Australian Government
Department of Health and Aged Care
Office of the Gene Technology Regulator

December 2022

Summary of the Risk Assessment and Risk Management Plan (consultation version) for Licence Application No. DIR 194

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 to low risk to the health and safety of people and animals, and negligible risk to 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

Project title	Limited and controlled release of perennial ryegrass genetically modified for increased metabolisable energy content [1]
Parent organism	Perennial ryegrass (*Lolium perenne* L.)
Genetic modifications	
Introduced genes	Introduced genes conferring increased metabolisable energy content: • *diacylglycerol o-transferase 1* (*DGAT1*) gene from garden nasturtium (*Tropaeolum majus*) – encodes triacylglycerol synthesis enzyme • *cysteine oleosin* gene from sesame (*Sesamum indicum*) – encodes oil body structural protein (oleosin) Introduced selectable marker gene: • *hygromycin phosphotransferase* (*hph*) – hygromycin B antibiotic resistance gene from *Escherichia coli*
Genetic modification method	*Agrobacterium*-mediated transformation
Number of events	Up to six events
Principal purpose	To evaluate the increased metabolisable energy content trait under field conditions
Previous releases	There have been no previous releases of these GMOs in Australia. The GMOs have been evaluated in the field in the United States.

[1] Original title: Limited and controlled release of *Lolium perenne* L genetically modified for increased metabolizable energy content

Proposed limits	
Proposed use of GM plants	Animal feeding trials may be conducted with GM perennial ryegrass silage. No use as human food or commercial animal feed is proposed for the GM perennial ryegrass.
Proposed location/s	Up to 7 trial sites per year to be selected from 119 possible local government areas in New South Wales, Victoria, Western Australia, and Queensland
Proposed release size	Up to 2.5 ha per year with a maximum of 12.5 ha over the period of release
Proposed period of release	From April 2023 to December 2028

Risk assessment

The risk assessment concludes that risks to the health and safety of people and animals are negligible to low and the risks to the environment from the proposed release are negligible. Specific risk treatment measures are included in the licence to manage these low 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 risks are considered.

Credible pathways to potential harm that were considered included exposure of people or other desirable organisms to the GM plant material, potential for persistence or dispersal of the GMOs, and transfer of the introduced genetic material to perennial ryegrass and related plants outside the field trial. Potential harms associated with these pathways included toxicity or allergenicity to people or other desirable organisms, and environmental harms due to weediness.

The principal reason for the conclusion of a substantive risk to the health and safety of people and animals is that the introduced cysteine oleosin is derived from a known allergenic oleosin in sesame. Risk characterisation was performed to further consider the likelihood and consequences of potential harm related to allergenicity to humans and animals. In the specific context of this proposed limited and controlled release, the risk was characterised as negligible to low. The principal reasons for this characterisation are that the proposed limits and controls will minimise exposure of people and animals to the GMOs and that the number of people with an allergy to sesame oleosin is expected to be relatively low. As the risk to people is greater than negligible, specific risk treatment was considered as part of the risk management.

The remaining risk scenarios were found to pose negligible risks. The principal reasons for the conclusion of negligible risks are that the proposed limits and controls will effectively minimise dispersal and persistence of the GMOs, and there is no evidence to suggest the introduced genetic modifications would lead to toxicity to people or animals, or increase pest fitness.

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

As the level of risk to the health and safety of people is considered to be low in regard to allergenicity, a licence condition is proposed to prevent people with a known sesame allergy from working with the GMOs in situations where they may be exposed to the introduced cysteine oleosin. In addition, 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 commercial animal

feed, to minimise dispersal of the GMOs or GM pollen from the trial sites, to transport the 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 the GMOs are destroyed.