



**EXECUTIVE 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 made a decision to issue a licence for dealings involving the intentional release of genetically modified (GM) sugarcane lines which are modified for altered plant architecture, enhanced water use efficiency or improved nitrogen use efficiency into the environment, in respect of application (DIR 070/2006) from the BSES Limited.

The DIR070/2006 licence permits the release of up to 2500 genetically modified (GM) sugarcane lines on a limited scale and under controlled conditions.

The *Gene Technology Act 2000* (the Act) and the *Gene Technology Regulations 2001* (the Regulations) govern the process undertaken by the Regulator before a decision is made on whether or not to issue a licence. 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 in consultation with a wide range of experts, agencies and authorities, and the public.

More information on the comprehensive assessment required for 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/>.

THE APPLICATION

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 size and shape, enhance water use efficiency (WUE)¹, or improve nitrogen use efficiency (NUE)². The remaining 600 GM sugarcane lines contain only introduced selectable and/or visual marker genes. All of the introduced genes are derived from plants (rice, sugarcane, barley, bean, thale cress, apple or maize) or the common gut bacterium *Escherichia coli*.

The trial is to take place at up to 3 sites of no more than 2 ha during each of the 3 cropping cycles between February 2007 to November 2010 (ie a total maximum area for the trial of 18 ha). The release may take place in the Queensland local government areas of Bundaberg, Caboolture and/or Cairns.

¹ WUE is defined as the measure of total yield (sugar) produced per unit of water supplied to the sugarcane crop.

² NUE is a term used to describe how effectively plants acquire and utilise nitrogen.

The trial involves early stage ‘proof of concept’ research. The GM sugarcane lines containing only marker genes would be used to compare different genetic modification methods. The other introduced genes are intended to alter plant size and shape, enhance WUE or improve NUE by regulating different biochemical pathways that may result in increased sugar yield. The agronomic performance of GM sugarcane lines containing these genes will be evaluated in the field; some under different irrigation and fertilizer treatments. No GM plant material from the release will be used for human food, animal feed or for the production of other sugarcane commodities.

BSES has proposed a number of measures to limit the spread and persistence of the GM sugarcane lines and the introduced genetic materials that were considered during the evaluation of the application.

RISK ASSESSMENT

The hazard identification process considered the circumstances by which people or the environment may be exposed 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, 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. 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 and short duration of the trial
- 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 of the 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, any risks of harm to the health and safety of people, or the environment, from the release of the GM sugarcane lines into the environment are considered to be **negligible**.

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 16 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. However, containment and disposal measures have been imposed to restrict the release to the locations, size and duration requested by the applicant, as these were an important part of establishing the context for assessing the risks.

The licence conditions require the applicant to limit the duration of the release to between February 2007 and November 2010 on a maximum total area of up to 18 hectares; prevent the use of the GMOs, or materials from the GMOs for any other purposes; maintain physical isolation of the release sites; and conduct post-harvest monitoring to ensure all GM plants are destroyed³.

CONCLUSIONS OF THE RARMP

The risk assessment concludes that this limited and controlled release of up to 2500 GM sugarcane lines into the areas proposed 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 contain the release to the locations, size and duration requested by the applicant.

³ The licence for DIR 070/2006 is available on the OGTR website (<<http://www.ogtr.gov.au/gmorec/ir.htm#table>> via the link to DIR 070/2006).