



**EXECUTIVE SUMMARY OF THE RISK ASSESSMENT AND RISK
MANAGEMENT PLAN**
for
APPLICATION NO. DIR 064/2006
from
MONSANTO AUSTRALIA LIMITED

Introduction

The Gene Technology Regulator (the Regulator) has made a decision to issue a licence for dealings involving the intentional release of cotton genetically modified to enhance water use efficiency into the Australian environment, in respect of application DIR 064/2006 from Monsanto Australia Limited (Monsanto).

The DIR 064/2006 licence permits the release of 24 genetically modified (GM) cotton lines on a limited scale and under controlled conditions.

The *Gene Technology Act 2000* (the Act) and the *Gene Technology Regulations 2001* (the Regulations) govern the process undertaken by the Regulator before a decision is made on whether or not to issue a licence. The decision is based upon a Risk Assessment and Risk Management Plan (RARMP) prepared by the Regulator in consultation with a wide range of experts, agencies, authorities and the public.

More information on the comprehensive assessment required for licence applications to release a genetically modified organism (GMO) into the environment is available from the Office of the Gene Technology Regulator (OGTR) (Free call 1800 181 030) or at <http://www.ogtr.gov.au/ir/process.htm>.

The application

Monsanto applied for a licence to release up to 24 cotton lines modified to enhance water use efficiency into the environment under limited and controlled conditions. The release was proposed to take place on up to 10 sites of up to 2 hectares (ie a maximum total area of 20 hectares) during each of the two summer growing seasons in 2006/07 and 2007/08¹.

The release may take place in the New South Wales shires of Balranald, Bourke, Central Darling, Carathool, Coonamble, Hay, Lachlan, Moree Plains, Narrabri, Narromine, Walgett, Warren or Lake Tandou (an unincorporated area) and/or in the Queensland shires of Paroo, Balonne, Murilla, Tara, Chinchilla, Waggamba, Wambo, Jondaryan or Pittsworth.

The GM cotton lines contain 1 of 24 different introduced genes. Twenty three of the genes are derived from the plants thale cress, corn, soybean, rice and cotton. One gene is derived from the common gut bacterium *Escherichia coli*². The introduced genes encode proteins that are intended to

¹ In its initial application, Monsanto proposed individual sites of up to 1 hectare (ie a maximum total area of 10 hectares) per season. The company subsequently varied its application to propose individual sites of up to 2 hectares.

² Monsanto altered its initial application, which indicated all 24 genes would be from plants, to include this gene.

enable normal plant growth with reduced amounts of water (drought tolerance) either by regulating the expression of cottons' own genes or by altering biochemical pathways in the cotton plants.

The GM cotton lines also contain either a herbicide tolerance gene (*cp4 epsps*, conferring tolerance to the herbicide glyphosate) or an antibiotic resistance gene (*nptII*, conferring resistance to the antibiotics kanamycin or neomycin) that were used as markers to select modified plants during initial research and development work in the laboratory.

The purpose of the trial is to conduct early stage ('proof of concept') research to assess the agronomic performance of the GM cotton lines in the field, including under different irrigation treatments. Seed will be collected for further studies and possible future releases of lines selected for further development (subject to additional applications and approvals). No products from the release will be used for human food, animal feed or for the production of fabrics and/or other cotton commodities.

Monsanto proposed a number of measures to limit the spread and persistence of the GM cotton lines and the introduced genetic materials that were considered during the evaluation of the application.

Risk assessment

The hazard identification process considered the circumstances by which people or the environment may be exposed to the GMOs, GM plant materials, GM plant by-products, the introduced genes, or products of the introduced genes.

A hazard (source of potential harm) may be an event, substance or organism. A risk is identified when a hazard is considered to have some chance of causing harm. Those events that do not lead to an adverse outcome, or could not reasonably occur, do not advance in the risk assessment process.

Eighteen events were identified and assessed whereby the proposed release of the GM cotton lines might give rise to harm to people or the environment.

These 18 events included consideration of whether, or not, expression of the introduced genes could result in products that are toxic or allergenic to people or other organisms, alter characteristics that may impact on the spread and persistence of the GM plants or produce unintended changes in their biochemistry or physiology. In addition, consideration was given to the opportunity for gene flow to other organisms and its effects.

None of the 18 events are considered to give rise to an identified risk that requires further assessment. The principle reasons comprise:

- small scale of the trial that is limited in both area and duration
- containment and disposal measures proposed by the applicant to limit the spread and persistence of the GM plants
- none of the GM plant materials will be used for any other purpose
- widespread presence of the same or similar proteins and enzymatic products in the environment and lack of evidence of harm from these proteins and their products
- the lack of known toxicity or allergenicity of the proteins (and enzymatic products) encoded by the introduced genes
- limited capacity of the GM cotton lines to spread and persist in the areas proposed for release
- limited ability and opportunity for the GM cotton lines to transfer the introduced genes to other sexually related species.

Therefore, any risks of harm to the health and safety of people, or the environment, from the proposed release of the GM cotton lines into the environment is considered to be **negligible**.

Risk management

The risk management process builds upon the risk assessment to determine whether measures are required in order to protect people and/or the environment. As none of the 18 events identified and characterised in the risk assessment are considered to give rise to an identified risk that requires further assessment, the level of risk is considered to be **negligible**.

The Regulator's *Risk Analysis Framework* defines negligible risks as insubstantial, with no present need to invoke actions for their mitigation. However, containment and disposal measures have been imposed to restrict the release to the locations, size and duration requested by the applicant, as these were an important part of establishing the context for assessing the risks.

The licence conditions require the applicant to limit the duration of the release to two summer cotton growing seasons (2006/07 and 2007/08) on a maximum total area of two hectares per site on up to ten sites per growing season; prevent the use of the GMOs, or materials from the GMOs for any other purposes; maintain physical isolation of the release sites; and conduct post-harvest monitoring to ensure all GM plants are destroyed³.

Conclusions of the RARMP

The risk assessment concludes that this limited and controlled release of up to 24 cotton lines modified to enhance water use efficiency into the areas proposed in New South Wales and Queensland poses **negligible** risks to the health and safety of people and the environment.

The risk management plan concludes that these negligible risks do not require specific risk treatment measures. However, licence conditions have been imposed to contain the release to the locations, size and duration requested by the applicant.

³ The licence and conditions for DIR 064/2006 are available on the OGTR website (<<http://www.ogtr.gov.au/gmorec/ir.htm#table>>, following the path to DIR 064/2006).