Australian Government
Department of Health
Office of the Gene Technology Regulator

15 June 2022

Summary of the Risk Assessment and Risk Management Plan

for

Licence Application No. DIR 188

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 has been prepared by the Regulator in accordance with 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 proposed 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

Applicant	Nuseed Pty Ltd
Project title	Limited and controlled release of canola and Indian mustard genetically modified for altered oil content and herbicide tolerance
Parent organisms	Canola (*Brassica napus* L.) Indian mustard (*Brassica juncea* (L.) Czern. & Coss.)
Introduced genes	Seven genes involved in biosynthesis pathway for long-chain polyunsaturated fatty acids: • *Lackl-Δ12D* from yeast *Lachancea kluyveri* • *Picpa- ω3D* from yeast *Pichia pastoris* • *Micpu-Δ6D* from microalga *Micromonas pusilla* • *Pyrco-Δ6E* from microalga *Pyramimonas cordata* • *Pavsa-Δ5D* from microalga *Pavlova salina* • *Pyrco-Δ5E* from microalga *Pyramimonas cordata* • *Pavsa-Δ4D* from microalga *Pavlova salina* One gene that confers herbicide tolerance: • *pat* gene from soil bacterium *Streptomyces viridochromogenes* for glufosinate tolerance
Proposed locations	Up to 20 trial sites per year to be selected from 96 possible local government areas in New South Wales, Victoria and Queensland
Proposed release size	Up to 150 ha per year
Proposed period of release	From November 2022 to January 2028
Principal purpose	To evaluate the altered oil content trait under field conditions

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

The principal reasons for the conclusion of negligible risks are that the proposed limits and controls will effectively minimise exposure to the GMOs, and 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.

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 commercial human food or 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.