



Summary of the Risk Assessment and Risk Management Plan for Licence Application No. DIR 149

Decision

The Gene Technology Regulator (the Regulator) has decided to issue a licence for this application for the limited and controlled release (field trial) of a genetically modified organism (GMO) into the environment. A Risk Assessment and Risk Management Plan (RARMP) for this application was prepared 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 concludes 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 149
Applicant	Nuseed Pty Ltd (Nuseed)
Project title	Limited and controlled release of Indian mustard (<i>Juncea canola</i>) genetically modified for altered oil content ¹
Parent organism	Indian mustard [<i>Brassica juncea</i> (L.) Czern. & Coss.]
Introduced genes and modified traits	<ul style="list-style-type: none">• Seven genes involved in the biosynthesis of omega-3 fatty acids (altered oil content for human nutrition, animal nutrition and food processing)²• One gene from a bacterium (selectable marker)²
Proposed location	Sites are to be selected from 102 possible local government areas in New South Wales, Victoria and Queensland
Proposed release size	4 sites in 2017 (maximum 2 ha per site), 10 sites in 2018 (maximum 5 ha per site) and 15 sites in each subsequent year (maximum 10 ha per site)
Proposed release dates	April 2017 – May 2022
Primary purpose	To evaluate the agronomic performance and oil profile of the GM Indian mustard under field conditions

Nuseed proposes to conduct a field trial with up to 50 lines³ of Indian mustard genetically modified to produce a high proportion of long chain omega-3 fatty acids (oils) relative to other fatty acids in the seed.

¹ The title of the project as supplied by the applicant is 'Limited and controlled release of *Brassica juncea* genetically modified for oil content'.

² The identities of the genes have been declared Confidential Commercial Information (CCI) under section 185 of the Act.

³ The term 'line' is used to denote plants derived from a single plant containing a specific genetic modification resulting from a single transformation event.

Risk assessment

The risk assessment concludes that risks to the health and safety of people, or the environment, from the proposed release are negligible. 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 animals to the GM plant material, dispersal of GM seed leading to spread and persistence of the GMOs, and transfer of the introduced genetic material to sexually compatible plants. 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 GM plant material will not be used for human food or animal feed, the proposed limits and controls effectively contain the GMOs and their genetic material and minimise exposure; and the GM Indian mustard has limited ability to establish populations outside cultivation or transfer the introduced genetic material to other plants.

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 GM seed or GM pollen from trial sites, to transport 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 trial sites to ensure all GMOs are destroyed.