Australian Government
Department of Health
Office of the Gene Technology Regulator

November 2018

Summary of the Risk Assessment and Risk Management Plan

for

Licence Application No. DIR 164

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 concluded 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 164
Applicant	Monsanto Australia Pty Ltd
Project title	Limited and controlled release of canola genetically modified for herbicide tolerance
Parent organism	Canola (*Brassica napus* L.)
Introduced genes and modified traits	• *dmo* gene from the bacterium *Stenotrophomonas maltophilia* (dicamba herbicide tolerance) • *cp4 epsps* gene from *Agrobacterium* sp. strain CP4 (glyphosate herbicide tolerance)
Proposed location	Up to 15 sites per year for the first two years and 20 sites for the third and fourth years, to be selected from 140 possible local government areas in New South Wales, Queensland, South Australia, Victoria and Western Australia
Proposed release size	Maximum area of 30 hectares (ha) in 2020 and 2021 (maximum area of 2 ha per site), 50 ha in 2022 (maximum area of 5 ha per site) and 100 ha in 2023 (maximum area of 20 ha per site)
Proposed release dates	January 2020 – January 2024
Primary purpose	To assess agronomic performance of the GM canola in all canola growing areas of Australia

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.

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 non-GM canola, commercially approved GM canola 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 increased 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 proposed limits and controls effectively control 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 the 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 each trial site to ensure the GMOs are destroyed.