



## Summary of the Risk Assessment and Risk Management Plan

for

### Licence Application No. DIR 199

#### **Decision**

The Gene Technology Regulator (the Regulator) has decided to issue a licence for the intentional, commercial-scale release of one line of genetically modified (GM) banana plants, QCAV-4, in Australia.

A Risk Assessment and Risk Management Plan (RARMP) for this application was prepared by the Regulator in accordance with the *Gene Technology Act 2000* (the Act) and corresponding state and territory legislation, and finalised following consultation with a wide range of experts, agencies and authorities, and the public. The RARMP concludes that this commercial release poses negligible risk to human health and safety and the environment and no specific risk treatment measures are imposed. However, general licence conditions have been imposed to ensure that there is ongoing oversight of the release.

Parallel regulatory approval was sought from Food Standards Australia New Zealand (FSANZ). FSANZ is a statutory agency responsible for maintaining the Australia New Zealand Food Standards Code. FSANZ has approved this GM banana for sale as a food in Australia and New Zealand. The GM bananas and any derived food products are subject to mandatory GM labelling. More information is available on the [FSANZ website](#).

#### **The application**

Application number	DIR 199
Applicant	Queensland University of Technology (QUT)
Project title	Commercial release of banana plants genetically modified for resistance to <i>Fusarium</i> wilt tropical race 4 (TR4)
Parent organism	Banana ( <i>Musa acuminata</i> subgroup Cavendish cv Grand Nain)
Introduced genes and modified traits	Introduced gene conferring disease resistance: <ul style="list-style-type: none"><li>• <i>MamRGA2</i> – <i>Fusarium oxysporum</i> f. sp. <i>cubense</i> tropical race 4 (TR4) resistance gene from <i>Musa acuminata</i> ssp <i>malaccensis</i> (wild banana)</li></ul> Introduced selectable marker gene: <ul style="list-style-type: none"><li>• <i>nptII</i> – antibiotic resistance gene from <i>Escherichia coli</i></li></ul>
Proposed locations	Australia-wide
Primary purpose	Commercial cultivation of the GM banana plants

## ***Risk assessment***

The risk assessment process considers how the genetic modification and activities conducted with the GM banana plants might lead to harm to people or the environment. Risks are characterised in relation to both the seriousness and likelihood of harm, taking into account information in the application, relevant previous approvals, current scientific knowledge and advice received from a wide range of experts, agencies and authorities consulted on the preparation of the RARMP. Both the short- and long-term risks are considered.

Credible pathways to potential harm that were considered included exposure of people or animals to the QCAV-4 GM banana plants, and commercial scale planting of the QCAV-4 GM banana plants. The potential harms considered were increased toxicity, allergenicity or weediness of the QCAV-4 GM banana plants compared to unmodified plants.

The risk assessment concludes that risks to the health and safety of people or the environment from the proposed dealings, either in the short or long term, are negligible. No specific risk treatment measures are required to manage these negligible risks.

The principal reasons for the conclusion of negligible risks are that the QCAV-4 GM banana plants have very limited ability to transfer the introduced genetic material to other banana plants; the QCAV-4 GM banana plants have limited ability to establish populations outside cultivation; the introduced proteins are not expected to be toxic or allergenic; and bananas are subject to strict biosecurity measures in the states and territories where bananas are commercially grown.

## ***Risk management***

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 and considers general risk management measures. The risk management plan is given effect through licence conditions.

The risk management plan concludes that risks from the proposed dealings can be managed so as to protect people and the environment by imposing general conditions to ensure that there is ongoing oversight of the release.

As the level of risk is assessed as negligible, specific risk treatment is not required. However, the Regulator has imposed licence conditions regarding post-release review (PRR) to ensure that there is ongoing oversight of the release and to allow the collection of information to verify the findings of the RARMP. The licence also contains several general conditions relating to ongoing licence holder suitability, auditing and monitoring, and reporting requirements, which include an obligation to report any unintended effects.