials in the environment that 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 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.

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 advance 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.

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 eight 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, locations and duration requested by the applicant as these were important considerations in establishing the context for assessing the risks.

The licence conditions require BSES to **limit** the release to a total area of 26 ha at six sites between November 2009 and November 2015. The **control** measures would 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 Regulator's transportation guidelines or as specified in the licence; 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 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, 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, locations and duration proposed by the applicant as these were important considerations in establishing the context for assessing the risks.