



29 August 2008

**TECHNICAL SUMMARY OF THE RISK ASSESSMENT AND RISK  
MANAGEMENT PLAN  
FOR  
APPLICATION NO. DIR 078/2007  
FROM  
THE UNIVERSITY OF QUEENSLAND**

### ***Introduction***

The Acting Gene Technology Regulator (the Acting Regulator) made a decision to issue a licence (DIR 078/2007) from The University of Queensland (UQ) for a limited and controlled release of genetically modified (GM) sugarcane lines into the Australian 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 GMO. The decision is based upon a Risk Assessment and Risk Management Plan (RARMP) prepared by the Acting Regulator in accordance with the *Risk Analysis Framework* and finalised following consultation with a wide range of experts, agencies and authorities and the public<sup>1</sup>.

### ***The application***

UQ applied for a licence for dealings involving the intentional release of up to 3000 lines<sup>2</sup> of sugarcane cultivars *Saccharum spp* (interspecific hybrid of *S. spontaneum* and *S. officinarum*), that have been genetically modified to produce isomaltulose and/or trehalulose on a limited scale and under controlled conditions. The trial is authorised to take place at fifteen sites in the local government areas of Burdekin, Moreton Bay, Hinchinbrook, Cairns, Bundaberg and Mackay in Queensland (QLD) on a total area of up to 65 ha between September 2008 and December 2014.

The GM sugarcane lines contain the *sucrose isomerase* gene (*SI*) derived from a bacterium (*Pantoea dispersa* or *Pseudomonas mesoacidophila*). This gene encodes the SI protein which

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<sup>1</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 (Free call 1800 181 030 or at <<http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/process-1>>), and in the Regulator's *Risk Analysis Framework* (OGTR 2007a) at <<http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/riskassessments-1>>.

<sup>2</sup> The term 'line' is used to denote plants derived from a single plant containing a specific genetic modification made by one transformation event.

converts sucrose to the structural isomers<sup>3</sup> isomaltulose or trehalulose. These sugars are produced in different ratios depending on the source of the gene. Expression of the *SI* gene from *Pantoea dispersa* is expected to produce predominantly isomaltulose whereas expression of the *SI* gene from *P. mesoacidophila* is expected to produce predominantly trehalulose in the GM sugarcane plant cells. In addition to sucrose, isomaltulose and trehalulose produced in the GM plants could be purified for use as alternative sweeteners. Protein stabilising sequences will also be expressed in some lines. A number of promoters and signal sequences are also being tested in order to identify those that allow for optimum expression of the *SI* gene in the various plant cellular compartments.

In addition, all of the GM sugarcane lines contain the antibiotic resistance selectable marker genes *bla* and *nptII*, which are derived from the common gut bacterium, *Escherichia coli*. The *bla* gene encodes the enzyme beta-lactamase and confers ampicillin resistance. It was used to select for bacteria containing the plasmid in the laboratory prior to production of GM plants, as this gene is under the control of a bacterial promoter and thus will not be expressed in the transformed plants. The *nptII* gene encodes the enzyme neomycin phosphotransferase and confers resistance to neomycin or kanamycin. It was used to identify transformed plants.

The purpose of the trial is to conduct initial field testing involving experiments to assess the agronomic properties of the GM sugarcane lines and to analyse sugar production and quality. Promising lines will be selected for propagation for possible future commercial development (subject to additional approvals) and some lines will also be crossed with non-GM sugarcane under controlled conditions to evaluate the feasibility of using them in future breeding programs. The GM sugarcane will not be used for human food or animal feed.

UQ proposed a number of controls to restrict the dissemination or persistence of the GM sugarcane lines into the environment. These controls have been considered during the evaluation of the application.

### **Confidential Commercial Information**

Some details, including the order in which the genetic elements are arranged, 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 contained 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 on the application (summarised in Appendix B of the RARMP). No new risks to people or the environment were identified from the advice received on the consultation RARMP.

Advice received from the public on the consultation RARMP (four submissions) and how it was considered, is summarised in Appendix C.

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<sup>3</sup> An isomer is a molecule with the same kind and number of atoms but in a different arrangement.

A reference document on the parent organism, *The Biology of 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.

Seven events were considered 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 seven 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 principle reasons for this include:

- limits on the size and duration of the release proposed by UQ
- suitability of controls proposed by UQ to restrict the dissemination or persistence of the GM sugarcane plants and their genetic material
- limited ability and opportunity for the GM sugarcane lines to transfer the introduced genes to commercial sugarcane crops or other sexually related species
- limited capacity of the GM sugarcane lines to spread and persist in the areas proposed for release
- none of the GM plant materials or products will be used in human food or animal feed
- widespread presence of the same or similar proteins encoded by, and end products produced as a result of the activity of, the introduced genes in the environment and lack of known toxicity or evidence of harm from them.

Therefore, 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 Acting Regulator considers that the dealings involved in this proposed release **do not pose a significant risk** to either people or the environment<sup>4</sup>.

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<sup>4</sup> As none of the proposed dealings were considered to pose a significant risk to people or the environment, section 52(2)(d)(ii) of the *Gene Technology Act 2000* mandates a minimum period of 30 days for consultation on the RARMP. However, the Regulator has allowed 6 weeks for the receipt of submissions from prescribed experts, agencies and authorities and the public.

## ***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 seven 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, a range of measures have been imposed to restrict the dissemination and persistence of the GMOs and their genetic material in the environment and to limit the proposed release to the size, location and duration requested by the applicant as these were important considerations in establishing the context for assessing the risks.

## ***Licence conditions to manage this limited and controlled release***

The Regulator has imposed a number of licence conditions to limit and control the release, including requirements to:

- conduct the release at fifteen sites in the Queensland local government areas of Burdekin, Moreton Bay, Hinchinbrook, Cairns, Bundaberg and Mackay on a total maximum area of 65 hectares, with a maximum site size of 20 ha, over a period of six years between September 2008 and December 2014.
- not use the GMO or products in human food or animal feed
- restrict personnel with access to the site to trained staff and UQ project staff
- locate the trial sites on land that is not subject to flooding and located at least 50 metres away from the nearest natural waterway
- inspect the western side of Lilliesmere lagoon at least once every 6 months for the presence of Volunteers and destroy any volunteers until Final Harvest at the adjacent Site
- separate GM sugarcane from any adjacent commercially harvested sugarcane by two guard rows and headlands maintained free of sugarcane
- separate GM sugarcane grown in the field from any adjacent experimental sugarcane by an isolation zone of at least 3 metres that is maintained free of sugarcane or a corresponding width of two planted rows of non-GM sugarcane
- separate GM sugarcane from any public area (accessible without crossing privately owned or controlled land) by at least two rows of non-GM sugarcane
- GM sugarcane plants grown at crossing facilities must be inspected every 4 days for signs of flower initiation and upon morphological transition to flowering cover the flowering stalk with a pollen lantern or prevent it from flowering by removing the flower stalks as to limit dispersal of pollen into the environment
- GM seedlings at a Nursery or Crossing Facilities must be clearly identifiable through eg physical separation or labelling
- transport GM plant materials to and from the proposed trial sites in accordance with OGTR transportation guidelines

- destroy all plant materials not required for further analysis or propagation;
- following final harvest, clean the sites and equipment used on the sites
- post harvest monitoring of the trial site for at least 12 months and destroying any volunteers until no volunteers are observed for a period of least 6 months.

The Regulator has issued guidelines and policies for the transport, supply and storage of GMOs (*Guidelines for the transport 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. 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>5</sup>.

FSANZ is responsible for human food safety assessment, including GM food. As the trial involves proof of concept 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 any of the GM sugarcane lines. FSANZ approval would need to be obtained before they could be used 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 any of these GM sugarcane lines that may be selected for further development, or to justify a reduction in control measures. This would include:

- characterisation of the introduced genetic material in the plants, including genotypic stability
- additional data on the potential toxicity and allergenicity of proteins encoded by the introduced genes, and of plant materials from the GM sugarcane lines selected for possible future releases
- data on potential gene transfer to non-GM sugarcane and other related species
- characteristics indicative of weediness including measurement of altered reproductive capacity, tolerance to abiotic and other environmental stresses and disease susceptibility.

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<sup>5</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>>.

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

The Regulator determined, at the commencement of the assessment process for this application, that UQ is suitable to hold a DIR licence under the requirements of section 58 of the Act. The Acting Regulator is satisfied that UQ remains suitable as no relevant convictions have been recorded, no licences or permits have been cancelled or suspended under OGTR legislation relating to the health and safety of people or the environment, and the organisation has confirmed its ability to comply with the licence conditions.

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

The risk assessment concludes that this proposed limited and controlled release of up to 3000 GM sugarcane lines on a maximum total area of 65 ha over six years in the Queensland local government area of Burdekin, Moreton Bay, Hinchinbrook, Cairns, Bundaberg and Mackay poses **negligible** risks to the health and safety of people or the environment 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 restrict the dissemination and persistence of the GMOs and their genetic material in the environment and to limit the proposed release to the size, locations and duration requested by the applicant as these were important considerations in establishing the context for assessing the risk.