



7 November 2007

**TECHNICAL 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 decided to issue a licence (DIR 074/2007) to Monsanto Australia Limited (Monsanto) for dealings involving the intentional release of three genetically modified (GM) *Gossypium barbadense* cotton lines into the environment, 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 comprehensive and highly consultative process undertaken by the Regulator before making a decision whether or not to issue a licence to deal with a GMO.

The Regulator's *Risk Analysis Framework* explains the approach used to evaluate licence applications and to develop the Risk Assessment and Risk Management Plans (RARMPs) that form the basis of her decisions<sup>2</sup>.

This RARMP for DIR 074/2007 has been finalised in accordance with the gene technology legislation. Matters raised in the consultation process regarding risks to health and safety of people or the environment from the proposed dealings were taken into account by the Regulator in deciding to issue a licence and the licence conditions that have imposed.

***Application***

*G. barbadense* is also known as Pima or Extra Long Staple (ELS) cotton. It produces a superior fibre to *G. hirsutum* but only constitutes approximately 1% of the total Australian cotton<sup>3</sup> crop due to its lower yield, different climate requirements and longer growing season.

Monsanto applied for a licence for the intentional release of GM *G. barbadense* lines on up to 13 sites of no more than 2 hectares each (ie maximum total area of 26 hectares) over 2

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<sup>1</sup> None of the amendments to the Act that came into effect on 1 July 2007 following a recent statutory review have applied to the processing of this application as it was received prior to that date.

<sup>2</sup> More information on the assessment of licence applications and copies of the Risk Analysis Framework are 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>> and <<http://www.ogtr.gov.au/pdf/public/raffinal2.2.pdf>> respectively.

<sup>3</sup> For the purpose of this document, unless specified otherwise, 'cotton' means both *G. barbadense* and *G. hirsutum* species.

summer growing seasons (between 2007 and 2009) in New South Wales (NSW) and Queensland (QLD) (Refer to Table 1 for locations).

**Table 1. Summary table for the application**

<b>Title:</b>	Limited and controlled release of GM insect resistant and/or herbicide tolerant <i>Gossypium barbadense</i> cotton <sup>a</sup>
<b>Applicant:</b>	Monsanto Australia Limited
<b>Common name(s) of the parent organism:</b>	Extra Long Staple (ELS) or Pima cotton
<b>Scientific name of the parent organism:</b>	<i>Gossypium barbadense</i>
<b>Modified traits:</b>	Insect resistance and antibiotic resistance and/or herbicide tolerance
<b>Identity of the genes responsible for the modified traits:</b>	<ul style="list-style-type: none"> <li>• <i>cry1Ac</i> and <i>cry2Ab</i> genes from the bacterium <i>Bacillus thuringiensis</i> (insect resistance)</li> <li>• <i>cp4 epsps</i> gene from <i>Agrobacterium sp.</i> strain CP4 (herbicide tolerance)</li> <li>• <i>nptII</i> gene from the bacterial Tn5 transposon (antibiotic resistance)</li> <li>• <i>aad</i> gene from the bacterial Tn7 transposon (antibiotic resistance)</li> <li>• <i>uidA</i> gene from <i>Escherichia coli</i> (reporter gene)</li> </ul>
<b>Proposed Locations</b>	Up to 13 sites in the NSW shires of Bourke, Carrathool, Griffith, Moree Plains, Narrabri, Walgett, Warren, Hay, Balranald, Central Darling and Lachlan; Lake Tandou (an unincorporated area) and the QLD shires of Paroo and Balonne
<b>Proposed Release Size:</b>	Maximum total of 26 hectares
<b>Proposed Release Dates:</b>	Summer cotton growing seasons 2007–08 and 2008–09

<sup>a</sup> The title of the licence application submitted by Monsanto Australia Ltd is “Licence application to the OGTR for field tests covering Bollgard II<sup>®</sup> (MON 15985) and Roundup Ready Flex<sup>®</sup> (MON 88913) in Extra Long Staple Cotton (*Gossypium barbadense*) in Australia”

The three GM *G. barbadense* lines approved for release contain two introduced genes for insect resistance (*cry1Ac* and *cry2Ab*) derived from a common soil bacterium (*Bacillus thuringiensis*) and/or two copies of the herbicide tolerance gene, *cp4 epsps* which is also derived from a soil bacterium (*Agrobacterium tumefaciens*). GM *G. hirsutum* 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* lines are being produced by conventional breeding between non-GM *G. barbadense* plants and plants from the GM Bollgard II<sup>®</sup> and Roundup Ready Flex<sup>®</sup> *G. hirsutum* lines. The trial will involve early stage research to breed and evaluate the agronomic performance of the GM *G. barbadense* lines; produce seed for further trials (subject to additional approvals); and collect data for future regulatory requirements.

The insect resistant GM *G. barbadense* lines also contain antibiotic resistance marker genes (*nptII* and *aad*) and a reporter gene (*uidA*) which helped identify and select modified bacteria, plant tissue or plants during the development of the parent GM *G. hirsutum* plants in the laboratory.

The GM *G. barbadense* lines also contains short regulatory sequences derived from the plants *Glycine max* (soybean), *Pisum sativum* (pea) and *Arabidopsis thaliana* and from the plant pathogens Cauliflower mosaic virus, Figwort mosaic virus and *Agrobacterium tumefaciens*. Although the last three of these organisms are plant pathogens, these regulatory sequences are not capable of causing disease.

Monsanto proposed a number of measures to limit the spread and persistence of the GM plants from the trial sites. The suitability of the proposed measures was considered as part of the risk assessment process.

## **Risk assessment**

The risk assessment considered information contained in the application, previous GM *G. hirsutum* assessments, current scientific knowledge, and issues relating to risks to human health and safety and the environment raised in submissions received during consultation with a wide range of prescribed experts, agencies and authorities on the application (summarised in Appendix B of the RARMP). No new risks to people or the environment were identified from the advice received on the consultation RARMP.

Advice received from the public on the consultation RARMP, and how it was considered, is summarised in Appendix C of the RARMP.

A reference document, *The Biology and Ecology of Cotton (Gossypium hirsutum) in Australia*, was produced to inform the risk assessment process for licence applications involving GM *G. hirsutum* plants. The document is available from the OGTR or from the website <<http://www.ogtr.gov.au>>, further information specific to *G. barbadense* can be found in Chapter 1, Section 3.2 of the RARMP.

The hazard identification process considered the circumstances or events 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.

The events that are considered to have the potential to lead to adverse outcomes are assessed further to determine the seriousness of harm (consequence) that could result and how likely it is that the harm would occur. The level of risk is then estimated using the *Risk Estimate Matrix* (see below and Chapter 2 of the RARMP).

		RISK ESTIMATE			
		Low	Moderate	High	High
LIKELIHOOD	Highly likely	Negligible	Low	High	High
	Likely	Negligible	Low	Moderate	High
	Unlikely	Negligible	Negligible	Low	Moderate
	Highly unlikely	Marginal	Minor	Intermediate	Major
		CONSEQUENCES			

**Risk Estimate Matrix:** A *negligible* risk is considered to be insubstantial with no present need to invoke actions for mitigation. A *low* risk is considered to be minimal but may invoke actions for mitigation beyond normal practices. A *moderate* risk is considered to be of marked concern that will necessitate actions for mitigation that need to be demonstrated as effective. A *high* risk is considered to be unacceptable unless actions for mitigation are highly feasible and effective.

Sixteen events were identified in the hazard identification process. These 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, produce unintended changes in the biochemistry, physiology or ecology of the GM *G. barbadense* plants, or alter characteristics

that may impact on spread and persistence of the GMO. 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 associated with both of these events is increased 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 the introduced proteins.

The two identified risks were assessed in comparison to the parent non-GM *G. barbadense* and GM *G. hirsutum* lines, also taking into account information from the commercial cultivation of the GM *G. hirsutum* lines in Australia, intended agronomic management practices, and the environmental conditions in the regions approved for the release.

The consequence and likelihood assessments that determined the risk estimates for the two identified risks are summarised in Table 2 (the detailed risk assessments are in Chapter 3 of the RARMP).

If a risk is estimated to be higher than **negligible**, risk treatment measures may be required to protect the health and safety of people or the environment. However, all risks were estimated to be **negligible** for this release.

**Table 2. Summary table for the risk assessment**

Event that may give rise to weediness	Consequence assessment	Likelihood	Risk estimate	Does risk require treatment?
<p><b>Identified Risk 1:</b> Expression of the introduced insect resistance and/or herbicide tolerance genes in GM <i>G. barbadense</i> lines leading to increased spread and persistence.</p>	<p><b>Minor</b> Cotton (including <i>G. barbadense</i>) does not have weedy characteristics and is not considered a serious weed anywhere in Australia. Although resistance to lepidopteran herbivory and glyphosate tolerance in combination may offer a small competitive advantage, abiotic and biotic factors, such as temperature, soil type, water and nutrient availability, is likely to be more important in limiting the spread and persistence of <i>G. barbadense</i>. Although glyphosate is the most widely used herbicide in Australia, it is not generally used to control established cotton plants</p>	<p><b>Highly unlikely</b> The proposed release is of small size and short duration Glyphosate tolerant cotton volunteers are effectively controlled by mechanical means or, if still at the seedling stage, by the use of alternative herbicides. Dispersal of <i>G. barbadense</i> seeds will be limited by a number of licence conditions concerning the location of the site, transport and storage of the GMOs, cleaning and post harvest monitoring. Commercially released GM <i>G. hirsutum</i> expressing the same insect resistance proteins and/or the same herbicide tolerance proteins, have not become problematic weeds in Australia.</p>	Negligible	No
<p><b>Identified Risk 2:</b> Expression of the introduced genes in other <i>G. barbadense</i> plants as a result of gene transfer leading to increased spread and persistence.</p>	<p><b>Minor</b> Cotton (including <i>G. barbadense</i>) does not have weedy characteristics and is not considered a serious weed anywhere in Australia. Although resistance to lepidopteran herbivory and glyphosate tolerance in combination may offer a small competitive advantage, abiotic and biotic factors, such as temperature, soil type, water and nutrient availability, is likely to be more important in limiting the spread and persistence of <i>G. barbadense</i>. Although glyphosate is the most widely used herbicide in Australia, it is not generally used to control established cotton plants.</p>	<p><b>Highly unlikely</b> <i>G. barbadense</i> is primarily a self-pollinating plant so gene transfer to other cotton plants is only expected to occur in close proximity at low frequencies. Outcrossing to <i>G. barbadense</i> plants would be limited due to agronomic management measures proposed by the applicant, and the small size, short duration of the trial. The chance of volunteer GM plants arising from unintended seed dispersal (eg transportation, used as stockfeed, via animals or flooding) finding suitable conditions to establish as weeds would be no greater than for non-GM cotton. Commercially released GM <i>G. hirsutum</i> expressing the same insect resistance proteins and/or the same herbicide tolerance proteins, have not become problematic weeds in Australia.</p>	Negligible	No

## ***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 from the two risks identified in the assessment process was estimated as **negligible**.

The *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 in the licence to restrict the release of the GM plants to the size, duration and locations requested by the applicant, as these were important considerations in establishing the context for assessing the risks.

## **Licence conditions to manage this limited and controlled release**

A number of licence conditions have been imposed by the Regulator to limit and control the release, including:

- limiting the duration of the release to two cotton growing seasons
- limiting the maximum number of sites to thirteen and the maximum area of each site to two hectares
- locating the sites 50 m away from natural waterways
- after harvest, destroying all GM plant material (excluding seed required for analysis and possible future releases)
- storing GM cotton seed and plant materials required for further study or future release in certified PC2 facilities
- preventing GM plant materials or products from being used in human food or animal feed
- the sale of lint (which does not contain viable plant material) is permitted
- after harvest, applying measures to promote the germination of seed, monitoring each site for at least twelve months and destroying any volunteer GM cotton plants that emerge and until no volunteers are detected for a six month period.
- restricting access to field trial sites to authorised personnel

No measures have been imposed to restrict the movement of pollen from the field trial sites as the introduced genetic material is already widespread in the environment due to the extensive cultivation of GM *G. hirsutum* containing the same genes.

The Regulator has issued guidelines and policies for the transport and supply of GMOs (*Guidelines for the transport of GMOs, July 2007; Policy on transport and supply of GMOs, July 2005*). Licence conditions based on these guidelines and policies have also been imposed, including transportation and to control possession, use or disposal of the GMOs for the purposes of, or in the course of, the authorised dealings.

## Other regulatory considerations

The Regulator is responsible for assessing and managing risks to the health and safety of people and/or the environment associated with the use and development of gene technology. However, additional approvals from other regulators with complimentary responsibilities including issues outside the scope of the *Gene Technology Act 2000* may be required<sup>4</sup>. For this application the relevant regulatory agencies are Food Standard Australia New Zealand (FSANZ) and the Australian Pesticides and Veterinary Medicines Authority (APVMA).

FSANZ, which is responsible for human food safety assessment and food labelling, including GM food, has approved the use of oil and linters from Bollgard II<sup>®</sup> and Roundup Ready Flex<sup>®</sup> cotton for use in food. This approval applies to both *G. hirsutum* and *G. barbadense*. However, the applicant does not intend, and is not permitted to use materials from any of the GM *G. barbadense* lines proposed for release in food.

The APVMA, which has regulatory responsibility for the use of agricultural chemicals, including herbicides and insecticidal products, in Australia, has registered the use of the insecticidal proteins produced by the insect resistance genes (*cry1Ac* and *cry2Ab*) in Bollgard II<sup>®</sup> cotton. This approval applies to both *G. hirsutum* and *G. barbadense*. Similarly, the registration issued by the APVMA for the use of the Roundup Ready<sup>®</sup> Herbicide for use on Roundup Ready Flex<sup>®</sup> cotton also applies to both *G. hirsutum* and *G. barbadense*. Therefore, no further approvals from the APVMA are required.

## Identification of issues to be addressed for future releases

The risk assessment identified additional information that may be required to assess an application for a larger scale release, reduced containment conditions, or commercial release of these GM *G. barbadense* lines. As detailed in Chapter 3, Section 4 of the RARMP this would include the following:

- Confirmation that the proteins expressed by the introduced genes in the two cotton species are functionally the same
- Expressions levels of the introduced proteins in various parts of the cotton plant
- The effect of lepidopteran herbivory on *G. barbadense*
- Comparison of establishment potential, including germination potential, of *G. barbadense* and *G. hirsutum*
- Data on agronomic characteristics indicative of weediness of the GM *G. barbadense* lines, compared to *G. hirsutum*

## 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>4</sup> More information on Australia's integrated regulatory framework for gene technology is contained in the *Risk Analysis Framework* available from the Office of the Gene Technology Regulator (OGTR). Free call 1800 181 030 or at <<http://www.ogtr.gov.au/pdf/public/raffinal2.2.pdf>>.