



July 2017

Summary of the Risk Assessment and Risk Management Plan for Licence Application No. DIR 153

Decision

The Gene Technology Regulator (the Regulator) has decided to issue a licence for this application for the limited and controlled release (field trial) of a genetically modified organism (GMO) into the environment. A Risk Assessment and Risk Management Plan (RARMP) for this application was prepared by the Regulator in accordance with the requirements of 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 concludes that the field trial poses negligible risks 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.

The application

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| 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 there are negligible risks to the health and safety of people, or the environment, from the proposed release.

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), relevant previous approvals and advice received from a wide range of experts, agencies and authorities consulted on the RARMP. 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.

As the level of risk is considered negligible, specific risk treatment is not required. However, since this is a limited and controlled release, the 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.