Australian Government
Department of Health
Office of the Gene Technology Regulator

April 2019

Summary of the Risk Assessment and Risk Management Plan

for

Licence Application No. DIR 165

Decision

The Gene Technology Regulator (the Regulator) has decided to issue a licence for this application for the intentional 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 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 165
Applicant	The University of Melbourne
Project Title	Limited and controlled release of wheat genetically modified for altered iron uptake, transport and bioavailability[1]
Parent Organism	Bread wheat (*Triticum aestivum*)
Introduced genes and modified traits	Iron-related genes derived from wheat, rice and other plant species: • 57 nicotianamine synthase (NAS) genes involved in iron uptake and transport • Seven genes from a gene family[2] (Class 2) involved in iron bioavailability • Six nicotianamine aminotransferase (NAAT) genes involved in iron uptake • Three deoxymugineic acid synthase (DMAS) genes involved in iron uptake • Six iron-related transcription factor (IRO) genes involved in iron uptake and transport • Six vacuolar iron transporter (VIT) genes involved in iron transport and storage • Six ferritin (Fer) genes involved in iron storage • 55 yellow stripe-like transporter (YSL) genes involved in iron transport Marker genes derived from bacteria: • Two selectable marker genes

[1] The original title for the application was: Limited and controlled release of *Triticum aestivum* L genetically modified for improved iron uptake, transport and bioavailability.

[2] The name of this gene family is not provided as it has been declared Confidential Commercial Information (CCI) under Section 185 of the Act. The information is included in a CCI Attachment to the RARMP, which is available to the prescribed experts and agencies that are consulted on the RARMP.

Application number	DIR 165
Proposed locations	Up to 2 sites in 2019 and 10 sites per year in 2020-2023, to be selected from 131 possible local government areas in Victoria, New South Wales and Western Australia
Proposed release size	Up to 4 ha in 2019 and 20 ha per year in 2020-2023
Proposed release dates	April 2019 – December 2023
Primary purpose	To gather research and regulatory data under field conditions

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 modifications 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), relevant previous approvals and advice received from a wide range of experts, agencies and authorities consulted on the RARMP. Both the short and long term are considered.

Credible pathways to potential harm that were considered included exposure of people or desirable animals to the GM plant material on the trial sites, transfer of the introduced genetic material to non-GM plants outside the trial sites and potential for persistence or dispersal of the GMOs outside the trial sites. 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 GM plant material will not be used for human food or animal feed and that the proposed limits and controls will effectively minimise exposure to the GMOs.

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.

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, 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 GMOs at the end of the trial, and to conduct post-harvest monitoring at the trial sites to ensure GMOs are destroyed.