Australian Government
Department of Health and Aged Care
Office of the Gene Technology Regulator

December 2024

Summary of the Risk Assessment and Risk Management Plan (Consultation Version) for Licence Application No. DIR 209

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 low risks to human health and safety and the environment, which can be managed through risk treatment measures. 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

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[1] and modified traits	Introduced genes conferring altered reproduction from sexual to asexual: • A parthenogenesis gene from a grass species • A gene-editing *cas9* gene with guide RNAs that knock out 4 endogenous sorghum genes and cause mitosis instead of meiosis Two marker genes
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

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

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 draft 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.