Australian Government
Department of Health
Office of the Gene Technology Regulator

March 2022

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

for

Licence Application No. DIR 189

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

Project Title	Limited and controlled release of sorghum genetically modified for asexual seed formation[1]
Parent organism	Sorghum (*Sorghum bicolor*)
Genetic modifications	
Introduced genes and modified traits:	Expression of a grass gene[2] involved in altering the reproduction mode of sorghum from sexual to asexual
Genetic modification method	*Agrobacterium*-mediated
Number of lines	Up to 10 independent lines of a number of sorghum cultivars
Principal purpose	To assess agronomic characteristics, seed viability, gene persistence, yield and yield components, and grain quality of the GM sorghum plants under field conditions
Previous releases	There have been no previous releases of the GMOs
Proposed limits	
Proposed use of GM plants	No use in human food or animal feed is proposed
Proposed location	University of Queensland's Gatton Campus - Crop Research Unit
Proposed release size	Up to 1 ha per year
Proposed period of release	From September 2022 to June 2025

[1] The title of the project as supplied by the applicant is 'Limited and controlled release of *Sorghum bicolor* genetically modified for altered reproduction from sexual to asexual'

[2] Confidential Commercial Information: The details of the introduced gene have been declared as Confidential Commercial Information under section 185 of the Act. This information will be made available to the prescribed experts and agencies that will be consulted on this application. CCI is not available to the public.

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 risks 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, and transfer of the introduced genetic material to non-GM sorghum 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 proposed limits and controls, such as not using GM plant material in food or animal feed, will effectively minimise exposure to the GMOs. In addition, there is no evidence to suggest the introduced genetic modifications would lead to harm to people or the environment.

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.

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 the GMOs are destroyed.