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

16 August 2013

Summary of the Risk Assessment and Risk Management Plan

for

Licence Application No. DIR 118

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 proposed. However, general licence conditions have been imposed to ensure that there is ongoing oversight of the licence.

The application

Application number	DIR 118
Applicant	Monsanto Australia Ltd (Monsanto)
Project title	Commercial release of GM herbicide tolerant (Roundup Ready Flex® MON 88913) pima cotton in Australia
Parent organism	*Gossypium barbadense* (pima cotton)
Introduced genes and modified trait	Two *cp4 epsps* genes conferring herbicide tolerance
Proposed location	All cotton growing areas in Australia
Primary purpose	Commercial release of the GM herbicide tolerant cotton

This commercial release follows field trial work conducted under licence DIR 074/2007.

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 considered 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 cotton has been produced by conventional breeding from a GM cotton line that has previously been assessed and authorised for commercial release in Australia, and which has been grown on a commercial scale in Australia since 2006 without any evidence of adverse effects on human health or environment as a result of gene technology; the widespread presence of the same or similar proteins encoded by the introduced genes in the environment and lack of known toxicity or evidence of harm from them; and the limited capacity of the GM cotton to spread and persist in undisturbed natural habitats.

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 proposed.

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 proposed 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.