



Summary of the Risk Assessment and Risk Management Plan for Licence Application No. DIR 163

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 163
Applicant	Nuseed Pty Ltd (Nuseed)
Project title	Limited and controlled release of canola modified for altered oil content and herbicide tolerance
Parent organism	Canola (<i>Brassica napus</i> L.)
Introduced genes and modified traits	<p>Seven genes involved in the metabolism of long-chain polyunsaturated fatty acids:</p> <ul style="list-style-type: none">• <i>Lackl-d12D</i> from the yeast <i>Lachancea kluyveri</i>• <i>Picpa-ω3D</i> from the yeast <i>Pichia pastoris</i>• <i>Micpu-d6D</i> from the microalga <i>Micromonas pusilla</i>• <i>Pyrco-d6E</i> from the microalga <i>Pyramimonas cordata</i>• <i>Pavsa-d5D</i> from the microalga <i>Pavlova salina</i>• <i>Pyrco-d5E</i> from the microalga <i>Pyramimonas cordata</i>• <i>Pavsa-d4D</i> from the microalga <i>Pavlova salina</i> <p>Four other genes for an altered oil profile¹</p> <p>Two selectable marker genes:</p> <ul style="list-style-type: none">• <i>pat</i> gene from the soil bacterium <i>Streptomyces viridochromogenes</i> for glufosinate tolerance.• <i>nptII</i> gene from <i>Escherichia coli</i> for kanamycin tolerance. <p>A herbicide tolerance gene²</p>

^{1,2} The identities of the genes have been declared as Confidential Commercial Information (CCI) under section 185 of the Act.

Proposed location	Site selection from 95 local government areas in New South Wales (NSW), Victoria (VIC) and Queensland (QLD).
Proposed release size	Up to 10 sites of 5 ha and 10 sites of 10 ha, i.e. up to 150 ha per year
Proposed release dates	Nov 2018 - December 2023
Primary purpose	To gather research and regulatory data, information and samples under field conditions for agronomic performance, oil profile and content, nutritional assessment, compositional analysis, molecular analysis, genetic stability and safety assessment.

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 population size of animal pests and increased weediness.

The principal reasons for the conclusion of negligible risks are that the GM plant material will not be used for commercial 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 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 commercial 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.