Australian Government
Department of Health
Office of the Gene Technology Regulator

14 March 2019

Summary of the Risk Assessment and Risk Management Plan (Consultation version)

for

Licence Application No. DIR 166

Introduction

The Gene Technology Regulator (the Regulator) has received a licence application for the intentional release of a genetically modified organism (GMO) into the environment. It qualifies as a limited and controlled release application under the *Gene Technology Act 2000* (the Act). The Regulator has prepared a Risk Assessment and Risk Management Plan (RARMP) for this application, which concludes that the proposed field trial poses negligible risks to human health and safety and the environment. Licence conditions have been drafted for the proposed field trial. The Regulator invites submissions on the RARMP, including draft licence conditions, to inform the decision on whether or not to issue a licence.

The application

Application Number	DIR 166
Project Title	Limited and controlled release of *Cicer arietinum* (chickpea) genetically modified for drought and other environmental stress tolerance
Parent organism	Chickpea (*Cicer arietinum* L.)
Introduced genes	Introduced genes conferring drought and environmental stress tolerance: • *AtBAG4* – abiotic stress resistance gene from *Arabidopsis thaliana* • *TlBAG4* – abiotic stress resistance gene from *Tripogon loliiformis* Introduced marker gene: • *nptII* selectable marker - antibiotic resistance gene from *Escherichia coli*
Genetic modification method	*Agrobacterium*-mediated transformation
Number of lines	Up to 60 lines
Proposed location/s	Walkamin (Queensland Department of Agriculture and Fisheries Walkamin Research Facility), Tablelands Regional Council, Queensland
Proposed release size	Up to 3 ha per year
Proposed period of release	From July 2019 until December 2024
Principal purpose	To assess the drought and heat tolerance and agronomic characteristics of GM chickpea under field conditions

Risk assessment

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

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) and relevant previous approvals. Both the short and long term impacts are considered.

Credible pathways to potential harm that were considered included exposure of people or other desirable organisms to the GM plant material, potential for persistence or dispersal of the GMOs, transfer of the introduced genetic material to non-GM chickpea plants. Potential harms associated with these pathways included toxicity or allergenicity to people, toxicity to desirable animals, 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 and that the proposed limits and controls will effectively minimise exposure to the GMOs.

Risk management

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. Draft licence conditions are detailed in Chapter 4 of the RARMP.

As the level of risk is considered negligible, specific risk treatment is not required. However, since this is a limited and controlled release, the draft 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 and animal feed, to minimise dispersal of the GMOs or GM pollen from the trial site, to transport GMOs in accordance with the Regulator's guidelines, to destroy GMOs at the end of the trial and to conduct post-harvest monitoring at the trial site to ensure all GMOs are destroyed.