

Australian Government

**Department of Health and Aged Care** Office of the Gene Technology Regulator

March 2025

# Summary of the Risk Assessment and Risk Management Plan for

## **Licence Application No. DIR 209**

### Introduction

The Gene Technology Regulator (the Regulator) has decided to issue a licence for this application for the intentional release of a genetically modified organism (GMO) into the environment. A Risk Assessment and Risk Management Plan (RARMP) for this application has been 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 concluded that the proposed field trial poses low risk 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.

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Project Title	Limited and controlled release of sorghum genetically modified for altered reproduction from sexual to asexual
Applicant	The University of Queensland
Parent organism	Sorghum (Sorghum bicolor)
Genetic modifications	
Introduced genes <sup>1</sup> and modified traits	<ul> <li>Introduced genes conferring altered reproduction from sexual to asexual:</li> <li>A parthenogenesis gene from a grass species</li> <li>A gene-editing <i>cas9</i> gene with guide RNAs that knock out 4 endogenous sorghum genes and cause mitosis instead of meiosis Two marker genes</li> </ul>
Genetic modification method	Agrobacterium-mediated transformation
Number of lines	Up to 10 lines
Principal purpose	To assess agronomic and genetic characteristics of the genetically modified (GM) sorghum plants under field conditions
Proposed limits	
Proposed use of GM plants	No use in human food or animal feed
Proposed location/s	One trial site at the University of Queensland's Gatton Campus
Proposed release size	Up to 1 hectare per year
Proposed period of release	From March 2025 to March 2028

#### The application

<sup>&</sup>lt;sup>1</sup> Confidential Commercial Information (CCI): Details about the introduced genetic elements have been declared as CCI under section 185 of the Act. This information is provided to the prescribed experts and agencies that are consulted on this application. CCI is not available to the public.

#### Risk assessment

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 short- and long-term risks are considered.

Credible pathways to potential harm that were considered included exposure of people or animals to the GM plant material, potential for persistence or dispersal of the GMOs, and transfer of the introduced genetic material to non-GM sorghum or related weeds. Potential harms associated with these pathways included toxicity or allergenicity to people, toxicity to desirable animals, and environmental harms due to weediness.

The risk assessment concludes that the proposed dealings pose negligible risks to the health and safety of people and low risks to the environment. The identified low risks involve transfer of introduced genetic material from the GM sorghum to related weeds, leading to environmental harms relating to increased weediness.

#### 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.

The risk management plan concludes that the identified low risks to the environment can be managed by risk treatment measures that minimise the dispersal of GM pollen from the trial sites. The licence also 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 from the trial sites, to transport GMOs in accordance with the Regulator's guidelines, to destroy the GMOs at the end of the trial and to conduct post-harvest monitoring at the trial sites to ensure the GMOs are destroyed.