



Summary of the Risk Assessment and Risk Management Plan

for

Licence Application DIR 145

Decision

The Gene Technology Regulator (the Regulator) has decided to issue a licence for this application for the intentional, commercial scale release of insect resistant and herbicide tolerant genetically modified (GM) cottons in Australia. A Risk Assessment and Risk Management Plan (RARMP) for this application was prepared by the Regulator in accordance with 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 this commercial release poses negligible risks to human health and safety and the environment and no specific risk treatment measures are imposed. However, general licence conditions have been imposed to ensure that there is ongoing oversight of the release.

The application

Application number	DIR 145
Applicant	Monsanto Australia Limited (Monsanto)
Project title	Commercial release of cotton genetically modified for insect resistance and herbicide tolerance (Bollgard® 3 XtendFlex™ (SYN-IR102-7 x MON 15985-7 x MON-88913-8 x MON 88701-3) and XtendFlex™ (MON-88913-8 x MON 88701-3) cotton)
Parent organism	Cotton (<i>Gossypium hirsutum</i> L.)
Introduced genes and modified traits	Three insect resistance genes: <ul style="list-style-type: none">• <i>vip3A</i> synthetic gene from <i>Bacillus thuringiensis</i> (Bt)• <i>cry1Ac</i> gene from Bt• <i>cry2Ab</i> gene from Bt Three herbicide tolerance genes: <ul style="list-style-type: none">• <i>cp4 epsps</i> gene (two copies) from <i>Agrobacterium</i> sp. strain CP4 (glyphosate tolerance)• <i>bar</i> gene from <i>Streptomyces hygroscopicus</i> (glufosinate tolerance)• <i>dmo</i> gene from <i>Stenotrophomonas maltophilia</i> (dicamba tolerance) Four selectable marker genes: <ul style="list-style-type: none">• <i>nptII</i> gene from <i>Escherichia coli</i> (antibiotic resistance)• <i>aph4</i> gene from <i>E. coli</i> (antibiotic resistance)• <i>uidA</i> gene from <i>E. coli</i> (reporter)• <i>aad</i> gene from <i>E. coli</i> (antibiotic resistance)
Proposed locations	Australia-wide
Primary purpose	Commercial release of the GM cotton

Risk assessment

The risk assessment concludes that risks to the health and safety of people or the environment from the proposed dealings, either in the short or long term, are negligible.

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 were 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 impacts were considered.

Credible pathways to potential harm that were considered included: toxic and allergenic properties of the GM cottons; potential for increased weediness of the GM cotton relative to unmodified plants; and vertical transfer of material to other sexually compatible plants.

The principal reasons for the conclusion of negligible risks are: the GM cottons have been produced by conventional breeding from GM parental cotton lines. Two of the three GM parent cottons have been approved for commercial release and the third has been approved for field trial in Australia. The risks associated with these cottons and combinations thereof, have been assessed previously as negligible. One of the GM parental lines (individually and in combination with another parental GM line) currently makes up over 90% of Australian commercial cotton production, without reports of adverse effects on human health or the environment. The genes and their products have been assessed as posing no increased risk of toxicity or allergenicity to humans or animals, or toxicity to other beneficial organisms. 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. In addition, 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

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 has been assessed as negligible, specific risk treatment is not required. However, the Regulator has imposed licence conditions 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 a number of general conditions relating to ongoing licence holder suitability, auditing and monitoring, and reporting requirements, which include an obligation to report any unintended effects.