Australian Government
Department of Health and Aged Care
Office of the Gene Technology Regulator

March 2025

# Summary of the Risk Assessment and Risk Management Plan (Consultation Version) for Licence Application No. DIR 215

### *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*

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| Applicant | Miruku Australia Pty Ltd (Miruku) |
| Project title | Limited and controlled release of canola genetically modified for dairy protein production[1] |
| Parent organism | Canola (*Brassica napus* L.) |
| Introduced genes | Introduced gene[2] producing dairy protein:<br>• modified β-casein gene based on the gene from cattle (*Bos taurus*) for dairy protein production<br>Introduced marker gene:<br>• *bar* gene from bacterium *Streptomyces hygroscopicus* for tolerance to the herbicide glufosinate |
| Genetic modification method | *Agrobacterium*-mediated transformation |
| Number of lines | Up to 50 lines |
| Previous releases | None in Australia or overseas |
| Proposed locations | Up to 2 sites per year in 2025, 5 in 2026, 10 in 2027, 15 in 2028 and 20 in 2029. Sites to be selected from 135 possible local government areas in New South Wales, Victoria, Western Australia and South Australia |

[1] The title of the project as supplied by the applicant is "Limited and controlled release of Canola genetically modified for dairy protein and fat composition".

[2] Confidential Commercial Information (CCI): Some details about the introduced genetic elements in GM canola have been declared as 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.

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| Proposed release size | Up to 1 ha in 2025, 5 ha in 2026, 25 ha in 2027, 105 ha in 2028, and 300 ha in 2029, with a maximum of 436 ha over the period of release |
| Proposed period of release | From May 2025 until December 2029 |
| Principal purpose | To produce dairy protein in GM canola under field conditions |

### *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, 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, transfer of the introduced genetic material to non-GM canola plants and potential for fitness advantages to pest organisms. 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 commercial 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 commercial 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.