



Summary of the Risk Assessment and Risk Management Plan for Licence Application No. DIR 162

Decision

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 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 concluded 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

Application number	DIR 162
Applicant	CSIRO
Project Title	Limited and controlled release of bread wheat and durum wheat genetically modified for enhanced rust disease resistance ¹
Parent Organism	Bread wheat (<i>Triticum aestivum</i>) Durum wheat (<i>Triticum turgidum</i> subsp. <i>durum</i>)
Introduced genes and modified traits	<ul style="list-style-type: none">• Eight genes involved in stem rust disease resistance• Three genes involved in multi-pathogen (stem rust, leaf rust, stripe rust and powdery mildew) resistance GM lines will contain between one and eight disease resistance genes <ul style="list-style-type: none">• Three selectable marker genes will be used across all lines
Proposed location	Ginninderra Experiment Station (ACT) and Boorowa Agricultural Research Station ² , Shire of Boorowa (NSW)
Proposed release size	Up to 1 ha per year ³
Proposed release dates	September 2018 - September 2023
Primary purpose	To evaluate agronomic performance of the GM bread wheat and durum wheat lines under field conditions

¹ The original title for the application was: Limited and controlled release of *Triticum aestivum* and *Triticum turgidum* subsp. *durum* genetically modified for enhanced rust disease resistance

² This site was previously named Boorowa Experiment Station.

³ The applicant requested a total area of 40m² per season, but revised the request to one hectare per season following release of the consultation RARMP. The revised area has been considered in this final version of the RARMP.

Risk assessment

The risk assessment concludes that risks to the health and safety of people or the environment from the proposed dealings, either in the short or long term, 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 other desirable organisms to the GM plant material, exposure of people and other desirable organisms to hybrids between different GMOs, potential for persistence or dispersal of the GMOs, transfer of the introduced genetic material to non-GM bread wheat and durum wheat plants and transfer of the introduced genetic material to plants of related species. 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 and that the imposed limits and controls will effectively contain the GMOs and their genetic material and minimise exposure.

Risk management

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, 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 trial sites to ensure all GMOs are destroyed.