



Summary of the Risk Assessment and Risk Management Plan for Licence Application No. DIR 147

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 147
Applicant	Monsanto Australia Limited (Monsanto)
Project title	Limited and controlled release of cotton genetically modified for insect resistance and herbicide tolerance
Parent organism	Cotton (<i>Gossypium hirsutum</i> L.)
Introduced genes and modified traits	<ul style="list-style-type: none">• Insect resistance: up to four genes derived from <i>Bacillus thuringiensis</i>• Herbicide tolerance: up to three genes derived from bacteria <i>Agrobacterium sp.</i>, <i>Stenotrophomonas maltophilia</i> and <i>Streptomyces hygroscopicus</i>• Selectable markers: up to three antibiotic resistance genes and one reporter gene derived from <i>Escherichia coli</i>
Proposed location	Maximum of 50 sites per year in New South Wales, Queensland, Northern Territory, Victoria and Western Australia
Proposed release size	Maximum area of 50 ha in 2017, 100 ha in 2018, and 250 ¹ ha per year in 2019 and 2020
Proposed release dates	March 2017 – July 2021
Primary purposes	To breed and assess agronomic performance of the genetically modified (GM) cottons in all cotton growing areas of Australia and generate data for possible future commercial release. To conduct trait development, breeding and variety development trials to establish the stacked traits into elite germplasm suitable for Australian conditions.

¹ The maximum area proposed in the original application was 500 ha per year in 2019 and 2020. The applicant later amended it to 250 ha.

The licence permits Monsanto to conduct the field trials in cotton growing areas of Australia from March 2017 to July 2021. The licence allows planting up to 50 sites per year with a maximum combined area of 50 ha in 2017, 100 ha in 2018, and 250 ha per year in 2019 and 2020. The maximum planting size of individual trial sites is 2 ha in 2017, 10 ha in 2018, and 50 ha per year in 2019 and 2020. The licence holder may release GM cotton MON88702 both individually and crosses of GM cottons obtained by conventionally breeding MON 88702 insect resistant cotton with previously released GM cottons Bollgard II® (insect resistant), COT102 (insect resistant), Roundup Ready Flex® (herbicide tolerant) and MON 88701 (herbicide tolerant).

The purpose of the trial is to generate data for future submissions to regulatory agencies, to breed and develop varieties using elite germplasm suitable for use under Australian conditions, and for seed increase. Material from the GM cotton would not be used in human food or animal feed during the release.

The licence imposes a number of controls to restrict the spread and persistence of the GM cottons and the introduced genetic materials in the environment that have been considered during the evaluation of the application.

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 impact 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 cotton 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; the introduced genetic modifications are unlikely to cause harm to people or the environment; and the introduced genes or highly similar genes are common in the environment.

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.