Australian Government
Department of Health
Office of the Gene Technology Regulator

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Summary of the Risk Assessment and Risk Management Plan

(consultation version) for

Licence Application DIR 186

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[1]

Project Title	Limited and controlled release of wheat and barley genetically modified for yield enhancement and improved abiotic stress tolerance
Parent organisms	Wheat (*Triticum aestivum* L.) and barley (*Hordeum vulgare* L.)
Genetically modified organisms	
Genetic modifications	• Expression of three genes involved in yield enhancement (expressed both individually and in combination) • Expression of five genes involved in yield and abiotic stress tolerance (water use efficiency) • Expression of three selectable marker genes (expressed both individually and in combination)
Number of lines	Up to 70 lines[2] in total
Principal purpose	To assess agronomic performance of the GM wheat and barley lines under field conditions
Proposed limits	
Proposed use of GM plants	No use in human food or animal feed is proposed
Proposed locations	The trial is proposed to take place at two sites – one site in South Australia (Light Regional Council), and one site in Western Australia (Shire of Merredin)
Proposed release size	Up to a total of 2 ha per year across both sites
Proposed period of release	From April 2022 to January 2027
Previous releases	Wheat and barley lines containing all or some of the three introduced genes for yield enhancement have previously been released under DIR 102,

[1] The applicant amended their application to remove GM wheat and barley knockout/knockdown lines which had been generated by CRISPR/Cas9 genome editing of endogenous *TaMUTE*, *TaYDA1*, *TaYDA2*, *TaOST1* and *TaSLAC1* genes.

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

	DIR 128 and DIR 152.

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 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 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

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.