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

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EXECUTIVE SUMMARY OF THE RISK ASSESSMENT AND RISK MANAGEMENT PLAN
FOR
APPLICATION NO. DIR 079/2007
FROM
QUEENSLAND UNIVERSITY OF TECHNOLOGY

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 17 lines of banana modified for disease resistance into the environment in respect of application DIR 079/2007 from the Queensland University of Technology (QUT).

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[1].

The application

QUT applied for a licence for dealings involving the intentional release of up to 17 GM banana lines on a limited scale and under controlled conditions. The GM banana lines have been modified for disease resistance. The trial is authorised to take place at one site in the local government area of Cassowary Coast, Queensland on a maximum total area of 1.4 hectares between 2008 and 2010.

Up to 16 of the GM banana lines will contain a gene that is expected to provide protection from certain disease-causing micro-organisms. The gene is derived from a nematode.

One GM banana line will contain a reporter gene that expresses a protein which provides a visual indication of where successful transformation of plant tissues has occurred. The gene is derived from a jellyfish.

All of the GM banana lines will contain an antibiotic resistance selectable marker gene, which was used to identify transformed plants during initial development of GM plants in the laboratory.

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

The purpose of the trial is to conduct proof of concept research involving experiments with the GM banana lines to assess their development and disease response. The GM bananas will not be used for human food or animal feed.

QUT proposed a number of controls that have been considered during the evaluation of the application to restrict the dissemination or persistence of the GM banana lines and the introduced genetic materials in the environment.

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.

Eight events were considered whereby the proposed dealings might give rise to harm to people or the environment. Consideration was then given as to 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.

Therefore, any risks of harm to the health and safety of people, or the environment, from the proposed release of the GM banana lines into the environment are estimated 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 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, 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 QUT to **limit** the release to a total area of up to 1.4 ha at one site between July 2008 and April 2010. 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 destroyed[2].

Conclusions of the RARMP

The risk assessment concludes that this limited and controlled release of up to 17 GM banana lines on a maximum total area of 1.4 ha over two years in the Queensland local government area of Cassowary Coast 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, location and duration requested by the applicant as these were important considerations in establishing the context for assessing the risks.

[2] The licence for DIR 079/2007 is available on the OGTR website (<http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/dir079-2007>) via the link to DIR 079/2007