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

May 2024

Summary of the Risk Assessment and Risk Management Plan for Licence Application No. DIR 203

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

Application number	DIR 203
Applicant	Monsanto Australia Pty Ltd
Project Title	Limited and controlled release of cotton genetically modified for herbicide tolerance and insect resistance[1]
Parent organism	Cotton (*Gossypium hirsutum* L.)
Genetic modifications	
Introduced genes	<u>Introduced genes:</u> • *cp4 epsps, dmo* and *bar* conferring herbicide tolerance • *mCry51Aa2*, *Cry1Ac, Cry2ab2 and Vip3Aa19* conferring insect resistance • Additional genes conferring herbicide tolerance and insect resistance[2] <u>Reporter and selectable marker genes:</u> • *uidA*, *nptII*, *aad* and *aph4*
Genetic modification method	*Agrobacterium*-mediated transformation

[1] The title of the project as supplied by the applicant is "Limited and controlled release of *Gossypium hirsutum* (upland cotton) genetically modified for herbicide tolerance and insect resistance."

[2] Confidential Commercial Information: Some details about gene names and sources in the GM cottons MON 96012 and MON 89151 have been declared as Confidential Commercial Information under section 185 of the Act. This information is available to the prescribed experts and agencies that will be consulted on this application upon request in the course of them performing duties or functions under the Act or under a corresponding State law. CCI is not available to the public.

Number of lines	Up to 10 lines using single and stacked combinations of the above herbicide tolerance and insect resistance genes
Principal purpose	To evaluate the agronomic performance of the genetically modified cotton under field conditions
Previous releases	The application proposes the use of some GM cotton (*G. hirsutum*) varieties previously authorised for release in Australia under the commercial licences DIR 066/2006, DIR 118, DIR 145, DIR 157 and DIR 173, and the limited and controlled licence DIR 147. The application also proposes the use of 2 GM cotton varieties[2] with herbicide tolerance and insect resistance traits, not previously authorised for release in Australia
Proposed limits	
Proposed use of GM plants	No use in human food or animal feed proposed
Proposed locations	Up to 25 trial sites to be selected from 62 possible local government areas in Victoria, New South Wales, Queensland, Western Australia, and the Northern Territory.
Proposed release size	A combined total area of 10 ha in 2024, 50 ha per year in 2025-2027 and 100 ha per year in 2028-2029
Proposed period of release	From September 2024 until September 2029

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 risks are considered.

Credible pathways to potential harm that were considered included exposure of people or other non-target organisms to the GM plant material, potential for persistence or dispersal of the GMOs, and transfer of the introduced genetic material to non-GM cotton plants. Potential harms associated with these pathways included adverse health effects in people or non-target 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 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 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 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 site to ensure the GMOs are destroyed.