



7 November 2007

**EXECUTIVE SUMMARY OF THE RISK ASSESSMENT AND RISK  
MANAGEMENT PLAN  
FOR  
APPLICATION NO. DIR 074/2007  
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 genetically modified (GM) *Gossypium barbadense* cotton lines into the environment, in respect of application DIR 074/2007 from Monsanto Australia Limited (Monsanto).

The DIR 074/2007 licence permits the release of up to three GM *G. barbadense* lines on a limited scale and under controlled conditions.

The *Gene Technology Act 2000*<sup>1</sup> (the Act), the *Gene Technology Regulations 2001* (the Regulations) and corresponding State and Territory law 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 accordance with the *Risk Analysis Framework* and in consultation with a wide range of experts, agencies, authorities and the public.

More information on the comprehensive assessment undertaken 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>>.

***The application***

Monsanto applied for a licence to release GM *G. barbadense* cotton on up to 13 sites of no more than 2 hectares each (ie maximum total area of 26 hectares) over 2 summer growing seasons (between 2007 and 2009). The release is authorised to take place in the New South Wales (NSW) shires of Bourke, Carrathool, Griffith, Moree Plains, Narrabri, Walgett, Warren, Hay, Balranald, Central Darling and Lachlan; Lake Tandou (an unincorporated area) and the Queensland (QLD) shires of Paroo and Balonne.

*G. barbadense* cotton is also known as Pima or extra long staple cotton. It produces a superior fibre to *G. hirsutum* cotton but only constitutes approximately 1% of the total Australian cotton crop due to its lower yield, different climate requirements and longer growing season.

The trial will involve early stage research to breed and evaluate the agronomic performance of the GM *G. barbadense* cotton lines; produce seed for further trials; and collect data for future regulatory requirements.

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<sup>1</sup> None of the amendments arising from a recent statutory review of the Act that came into effect on 1 July 2007 apply directly to the processing of this application which commenced prior to this date.

The three GM *G. barbadense* cotton lines approved for release into the environment contain two introduced genes for insect resistance (*cry1Ac* and *cry2Ab*) derived from a common soil bacterium (*Bacillus thuringiensis*) and/or two copies of a herbicide tolerance gene (*cp4 epsps*) which is also derived from a soil bacterium (*Agrobacterium tumefaciens*).

GM *G. hirsutum* cotton lines containing the same introduced genes for insect resistance and herbicide tolerance have been approved for commercial release in Australia (under the trade names Bollgard II<sup>®</sup>, Roundup Ready Flex<sup>®</sup> and Bollgard II<sup>®</sup>/Roundup Ready Flex<sup>®</sup>) and currently comprise approximately 90% of all cotton grown in Australia.

The GM *G. barbadense* cotton lines contain antibiotic resistance marker genes and a reporter gene that were used in the development of the parent GM *G. hirsutum* plants in the laboratory, and regulatory sequences derived from other plants, viruses and a bacterium.

Monsanto proposed a number of measures to limit the spread and persistence of the GMO plants that were considered during the evaluation of the application.

## **Risk assessment**

### **Hazard Identification**

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.

Sixteen events were identified and considered whereby the release of the GM *G. barbadense* cotton lines might give rise to harm to people or the environment. These included consideration of whether expression of the introduced genes could result in products that are toxic or allergenic to people or other organisms, produce unintended changes in the biochemistry or physiology of the GM plants, or alter characteristics that may impact on their spread and persistence. In addition, consideration was given to the potential for gene flow to other organisms and its effect if this occurred.

All events were characterised in relation to both the magnitude and probability of harm in the context of the controls proposed by the applicant to limit the spread and persistence of the GMOs in both time and space. This detailed consideration identified two events requiring further assessment. The potential adverse outcome to the environment associated with both of these events was enhanced spread and persistence (weediness). The remaining 14 events were not assessed further as they were considered not to give rise to an identified risk to human health and safety or the environment (refer to Chapter 2 of the RARMP for more information). The principle reasons comprise:

- the small scale and limited duration of the trial
- containment, monitoring and disposal measures proposed by the applicant will limit the spread and persistence of the GM *G. barbadense* plants
- none of the GM *G. barbadense* plant materials or products will be used in human food or animal feed

- widespread presence of the same or similar proteins encoded by the introduced genes in the environment and in commercially released GM *G. hirsutum* lines
- lack of known toxicity or allergenicity from these proteins

### **Risk of weediness**

The two events considered that might result in the introduced genes causing greater weediness than the parent non-GM *G. barbadense* were:

- Expression of the introduced insect resistance and/or herbicide tolerance genes in the GM *G. barbadense* lines leading to increased spread and persistence (Identified Risk 1).
- Expression of the introduced genes in other *G. barbadense* plants as a result of gene transfer leading to increased spread and persistence (Identified Risk 2).

The consequence and likelihood of harm that might result from each of the above events was assessed in Chapter 3 of the RARMP. The estimate of risk for the two identified risks is **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. The level of risk to health and safety of people or the environment for the two identified risks was estimated as **negligible**. The *Risk Analysis Framework* defines negligible risks as insubstantial, with no present need to invoke actions for their mitigation. However, licence conditions have been imposed to restrict the release in size, duration and locations to those requested in the application, as these were an important part of establishing the context for assessing the risks<sup>2</sup>.

The licence conditions require Monsanto to limit the duration of the release to two cotton growing seasons (between 2007 and 2009); the total number of sites to thirteen; and the maximum area of each site to two hectares. The control measures imposed include prohibiting the use of the GM plant materials in food and animal feed, and Monsanto must transport GM material in accordance with OGTR guidelines; and conduct post-harvest monitoring of the release site to ensure all GMOs are destroyed. The sale and transport of lint is permitted as this does not contain viable GM plant materials. No measures have been imposed to restrict the spread of the pollen from the trial sites as the introduced insect resistance and herbicide tolerance genes are already widespread in the environment and present in commercially grown GM *G. hirsutum* cotton lines in Australia.

### **Conclusions of the RARMP**

The risk assessment concluded that this limited and controlled release of three GM *G. barbadense* cotton lines in NSW and QLD poses **negligible** risks to the health and safety of people and the environment as a result of gene technology.

The risk management plan concluded that these **negligible** risks do not require specific risk treatment measures. However, licence conditions have been imposed to restrict the release to the size, duration and locations requested by the applicant as these were important considerations in establishing the context for assessing the risks.

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<sup>2</sup> The licence for DIR 074/2007 is available from the OGTR, or on the website (<<http://www.ogtr.gov.au/gmorec/ir.htm#table>>, via the link to DIR 074/2007).