Australian Government
Department of Health, Disability and Ageing
Office of the Gene Technology Regulator

June 2025

Summary of the Risk Assessment and Risk Management Plan for Licence Application No. DIR 211

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 risk 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	Miruku Australia Pty Ltd (Miruku)
Project title	Limited and controlled release of safflower genetically modified for dairy protein production and altered fat composition[1]
Parent organism	Safflower (*Carthamus tinctorius* L.)
Introduced genes[2]	Introduced genes producing dairy protein and altering fat composition: • modified β-casein gene based on the gene from *Bos taurus* (cattle) for dairy protein production • RNA hairpin constructs to down-regulate endogenous fatty acid genes *FAD2* and *SAD*. Introduced marker genes: • *bar* gene from bacterium *Streptomyces hygroscopicus* for tolerance to the herbicide glufosinate • *hph* gene from *Streptomyces hygroscopicus* for hygromycin antibiotic resistance • codon-optimised *gusA* gene from *Staphylococcus* sp. for visual marker selection.

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

[2] Confidential Commercial Information: Some details about the introduced genetic elements in GM safflower are the subject of an application for declaration as Confidential Commercial Information 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.

Genetic modification method	*Agrobacterium*-mediated transformation
Number of lines	Up to 120 lines
Previous releases	None in Australia or overseas
Proposed locations	Up to 52 sites to be selected from 135 possible local government areas in New South Wales, Victoria, Western Australia and South Australia
Proposed release size	Up to 1 ha in 2025, 5 ha in 2026, 50 ha in 2027, 225 ha in 2028, and 700 ha in 2029, totalling a maximum of 981 ha over the period of release
Proposed period of release	From issue of licence until December 2029
Principal purpose	To produce dairy protein and alter fat composition in GM safflower 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[3] to the GM plant material, potential for persistence or dispersal of the GMOs, and transfer of the introduced genetic material to non-GM safflower plants. 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.

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.

[3] Desirable organisms are those that are valued and should be protected, while undesirable organisms cause harm and should be controlled (OGTR, 2013). This is determined by legislation, government policies, national and international guidance material, and widely acceptable community norms. Undesirable plants that cause economic, social or environmental harm, or harm to human/animal health, are called weeds. Animals that cause harm are known as pests.