Australian Government
Department of Health
Office of the Gene Technology Regulator

February 2017

# Summary of the Risk Assessment and Risk Management Plan for Licence Application No. DIR 150

## *Decision*

The Gene Technology Regulator (the Regulator) has decided to issue a licence for this application for the limited and controlled release (field trial) of a genetically modified organism (GMO) into the environment. A Risk Assessment and Risk Management Plan (RARMP) for this application was prepared by the Regulator in accordance with the requirements of 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 the field trial poses negligible risks to human health and safety and the environment and that any risks posed by the dealings can be managed by imposing conditions on the release.

## *The application*

| | |
|---|---|
| Application number | DIR 150 |
| Applicant | Queensland University of Technology (QUT) |
| Project title | Limited and controlled release of potato genetically modified for disease resistance |
| Parent organism | Potato (*Solanum tuberosum* cv. "Russet Burbank") |
| Introduced genes and modified traits | The following disease resistance genes either singly or in combination:<br>• *Rx* gene derived from *S. tuberosum* cv. "Cara" conferring resistance to Potato virus X (PVX)<br>• *Rpi-blb1* and *Rpi-blb2* genes derived from *S. bulbocastanum* conferring resistance to late blight (*Phytophthora infestans*) |
| Proposed location | One site in Redland City, Queensland |
| Proposed release size | Up to 0.1 hectare (ha) in total |
| Proposed release dates | February 2017 – January 2019 |
| Primary purpose | To assess the agronomic characteristics and PVX disease response of GM potato plants under field conditions |

## *Risk assessment*

The risk assessment concludes that there are negligible risks to the health and safety of people, or the environment, from the proposed release.

The risk assessment process considers how the genetic modification and proposed activities conducted with the GMOs 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 current scientific/technical knowledge, information in the application (including proposed limits and

controls), relevant previous approvals and advice received from a wide range of experts, agencies and authorities consulted on the RARMP. Both the short and long term impacts are considered.

Credible pathways to potential harm that were considered included exposure of people or animals to the GM plant material, potential for spread and persistence of the GMOs, and transfer of the introduced genetic material to sexually compatible plants. Potential harms associated with these pathways included toxicity or allergenicity to people, toxicity to other desirable organisms, and environmental harms due to weediness.

The principal reasons for the conclusion of negligible risks are that the GM plant material will not be used for human food or animal feed, the proposed limits and controls effectively contain the GMOs and their genetic material and minimise exposure; and the GM potato has limited ability to establish populations outside cultivation or transfer the introduced genetic material to other plants.

## *Risk management plan*

The risk management plan describes measures to protect the health and safety of people and to protect the environment by controlling or mitigating risk. The risk management plan is given effect through licence conditions.

As the level of risk is considered negligible, specific risk treatment is not required. However, since this is a limited and controlled release, the licence includes limits on the size, location and duration of the release, as well as controls to prohibit the use of GM plant material in human food or animal feed, to minimise dispersal of the GMOs from trial sites, to transport GMOs in accordance with the Regulator's guidelines, to destroy GMOs not required for testing or further planting, and to conduct post-harvest monitoring at trial sites to ensure all GMOs are destroyed.