



19 June 2014

## Summary of the Risk Assessment and Risk Management Plan for Licence Application No. DIR 124

### **Decision**

The Gene Technology Regulator (the Regulator) has decided to issue a licence for this application for the intentional, commercial scale release of a genetically modified organism (GMO) into the environment. 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 required. However, general licence conditions have been imposed to ensure that there is ongoing oversight of the licence.

### **The application**

Application number	DIR 124
Applicant:	Monsanto Australia Ltd (Monsanto)
Project Title:	Commercial release of cotton genetically modified for insect resistance and herbicide tolerance (Bollgard <sup>®</sup> III and Bollgard <sup>®</sup> III x Roundup Ready Flex <sup>®</sup> ) <sup>1</sup>
Parent organism:	Cotton ( <i>Gossypium hirsutum</i> L.)
Introduced genes and modified traits:	<i>vip3A</i> (vegetative insecticidal protein 3A) synthetic gene derived from a gene from the bacterium <i>Bacillus thuringiensis</i> (insect resistance) <i>cry1Ac</i> ( <i>crystal protein 1Ac</i> ) gene from <i>B. thuringiensis</i> (insect resistance) <i>cry2Ab</i> ( <i>crystal protein 2Ab</i> ) gene from <i>B. thuringiensis</i> (insect resistance) <i>cp4 epsps</i> ( <i>5-enolpyruvylshikimate-3-phosphate synthase</i> ) gene from the bacterium <i>Agrobacterium</i> sp. strain CP4 (herbicide tolerance) <i>nptII</i> ( <i>neomycin phosphotransferase type II</i> ) gene from the bacterium <i>Escherichia coli</i> (antibiotic resistance) <i>aph4</i> ( <i>hygromycin B phosphotransferase</i> ) gene from <i>E. coli</i> (antibiotic resistance)

<sup>1</sup> The title of the licence application submitted by Monsanto is “General release of cotton genetically modified for insect resistance and herbicide tolerance”.

	<i>uidA</i> ( $\beta$ -glucuronidase) gene from <i>E. coli</i> (reporter) <i>aad</i> (3''(9)-O-aminoglycoside adenylyltransferase) gene from <i>E. coli</i> (antibiotic resistance)
Proposed locations:	Current and potential cotton growing areas of Australia
Primary purpose	Commercial release of the GM cotton

This commercial release follows field trial work conducted under licence DIR 101.

### **Risk assessment**

The risk assessment concludes that risks to the health and safety of people, or the environment, from the proposed release are negligible, either in the short or long term. No controls are required to treat these negligible risks.

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 are considered.

Credible pathways to potential harm that were considered included: toxic and allergenic properties of the GM cotton; increased spread and persistence leading to increased weediness of the GM cotton relative to unmodified plants; and vertical transfer of the introduced genetic 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 that have previously been assessed and authorised for field trial and/or commercial release in Australia; two of the parental cottons have been grown on a commercial scale in Australia since 2006 without adverse effects on human health or environment; the limited capacity of the GM cotton to spread and persist in undisturbed natural habitats; the widespread presence in the environment of proteins the same as or similar to the those encoded by the introduced genes; and the lack of toxicity of the introduced proteins to vertebrates and most invertebrates. Toxicity of the introduced insect-resistance proteins is limited to certain insects, including major pests of cotton.

### **Risk management**

The risk management plan concludes that the risks from the proposed dealings, either in the short or long term, to the health and safety of people, or the environment, are negligible. No specific risk treatment measures are imposed.

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.

As the level of risk is assessed as negligible, specific risk treatment is not required. However, the Regulator has imposed licence conditions under 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 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.