



July 2017

Summary of the Risk Assessment and Risk Management Plan for Licence Application No. DIR 152

Decision

The Gene Technology Regulator (the Regulator) has decided to issue a licence for this application for the limited and controlled release of genetically modified organisms (GMOs) 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 concludes 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 152
Applicant	The University of Adelaide
Project Title	Limited and controlled release of wheat and barley genetically modified for abiotic stress tolerance and yield improvement.
Parent Organism	Wheat (<i>Triticum aestivum</i> L.) and barley (<i>Hordeum vulgare</i> L.)
Introduced genes and modified traits	Two groups of introduced genes are proposed: <ul style="list-style-type: none">• Group 1: three genes involved in yield enhancement, individually and in combinations• Group 2: seven genes involved in frost tolerance¹ In addition, one selectable marker gene is used across both groups
Proposed location	Maximum of four locations per season across South Australia, Western Australia, and New South Wales.
Proposed release size	Maximum total area of 3.75 ha in Seasons 1 and 2 and 1.5 ha in Season 3.
Proposed release dates	July 2017 – January 2021
Primary purpose	To assess agronomic performance of the GM wheat and barley lines under field conditions.

¹ The identities and details regarding these genes, some promoters, regulatory sequences and some references have been declared Confidential Commercial Information (CCI).

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 and desirable animals to the GM plant material; increased potential for spread and persistence of the GMOs in the environment and transfer of introduced genetic material into sexually compatible plants. Potential harms associated with these pathways included increased toxicity or allergenicity to humans or increased toxicity to other desirable organisms and environmental harms due to increased 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, the imposed limits and controls effectively contain the GMOs and their genetic material and minimise exposure; and the GM wheat and barley have limited ability to establish populations outside cultivation or transfer the introduced genetic material to other plants.

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.

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 or animal feed, to minimise dispersal of the GMO or GM pollen from trials, to transport GMOs in accordance with the Regulator's guidelines, to destroy GMOs not required for testing or further planting, and to conduct post-harvest monitoring at release sites to ensure all GMOs are destroyed.