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

January 2026

Summary of the Risk Assessment and Risk Management Plan for Licence Application No. DIR 218

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 release 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	All Aussie Avocados Pty Ltd (trading as All Aussie Farmers)
Project Title	Commercial release of tomato genetically modified for purple fruit colour[1]
Parent organism	Tomato (*Solanum lycopersicum*)
Genetic modifications	
Introduced genes	Introduced genes conferring purple fruit colour, sourced from garden snapdragon (*Antirrhinum majus*): • *Delila* gene • *Rosea1* gene These 2 genes switch on production of natural purple/blue pigments, anthocyanins, in the ripening fruit. Introduced marker gene: • *nptII* gene from the bacterium *Escherichia coli* conferring resistance to the antibiotic kanamycin and structurally related antibiotics
Genetic modification method	*Agrobacterium*-mediated transformation
Identifier	Developer's event name: Del/Ros1-N Commercial name: The Purple Tomato™ OECD Unique Identifier: NPS-01201-8
Principal purpose	Commercial cultivation of the GM Purple Tomato in greenhouses

[1] The original title for the application was *Commercial release of Lycopersicon esculentum genetically modified for purple anthocyanin pigment in ripe fruit*.

Previous releases	**Australia** The GM Purple Tomato has not been previously grown in Australia. **United States (US)** The US Department of Agriculture Animal and Plant Health Inspection Service deemed the GM Purple Tomato not a regulated article. Seed has been sold to home gardeners since 2024. The US Food and Drug Administration authorised the GM Purple Tomato as food in 2023. In 2024 and 2025, commercially produced fruit was sold in grocery stores. **Canada** In August 2025, food safety and unconfined release approvals were granted in Canada.

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, horizontal gene transfer of the antibiotic resistance gene, potential for persistence or dispersal of the GMOs, and transfer of the introduced genetic material to non-GM tomato plants. Potential harms associated with these pathways included increased allergenicity or toxicity to people, toxicity to other desirable organisms, increased antimicrobial resistance 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. The principal reasons for the conclusion of negligible risks are that the introduced proteins are not expected to be toxic or allergenic, the *nptII* gene is not expected to increase antimicrobial resistance, tomatoes are not considered to be weedy and the genetic modifications are not expected to make the GM Purple Tomato weedier, and tomatoes have limited ability to naturally hybridise with sexually compatible species.

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 assessed as negligible, specific risk treatment is not required. However, licence conditions are imposed regarding post-release review (PRR) to ensure that there is ongoing oversight of the release and to allow the collection of information to verify the findings of the RARMP. The licence also contains several general conditions relating to ongoing licence holder suitability, auditing and monitoring, and reporting requirements, which include an obligation to report any unintended effects.