Australian Government
Department of Health and Ageing
Office of the Gene Technology Regulator

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TECHNICAL 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 application (DIR 095) from BSES Limited (BSES). The licence authorises dealings involving the limited and controlled release of up to 12,500 lines[1] 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 public[2].

The application

BSES has 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 GM 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 take 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. BSES applied to conduct the trial between June 2009 and June 2024.

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. Others will contain genes or parts of genes designed to suppress the function of endogenous sugarcane genes, through a mechanism known as gene silencing or RNA interference (RNAi). 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.

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[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 2007a) at <http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/riskassessments-1>.

The applicant aims to modify plant growth by expression of gibberellin biosynthetic enzymes from runner bean and barley to modify plant height, and by expression or silencing of a transcription factor from rice or sugarcane which controls tillering. Enhanced drought tolerance is expected as a result of the expression of genes from a common plant and a common bacterium involved in plant hormone biosynthesis, or by expression of a transcription factor from rice. Enhanced nitrogen use efficiency is expected to result from expression of a maize transcription factor involved in carbon skeleton production for amino acid synthesis. Sucrose accumulation is expected to be modified with RNAi constructs containing gene fragments from a common crop plant designed to alter sucrose transport, carbohydrate metabolism or osmotic stress tolerance. The efficiency of cellulosic ethanol production from sugarcane biomass is expected to be improved by expression of bacterial cellulase enzymes, or by silencing of a gene to modify plant cell wall chemical structure.

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). Expression of the introduced genes will be controlled with a variety of regulatory sequences, with the aim of optimising expression patterns. 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.

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 represent an identified risk and do not advance any further 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. The principal reasons for this include:

- limits on the size and locations 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 line 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 in human food or animal feed
- widespread presence of most of the same or similar proteins and gene sequences encoded by the introduced genes and RNAi constructs 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 nine 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 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.

Licence conditions to manage this limited and controlled release

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

- limit the release to six years

- surround the field trial sites with 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 (glasshouses, pot holding areas, photoperiod glasshouses and crossing shed) and clearly identify GM material
- monitor GM sugarcane in photoperiod facilities for spikelet opening three times weekly and enclose inflorescences in pollen lanterns for controlled crossing, and destroy open spikelets not enclosed in pollen lanterns
- locate the field trial sites at least 50 m away from natural waterways
- harvest and process the GM sugarcane separately from any other sugarcane
- carry out analysis of plant materials only at the BSES stations or in PC2 laboratories
- destroy all plant materials not required for experimentation or propagation
- after cleaning of sites, monitor for and destroy any GM sugarcane that may grow for at least 12 months, and until no volunteers have been detected at the sites for a continuous 6 month period
- transport the GM plant materials in accordance with the Regulator's transportation guidelines
- 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 part of an integrated legislative framework 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, National Industrial Chemicals Notification and Assessment Scheme and Australian Quarantine Inspection Service (AQIS)[3].

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 in human food. Accordingly, the applicant has not applied to FSANZ to evaluate the GM sugarcane lines. FSANZ

[3] 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>.

approval would need to be obtained before they could be sold for use in 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 allergenicity and toxicity 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, altered reproductive capability and ability to disperse in the environment
- molecular characterisation of the GM sugarcane lines
- additional information on potential pollen flow from sugarcane to sexually compatible species.

Suitability of the applicant

The previous 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 12,500 GM sugarcane lines 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.