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

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Summary of the Risk Assessment and Risk Management Plan

Consultation Version

for

Licence Application No. DIR 216

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. The Regulator has prepared a draft Risk Assessment and Risk Management Plan (RARMP) for this application, which concludes that the proposed release poses negligible risks to the health and safety of people and the environment. Licence conditions have been drafted for the proposed release. 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

Project title	Commercial release of cotton genetically modified for insect resistance and herbicide tolerance (Bollgard® 3 ThryvOn® with XtendFlex® Technology cotton)[1]
Parent organism	Cotton (*Gossypium hirsutum L.*)
Introduced genes and modified traits	**4 insect resistance genes:** • *mCry51Aa2* gene from *Bacillus thuringiensis* (Bt) • *cry1Ac* gene from Bt • *cry2Ab* gene from Bt • *vip3A* synthetic gene from Bt **3 herbicide tolerance genes:** • *cp4 epsps* gene (two copies) from *Agrobacterium sp*. strain CP4 (glyphosate tolerance) • *bar* gene from *Streptomyces hygroscopicus* (glufosinate tolerance) • *dmo* gene from *Stenotrophomonas maltophilia* (dicamba tolerance) **4 selectable marker genes:** • *nptII* gene from *Escherichia coli* (antibiotic resistance) • *aph4* gene from *E. coli* (antibiotic resistance) • *uidA* gene from *E. coli* (reporter) • *aad* gene from *E. coli* (antibiotic resistance)
Previous releases	The proposed GM cotton has been approved for field trials in Australia under DIR 147 and DIR 203 in Australia. It has been approved for

[1] The title of the project as supplied by the applicant is "Commercial release of cotton genetically modified for insect resistance and herbicide tolerance"

	commercial cultivation in the United States of America (USA) and for food and feed use in several other countries.
Proposed locations	Australia-wide
Principal purpose	Commercial release of the GM cotton

Risk assessment

The risk assessment process considers how the genetic modification and activities conducted with the GMO 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 information in the application, relevant previous approvals, current scientific knowledge and advice received from a wide range of experts, agencies and authorities consulted on the preparation of the RARMP. Both the short- and long-term risks were 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 other GM or non-GM cotton plants. Potential harms associated with these pathways included adverse health effects in people or toxicity to organisms, 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:

- the GM cotton has been produced by conventional breeding of 5 GM parental cotton lines, of which 4 have been approved for commercial release. The fifth has been approved for field trial in Australia. The risks associated with the GM parental cottons and combinations thereof, have been assessed previously as negligible and this RARMP has found no new information to change these conclusions.
- the genes and their products have been assessed as posing no increased risk of toxicity or allergenicity to humans, or toxicity to other organisms.
- the GM cotton has limited capacity to spread and persist in undisturbed environments and can be controlled using integrated weed management in agricultural and high intensity use areas.
- food made from the GM parental cotton lines has been approved by Food Standards Australia New Zealand (FSANZ) as safe for human consumption and this approval also covers food from offspring produced by conventional breeding.

Risk management

Risk management is used to protect the health and safety of people and to protect the environment by controlling or mitigating risk. The risk management plan evaluates and treats identified risks and considers general risk management measures. The risk management plan is given effect through licence conditions.

The risk management plan concludes that risks from the proposed dealings can be managed to protect people and the environment by imposing general conditions to ensure that there is ongoing oversight of the release.

As the level of risk is assessed as negligible, specific risk treatment is not required. However, the Regulator has drafted licence conditions 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 draft licence, detailed in Chapter 4 of the consultation RARMP, 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.