Australian Government
Department of Health and Aged Care
Office of the Gene Technology Regulator

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Summary of the Risk Assessment and Risk Management Plan (Consultation Version) for Licence Application No. DIR 204

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

Project Title	Limited and controlled release of wheat genetically modified for increased tolerance to environmental stress
Applicant	Trigall Australia Pty Ltd
Parent organism	Wheat (*Triticum aestivum* L.)
Genetic modifications	
Introduced genes and modified traits	• *HaHB4* gene from *Helianthus annuus* conferring environmental stress tolerance • *bar* gene from *Streptomyces hygroscopicus* as a selectable marker gene conferring glufosinate herbicide tolerance
Genetic modification method	Biolistic transformation
Unique identifier of GMO	IND-ØØ412-7
Trade name of GMO	HB4 wheat
Principal purpose	To gather research and regulatory data for HB4 wheat under Australian growing conditions, including under environmental stress
Previous releases	HB4 wheat is approved for commercial cultivation in Argentina, Brazil and Paraguay
Proposed limits	
Proposed use of GM plants	No use in human food or animal feed proposed
Proposed location/s	Up to 10 sites per year in wheat growing areas of New South Wales, Victoria, Western Australia and South Australia
Proposed release size	Up to 20 hectares per year in total
Proposed period of release	From issue of licence until December 2029

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 short- and long-term risks 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 non-GM plants. Potential harms associated with these pathways included adverse health effects in people or 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. The principal reasons for the conclusion of negligible risks are that the proposed limits and controls will effectively minimise exposure to the GMOs. In addition, there is no evidence to suggest the introduced genetic modifications could lead to harm to people or the environment.

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 and animal feed, to minimise dispersal of the GMOs or GM pollen from the trial sites, 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 sites to ensure the GMOs are destroyed.