Australian Government
Department of Health
Office of the Gene Technology Regulator

13 December 2016

Issue of licence DIR 146 to Queensland University of Technology for the limited and controlled release of GM banana

On 13 October 2016, the Gene Technology Regulator invited submissions on the consultation version of the Risk Assessment and Risk Management Plan (RARMP) for licence application DIR 146 from Queensland University of Technology.

The Regulator has now issued a licence in response to application DIR 146, authorising the limited and controlled release (field trial) of banana genetically modified (GM) for resistance to Fusarium wilt disease.

The release is authorised to take place at one site of up to 6 hectares in Litchfield Municipality, Northern Territory, for a period of 5 years. The purpose of the field trial is to evaluate the level of disease resistance and agronomic performance of the GM banana plants under Australian field conditions. The GM banana is not permitted be used for human food or animal feed. In addition to requirements by the Regulator, this field trial will remain subject to State and Territory laws that cover the cultivation and transport of bananas and control of plant diseases, including Banana Freckle disease.

The Regulator's decision to issue the licence was made after consultation on the RARMP with the public, State and Territory governments, Australian Government agencies, the Minister for the Environment, the Gene Technology Technical Advisory Committee and local councils, as required by the *Gene Technology Act 2000* and the corresponding State and Territory legislation.

The Regulator considered all submissions provided during the consultation process that related to the health and safety of people or the protection of the environment. The comments were considered in the context of current scientific information and used in finalising the RARMP. The finalised RARMP informed the Regulator's decision to issue the licence.

The finalised RARMP concludes that this limited and controlled release poses negligible risks to people and the environment and does not require specific risk treatment measures. However, licence conditions have been imposed to restrict spread and persistence of the GMOs and their genetic material in the environment and to limit the release in size, location and duration, as these were important considerations in the evaluation process.

Appendix A of the RARMP summarises the advice received from prescribed experts, agencies and authorities, and indicates how issues raised relating to risks to human health and safety or the environment were considered in preparing and finalising the document. Submissions received from the public on the consultation RARMP and the issues raised, and their consideration, are summarised in Appendix B of the RARMP.

The finalised RARMP, together with a summary of the RARMP, a set of Questions and Answers on this decision and a copy of the licence, can be obtained on-line from the DIR 146 page of the Office of the Gene Technology Regulator's website or requested via the contacts detailed below.

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