



August 2014

Summary of the Risk Assessment and Risk Management Plan for Licence Application No. DIR 128

Decision

The Gene Technology Regulator (the Regulator) has decided to issue a licence for this application for a limited and controlled 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 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 this 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 128
Applicant:	The University of Adelaide
Project Title:	Limited and controlled release of wheat and barley modified for abiotic stress tolerance or micronutrient uptake
Parent organisms:	Bread wheat (<i>Triticum aestivum</i> L.) and barley (<i>Hordeum vulgare</i> L.)
Introduced genes and modified traits:	<ul style="list-style-type: none">• Thirty-three genes that are involved in salt tolerance, aluminium tolerance, drought tolerance (water use efficiency), nitrogen use efficiency, or micronutrient uptake.¹• Two selectable marker genes from bacteria
Proposed release dates:	August 2014 – December 2019
Proposed locations:	Five sites, two in South Australia and three in Western Australia
Proposed release size:	Total of 2.5 hectares per season
Primary purpose:	To assess whether the introduction and expression of the specified group of genes in plants affects yield potential under field conditions

Risk assessment

The risk assessment concludes that risks to the health and safety of people, or the environment, from the proposed release are negligible.

The risk assessment process considers how the genetic modification and 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 information in the application

¹ The identities of some of the genes have been declared as Confidential Commercial Information (CCI) under section 185 of the Act.

(including proposed limits and controls), relevant previous approvals, current scientific/technical knowledge, and advice received from a wide range of experts, agencies and authorities consulted on the RARMP. Both the short and long term potential harms are considered.

Credible pathways to potential harm that were considered included: unintended exposure to the GM plant material; increased spread and persistence of the GM wheat and barley relative to unmodified plants; and transfer of the introduced genetic material to non GM wheat or barley, or other sexually compatible plants. Potential harms associated with these pathways included toxicity to people and other animals, allergic reactions in people and environmental harms associated with weediness.

The principal reasons for the conclusion of negligible risks are that the introduced genetic modifications are unlikely to cause harm to human health or safety or to the environment, the introduced genes are similar to those already existing in the environment, and furthermore, the proposed limits and controls effectively contain the GMOs and their genetic material and minimise exposure.

Risk management plan

The risk management plan concludes that risks posed by the proposed dealings can be managed so as to protect people and the environment by imposing conditions on the release.

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, evaluates controls and limits proposed by the applicant, and considers general risk management measures. The risk management plan is given effect through licence conditions.

As the level of risk is assessed as negligible, specific risk treatment is not required. However, as this is a limited and controlled release, the licence includes limits on the size, locations and duration of the release, as well as controls including containment provisions at the trial site; prohibiting the use of GM plant materials in human food or animal feed; destroying GM plant materials not required for further studies; transporting GM plant materials in accordance with the Regulator's guidelines; and conducting post-harvest monitoring at the trial sites to ensure all GMOs are destroyed.