Australian Government
Department of Health
Office of the Gene Technology Regulator

May 2017

Summary of the Risk Assessment and Risk Management Plan for Licence Application No. DIR 151

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 151
Applicant	CSIRO
Project title	Limited and controlled release of wheat genetically modified for disease resistance, drought tolerance, altered oil content and altered grain composition
Parent organism	Wheat (*Triticum aestivum* L.)
Introduced genes and modified traits	Five groups of introduced genes are proposed: • Group A: nine genes (or gene fragments) involved in resistance to rust disease • Group B: thirteen genes involved in drought adaptation • Group C: three genes (or gene fragments) involved in altered starch metabolism • Group D: four genes involved in increased oil content • Group E: eight genes involved in altered grain dietary fibre content In addition, four genes are used as selectable markers across all groups
Proposed location	Ginninderra Experiment Station (ACT) and Boorowa Experiment Station, Shire of Boorowa (NSW)
Proposed release size	Up to 1 hectare (ha) per site per year
Proposed release dates	May 2017 – May 2022
Primary purpose	To evaluate the agronomic performance of all GM wheat lines under field conditions. For Group C and Group E, to generate flour for laboratory evaluation of food performance. For Group E, possibly to conduct animal and/or human feeding studies to assess nutritional value.

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 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 or animals to the GM plant material, increased potential for spread and persistence of the GMOs, and transfer of the introduced genetic material to sexually compatible plants. Potential harms associated with these pathways included toxicity or allergenicity to people, toxicity to other desirable organisms, and environmental harms due to 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 apart from possible carefully controlled small scale animal and/or human nutritional trials, the proposed limits and controls effectively contain the GMOs and their genetic material and minimise exposure; and the GM wheat has 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 commercial human food or animal feed, to minimise dispersal of the GMOs or GM pollen from trial sites, 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 trial sites to ensure all GMOs are destroyed.