



Summary of the Risk Assessment and Risk Management Plan (Consultation Version) for Licence Application No. DIR 205

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 draft Risk Assessment and Risk Management Plan (RARMP) for this application, which concludes that the proposed field trial poses negligible risks to the health and safety of people 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

Applicant	CSIRO
Project title	Limited and controlled release of canola genetically modified for increased abiotic stress tolerance ¹
Parent organism	Canola (<i>Brassica napus</i> L.)
Introduced genes	<ul style="list-style-type: none">• A gene from yeast² conferring abiotic stress tolerance• <i>pat</i> gene from <i>Streptomyces viridochromogenes</i> as a selectable marker conferring glufosinate herbicide tolerance
Proposed locations	Up to 3 sites per year in canola growing areas of New South Wales and South Australia
Proposed release size	Up to a maximum planting area of 1.5 hectares (ha) for each site in the first year and 2 ha for each site in the subsequent years
Proposed period of release	From May 2025 to December 2030
Principal purpose	To evaluate the performance of GM canola plants under field conditions with and without irrigation

Risk assessment

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,

¹ The title of the project as supplied by the applicant is “Limited and controlled release of *Brassica napus* (Canola) genetically modified for increased physiological growth in response to abiotic stresses”.

² Details about the identity and source of the introduced gene in the GM canola lines have been declared as Confidential Commercial Information (CCI) under section 185 of the Act. This information will be made available to the prescribed experts and agencies that will be consulted on this application. CCI is not available to the public.

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 other desirable organisms to the GM plant material, potential for persistence or dispersal of the GMOs, and transfer of the introduced genetic material to non-GM canola plants. Potential harms associated with these pathways included toxicity and allergenicity to people, toxicity to desirable animals, and environmental harms due to weediness.

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 principal reasons for the conclusion of negligible risks are that the proposed limits and controls, such as not using GM plant material in human food or animal feed, will effectively minimise exposure to the GMOs. In addition, there is no evidence to suggest the introduced genetic modifications would lead to harm to people or the environment.

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