



### Summary of Licence Application DIR 199

Queensland University of Technology (QUT) has made an application under the *Gene Technology Act 2000* (the Act) for Dealings involving the Intentional Release (DIR) of a genetically modified organism (GMO) into the Australian environment.

<b>Project Title</b>	Commercial release of banana genetically modified for resistance to Fusarium wilt Tropical Race 4 (TR4)
<b>Parent organism</b>	Banana ( <i>Musa acuminata</i> subgroup Cavendish cv Grand Nain)
<b>Genetic modifications</b>	
Introduced genes	Introduced genes conferring resistance to TR4 (Panama disease): <ul style="list-style-type: none"> <li>• <i>MamRGA2</i> – <i>Fusarium oxysporum</i> f. sp. <i>ubense</i> tropical race 4 (TR4) resistance gene from <i>Musa acuminata ssp 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>
Genetic modification method	<i>Agrobacterium</i> -mediated transformation
Number of lines	One line (QCAV-4)
<b>Principal purpose</b>	Commercial cultivation of the GM banana plants (if the Australian banana industry is heavily impacted by Panama disease)
<b>Previous releases</b>	QCAV4 GM banana plants have been previously approved for field trials in Australia under DIR-107 and DIR-146
<b>Proposed locations</b>	Australia-wide
<b>Proposed period of release</b>	From issue of licence

#### Next steps

The Gene Technology legislation sets out what the Regulator must do, as well as what the Regulator can or must consider, before deciding whether or not to issue a licence for this application.

After seeking advice from prescribed experts, agencies and authorities, the Regulator’s staff will prepare a consultation version of the Risk Assessment and Risk Management Plan (RARMP) considering aspects of the application in accordance with the legislation.

The Regulator will seek comment on the consultation RARMP from the public, as well as a wide range of experts, agencies and authorities. These stakeholders will be invited to provide submissions on the risks to human health and safety, and on risks to the environment from the proposed release.

At this stage, the consultation RARMP is expected to be released for comment in **August 2023**.

After consultation, the Regulator’s staff will finalise the RARMP, taking into account advice on relevant matters. The finalised RARMP will form the basis of the Regulator’s decision whether or not to issue a licence. The consultation and final versions of the RARMP and associated documents will be available on the [OGTR website](#) when they are released.

Note that issues around food safety, including food labelling, fall into the remit of Food Standards Australia New Zealand (FSANZ). QUT has also applied to FSANZ for the fruit and other products of this GM banana to be permitted for sale as food. This application was given the FSANZ identifier A1274. FSANZ will make a decision in accordance with its legislation in a separate regulatory process. You can access information relating to this GM food application, including food labelling, on the [FSANZ](#) website.

**Other information available from the OGTR website:**

- 'Questions and Answers' document for this application
- documents on genetic modification methods and selectable marker genes
- information on Australia's national scheme for regulation of gene technology
- information on the DIR application process and
- information on the regulatory scope of the Gene Technology Regulator and Food Standards Australia New Zealand, respectively.

Please use the contact details below, if you

- would like a copy of the application to the Regulator. Please include the identifier DIR-199.
- have any questions about the application or the legislated decision-making process or
- wish to register on the mailing list.

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