



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 107
FROM
QUEENSLAND UNIVERSITY OF TECHNOLOGY**

Introduction

The Gene Technology Regulator (the Regulator) has made a decision to issue a licence in respect of application DIR 107 from Queensland University of Technology (QUT). The licence authorises dealings involving the limited and controlled release of genetically modified (GM) banana 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 or not 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 requirements of the legislation. RARMPs apply the *Risk Analysis Framework* and are finalised following consultation with a wide range of experts, agencies and authorities, and the public¹.

The application

QUT has applied for a licence for dealings involving the intentional release of GM banana into the environment on a limited scale and under controlled conditions. The GM banana lines have been genetically modified for disease resistance. The field trial is authorised to take place at one site in the local government area (LGA) of Litchfield Municipality, Northern Territory, on a maximum area of 1.5 ha between the date of issue of the licence and November 2014.

The purpose of the field trial is to conduct proof of concept experiments to assess the disease response and/or development of the GM banana lines. Material from the GM banana plants will not be used in human food or animal feed.

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/>>), and in the Regulator's *Risk Analysis Framework* (OGTR 2009) at <<http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/riskassessments-1>>.

A total of up to 151 lines² of GM banana are intended for release, comprising 18 GM Cavendish banana lines and 133 GM Lady Finger banana lines. Each line contains one or two genes that are expected to provide protection from certain disease-causing microorganisms, or the *uidA* reporter gene, as described below.

Up to 19 of the GM banana lines contain one of two specific disease resistance gene candidates, which were isolated from a species of non-GM banana that is resistant to the pathogen *Fusarium oxysporum* f.sp. *cubense* Tropical Race 4.

Up to 112 of the GM banana lines contain one or two of nine anti-apoptotic genes derived from a range of organisms including viruses, bacteria and plant species. These genes are expected to confer disease resistance by preventing cells from undergoing programmed cell death (or apoptosis) in response to infection by certain pathogenic microorganisms. Expression of the anti-apoptotic genes may also affect growth and development of the GM banana plants and confer enhanced tolerance to a range of biotic and abiotic stresses.

The remaining 20 GM banana lines contain the reporter gene *uidA* derived from *Escherichia coli*. The *uidA* gene encodes an enzyme, β -glucuronidase (GUS), which enables visual identification of plant tissues in which it is expressed. GM banana plants containing the *uidA* gene will be used as controls to ascertain if any observed phenotype is a result of the expression of the introduced genes for disease resistance and not the transformation process.

In addition, all of the GM banana lines contain the antibiotic resistance gene *neomycin phosphotransferase type II (nptII)*, which is also derived from *E. coli*. The *nptII* gene encodes the enzyme neomycin phosphotransferase, which confers kanamycin or neomycin resistance on the GM plants. This was used as a selective marker during initial development of GM plants in the laboratory.

The expression of the introduced genes in the GM banana lines is under the control of short regulatory sequences. These are derived from: the plants *Zea mays* (maize), *Ricinus communis* (castor bean) and *Musa acuminata* ssp. *malaccensis* (banana); the soil bacterium *Agrobacterium tumefaciens*; and the plant viruses Cauliflower mosaic virus (CaMV) and Tobacco etch virus (TEV). Although *A. tumefaciens*, CaMV and TEV are plant pathogens, the regulatory sequences comprise only a small part of their respective total genomes, and are not in themselves capable of causing disease.

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

Risk assessment

The risk assessment takes into account information in the application (including proposed containment measures), previous approvals and relevant scientific/technical knowledge. Advice relating to risks to human health and safety and the environment provided in submissions received during consultation on the RARMP has also been considered. No new risks to people or the environment were identified from the advice received on the consultation RARMP.

A reference document, *The Biology of Musa L. (banana)*, was produced to inform the risk assessment process for licence applications involving GM banana plants. The document is available from the OGTR or from the website <http://www.ogtr.gov.au>.

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

Initially, potential pathways that might lead to harm to people or the environment as a result of gene technology are postulated (risk scenarios) and these scenarios are evaluated to identify those that warrant detailed characterisation. This process is described as risk identification.

Eight risk scenarios were postulated, including 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 banana lines; or produce unintended changes in the biochemistry of the GMO. The opportunity for gene flow to other organisms, and its effects if it were to occur, was also assessed.

A **risk** is only identified for further assessment when a risk scenario is considered to have some chance of causing harm. Pathways 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 risk scenarios in relation to both the seriousness and likelihood of harm, in the context of the control measures proposed by the applicant, did not identify any risks that required further assessment. The principal reasons for this include:

- limits on the size, location and duration of the release proposed by QUT
- suitability of controls proposed by QUT to restrict the spread and persistence of the GM banana plants and their genetic material
- limited ability and opportunity for the GM banana plants to transfer the introduced genes to commercial banana crops or other sexually related species
- effectiveness of removal of GM *A. tumefaciens*, which were used during the genetic modification process, from the GM banana plants prior to field 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 the introduced genes in the environment and lack of known toxicity or evidence of harm from them.

Risks to the health and safety of people, or the environment, from the proposed release of the GM banana into the environment are assessed to be **negligible**. Hence, the 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 plan

Risk management is used to protect the health and safety of people and to protect the environment by controlling or mitigating risk. The risk management plan evaluates and treats identified risks, evaluates controls and limits proposed by the applicant, and considers general risk management measures. The risk management plan is given effect through the licence conditions.

As none of the eight risk scenarios characterised in the risk assessment gave rise to an identified risk that required further assessment, the level of risk from the proposed dealings was assessed 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 spread and persistence of the GMOs and their genetic material in the environment and to limit the 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

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

- limit the release to a maximum total area of 1.5 ha at one site in the Litchfield Municipality LGA between the date of issue of the licence and November 2014
- locate the trial site at least 50 m away from waterways
- maintain a 10 m zone around the GM bananas in which no bananas may be grown
- remove and destroy all male/hermaphrodite flowers on the inflorescences unless they are required for experimental analysis
- cover any male/hermaphrodite flowers left on the inflorescences
- cover fruit bunches
- harvest the GM banana separately from other crops
- clean all equipment used in connection with the GMOs
- monitor the field site for at least 12 months after harvest and destroy any volunteer banana plants that may grow
- destroy all GM plant material, including fruit, not required for further analysis
- transport and store all GMOs in accordance with the Regulator's guidelines
- not permit any GM banana plant material to be used in human food or animal feed.

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. The Regulator is responsible for assessing risks to the health and safety of people and the environment associated with the use of gene technology. However, dealings conducted under a licence issued by the Regulator may also be subject to regulation by other Australian government agencies that regulate GMOs or GM products, including Food Standards Australia New Zealand (FSANZ), Australian Pesticides and Veterinary Medicines Authority, Therapeutic Goods Administration, National Industrial Chemicals Notification and Assessment Scheme and Australian Quarantine Inspection Service³.

FSANZ is responsible for human food safety assessment and food labelling, including GM food. The applicant does not intend to use materials from the GM banana lines in human food, accordingly an application to FSANZ has not been submitted. FSANZ approval would need to be obtained before materials from these GM banana lines could be sold as food.

In addition, dealings authorised by the Regulator may be subject to the operation of State legislation declaring areas to be GM, GM free, or both, for marketing purposes.

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>>.

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 banana lines, or to justify a reduction in containment conditions. This would include:

- additional data on the potential toxicity and allergenicity of plant materials from the GM banana lines
- additional phenotypic characterisation of the GM banana lines, particularly with respect to traits that may contribute to weediness, including tolerance to environmental stresses and disease susceptibility
- additional molecular and biochemical characterisation of the GM banana lines.

Suitability of the applicant

The Regulator is satisfied that QUT is suitable to hold a DIR licence as no relevant convictions have been recorded, no licences or permits have been cancelled or suspended under laws relating to the health and safety of people or the environment, and the organisation has the capacity to meet the conditions of the licence.

Conclusions of the RARMP

The risk assessment concluded that this limited and controlled release of up to 151 lines of GM banana on a maximum total area of 1.5 ha over four years in the Northern Territory LGA of Litchfield Municipality, 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 limit the release to the size, location and duration proposed by the applicant, and to require controls in line with those proposed by the applicant, as these were important considerations in establishing the context for assessing the risks.