Australian Government
Department of Health
Office of the Gene Technology Regulator

7 December 2017

Summary of the Risk Assessment and Risk Management Plan (Consultation Version)

for

Licence Application No. DIR 160

Introduction

The Gene Technology Regulator (the Regulator) has received a licence application for the intentional release of a genetically modified organism (GMO) into the environment. It qualifies as a limited and controlled release application under the *Gene Technology Act 2000* (the Act). The Regulator has prepared a Risk Assessment and Risk Management Plan (RARMP) for this application, which concludes that the proposed field trial poses negligible risks to human health and safety and the environment. Licence conditions have been drafted for the proposed field trial. The Regulator invites submissions on the RARMP, including draft licence conditions, to inform the decision on whether or not to issue a licence.

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 impacts are considered.

Credible 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, the proposed 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. Draft licence conditions are detailed in Chapter 4 of the RARMP.

As the level of risk is considered negligible, specific risk treatment is not required. However, since this is a limited and controlled release, the draft 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.