



Summary of the Risk Assessment and Risk Management Plan (Consultation Version) for Licence Application No. DIR 153

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 153
Applicant	The University of Queensland (UQ)
Project title	Limited and controlled release of sorghum genetically modified for grain quality traits
Parent organism	Sorghum (<i>Sorghum bicolor</i>)
Introduced genes and modified traits	<ul style="list-style-type: none">• modified kafirin gene¹ from sorghum for altered seed protein content and digestibility• fragment of a foldase enzyme gene¹ from sorghum for altered seed size, protein content and digestibility• fragments of three membrane protein genes¹ from sorghum for altered seed size or number of seeds• <i>nptII</i> selectable marker gene from <i>Escherichia coli</i>
Proposed location	One site in the first year and up to four sites in the second and third years in south-east Queensland
Proposed release size	Up to 1 ha in the first year and up to 5 ha in the second and third years
Proposed release dates	October 2017 – June 2020
Primary purpose	To assess agronomic characteristics, yield and grain quality of the GM sorghum plants

¹ Specific gene names are not provided as they have been declared Confidential Commercial Information.

Risk assessment

The risk assessment concludes that risks to the health and safety of people, or the environment, from the proposed release 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 animals to the GM plant material, potential for persistence or dispersal of the GMOs, and transfer of the introduced genetic material to other sorghum plants 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 principal reasons for the conclusion of negligible risks are that the GM plant material will not be used for human food or animal feed except in an experimental poultry feeding trial, the proposed limits and controls effectively contain the GMOs and their genetic material and minimise exposure, and the GM sorghum has limited ability to establish populations outside cultivation.

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, locations and duration of the release, as well as controls to prohibit the use of GM plant material in human food or animal feed except in a poultry feeding trial, to minimise dispersal of the GMOs or GM pollen 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.