



Summary of the Risk Assessment and Risk Management Plan for Licence Application No. DIR 201

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 has been prepared by the Regulator in accordance with 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 proposed 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

Project Title	Limited and controlled release of wheat and barley genetically modified for yield enhancement
Parent organism	Wheat (<i>Triticum aestivum</i> L.) and barley (<i>Hordeum vulgare</i> L.)
Genetic modifications	
Introduced genes and modified traits	<u>Wheat:</u> <ul style="list-style-type: none">• Expression of three genes involved in yield enhancement (expressed both individually and in combination)• Expression of five genes involved in yield enhancement and water use efficiency (expressed individually)• Knockout of two endogenous genes involved in yield enhancement• Expression of three selectable marker genes and one reporter gene (expressed both individually and in combination) <u>Barley:</u> <ul style="list-style-type: none">• Knockout of eight endogenous genes involved in yield, architecture, and nutrient use efficiency• Expression of one selectable marker gene (expressed individually)
Genetic modification method	Biolistic or <i>Agrobacterium</i> -mediated transformation; gene editing
Number of lines	Up to 103 lines ¹ in total
Principal purpose	To assess agronomic performance of the GM wheat and barley lines under field conditions

¹ The term 'line' is used to denote plants derived from a single plant containing a specific genetic modification resulting from a single transformation event.

Proposed limits	
Proposed use of GM plants	No use in commercial food or animal feed proposed
Proposed location/s	The trial is proposed to take place at one site in South Australia (Light Regional Council)
Proposed release size	Up to a total of 2 ha per year
Proposed period of release	From May 2024 to January 2029
Previous releases	<ul style="list-style-type: none"> • Wheat lines containing all or some of the three introduced genes for yield enhancement have previously been released under DIR 102, DIR 128, DIR 152 and DIR 186. • Wheat lines containing the five genes involved in yield enhancement and water use efficiency have previously been released under DIR 186.

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 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 wheat and barley plants. 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 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 principal reasons for the conclusion of negligible risks are that the proposed limits and controls, such as the small trial size and 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

Risk management is used to protect the health and safety of people and to protect the environment by controlling or mitigating risk. The risk management plan evaluates and treats identified risks and considers general risk management measures. 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 the GMOs at the end of the trial and to conduct post-harvest monitoring at the trial site to ensure the GMOs are destroyed. In addition, there are several general conditions relating to ongoing licence holder suitability, auditing and monitoring, and reporting requirements which include an obligation to report any unintended effects.