Australian Government
Department of Health
Office of the Gene Technology Regulator

March 2018

Summary of the Risk Assessment and Risk Management Plan for Licence Application DIR 160

Decision

The Gene Technology Regulator (the Regulator) has decided to issue a licence for this application for the limited and controlled release (field trial) 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 160
Applicant	Department of Economic Development, Jobs, Transport and Resources (DEDJTR)
Project title	Limited and controlled release of perennial ryegrass genetically modified for fructan biosynthesis
Parent organism	Perennial ryegrass (*Lolium perenne*)
Introduced genes and modified traits	• Two fructan biosynthesis genes (sucrose:sucrose 1-fructosyltransferase and fructan:fructan 6G-fructosyltransferase) from perennial ryegrass for increased plant nutritional quality and biomass production • *hph* selectable marker gene from *Escherichia coli*
Proposed location	One site in the Southern Grampians Shire in south-west Victoria.
Proposed release size	Up to 160 m^2 each year
Proposed release dates	May 2018 – June 2020
Primary purpose	To assess agronomic characteristics and to multiply seed for future trials

Risk assessment

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

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 other perennial ryegrass plants or related species. 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 the imposed limits and controls effectively contain the GMOs and their genetic material and minimise exposure.

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 GMOs or GM pollen from the trial site, 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 the trial site to ensure all GMOs are destroyed.