



29 August 2008

**EXECUTIVE 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) has made a decision to issue a licence for dealings involving the limited and controlled release of up to 3000 lines of sugarcane genetically modified for altered sugar production into the environment in respect of application DIR 078/2007 from The University of Queensland (UQ).

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 public¹.

The application

UQ applied for a licence for dealings involving the intentional release of up to 3000 lines² of genetically modified (GM) sugarcane on limited scale and under controlled conditions. The GM sugarcane lines have been modified for altered sugar production. The trial would 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 maximum area of up to 65 hectares between September 2008 and December 2014.

The GM sugarcane lines contain one of two genes which encode an enzyme that converts sucrose into two other similar sugars. The genes are both derived from commonly occurring

¹ 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>>.

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

bacteria. Expression of the introduced gene is expected to produce sugars similar to sucrose, which could be used as alternative sweeteners.

In addition, all of the GM sugarcane lines contain two antibiotic resistance selectable marker genes, which were used to identify transformed plants during their initial development in the laboratory.

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. A number of regulatory and protein stabilising sequences are also being tested to identify those that allow for optimum expression of the introduced genes in the various plant cellular compartments. 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 and the introduced genetic materials 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 takes into account information in the application (including proposed containment measures), relevant previous approvals, current scientific knowledge, advice received from a wide range of experts, agencies and authorities consulted on the RARMP and submissions from the public.

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

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, physiology or ecology. 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 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.

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 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 seven 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, 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.

The licence conditions require UQ to **limit** the release to a total area of 65 ha, at fifteen sites between September 2008 and December 2014. The **control** measures to restrict the spread and persistence of the GMOs include 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 OGTR transportation guidelines; and conducting post-harvest monitoring at the trial site to ensure all GMOs are destroyed³.

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

³ The licence for DIR 078/2007 is available on the OGTR website <<http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/ir-1>> via the link to DIR 078/2007