



**TECHNICAL SUMMARY OF THE RISK ASSESSMENT
AND RISK MANAGEMENT PLAN**
for
APPLICATION NO. DIR 066/2006
from
MONSANTO AUSTRALIA LTD

INTRODUCTION

The Gene Technology Regulator (the Regulator) has decided to issue a licence (DIR 066/2006) to Monsanto Australia Ltd (Monsanto) for dealings involving the intentional release of five herbicide tolerant and/or insect resistant genetically modified (GM) cotton lines into the Australian environment.

The DIR 066/2006 licence permits the commercial release of the GM cotton lines on an unrestricted basis in northern Australia, north of latitude 22° South. It should be noted that cultivation of these GMOs may require additional approvals under State or Territory legislation that restrict the commercial release of GM crops on marketing grounds.

The Gene Technology Act 2000 (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 decisions¹.

The RARMP for DIR 066/2006 has been finalised in accordance with the gene technology legislation. Matters raised in the consultation process regarding risks to the health and safety of people or the environment from the dealings proposed by the applicant were taken into account by the Regulator in deciding to issue a licence and the conditions that have been imposed.

Consistent with Australia's integrated regulatory framework for gene technology, the Regulator has also liaised closely with other regulatory agencies that have been considering applications relating to this release, namely Food Standard Australia New Zealand (FSANZ) and the Australian Pesticides and Veterinary Medicines Authority (APVMA), to avoid duplication and enable coordinated decision making.

¹ 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.

SECTION 1 APPLICATION

Title:	Commercial release of GM herbicide tolerant and/or insect resistant cotton lines north of latitude 22°South*
Applicant:	Monsanto Australia Ltd
Common name of the parent organism:	Cotton
Scientific name of the parent organism:	<i>Gossypium hirsutum</i> L.
Modified trait(s):	Herbicide tolerance and/or insect resistance
Identity of the gene(s) responsible for the modified trait(s):	<ul style="list-style-type: none"> • <i>cp4 epsps</i> gene from <i>Agrobacterium</i> sp. strain CP4 (herbicide tolerance) • <i>cry1Ac</i> and <i>cry2Ab</i> genes from the bacterium <i>Bacillus thuringiensis</i> (insect resistance) • <i>nptII</i> gene from the bacterial Tn5 transposon (antibiotic resistance) • <i>uidA</i> gene from <i>Escherichia coli</i> (reporter gene)
Proposed location(s):	North of latitude 22° South in areas suitable for cotton growing
Proposed release size:	Plant breeding, agronomic trials and seed production and if feasible, commercial scale planting in the future
Proposed time of release:	Ongoing from November 2006

*The title of the licence application submitted by Monsanto was Licence Application covering use of Bollgard II (MON 15985), Roundup Ready Flex (MON 88913) and Roundup Ready (MON 1445) technology in cotton in areas north of latitude 22° South.

Monsanto applied for a licence to release the following GM cotton lines, without specific containment measures, north of latitude 22°S:

- insect resistant Bollgard II[®] cotton (also known as MON15985)
- herbicide tolerant Roundup Ready[®] cotton (also known as MON1445)
- herbicide tolerant Roundup Ready Flex[®] cotton (also known as MON88913)
- herbicide tolerant/insect resistant Roundup Ready[®]/Bollgard II[®] cotton (also known as MON1445/MON15985)
- herbicide tolerant/insect resistant Roundup Ready Flex[®]/Bollgard II[®] cotton (also known as MON88913/MON15985).

Bollgard II[®] cotton has been developed from GM Ingard[®] cotton (containing a single insect resistance gene, *cry1Ac*) by the introduction of a second insect resistance gene, *cry2Ab*. Both of the insect resistance genes are derived from *Bacillus thuringiensis* variety *kurstaki*, a common soil bacterium. These genes produce insect resistant proteins (Cry1Ac and Cry2Ab) that are highly specific and toxic to caterpillars of some lepidopterans (butterflies and moths), including *Helicoverpa armigera* and *H. punctigera*, the two major insect pests of cultivated cotton in Australia.

Roundup Ready[®] cotton has been modified by the introduction of one copy of the herbicide tolerance *cp4 epsps* gene, derived from *Agrobacterium* sp. strain CP4. This gene produces a protein (CP4 EPSPS) that provides tolerance to glyphosate, the active constituent in Roundup Ready[®] Herbicide. The presence of the gene enables GM cotton plants to be sprayed with glyphosate prior to flower formation (approximately 3-5 weeks after planting) to kill weeds without damaging the cotton plants.

Roundup Ready Flex[®] cotton has been modified by the introduction of two copies of the same herbicide tolerance *cp4 epsps* gene and is tolerant to the herbicide throughout the growing season (approximately 24-28 weeks). This gives growers increased flexibility in the timing of herbicide application and for integrated weed management.

Roundup Ready[®]/Bollgard II[®] cotton and Roundup Ready Flex[®]/Bollgard II[®] cotton were produced by conventional crossing of the respective herbicide tolerant cotton with Bollgard II[®] cotton and contain all the genes introduced into each of the parent plants.

Some of the GM cotton lines also contain antibiotic resistance marker genes (*nptII* and *aad*) and a reporter gene (*uidA*) which helped identify and select modified bacteria, plants or plant tissues during the development of the GM plants in the laboratory.

More detailed information on the GMOs, the introduced genes and their products is provided in Chapter 1.

The GM cotton lines proposed for release have previously been comprehensively assessed prior to licences being issued for their unrestricted commercial release south of latitude 22°S (under DIRs 012/2002, 023/2002 and 059/2005) and for field trials north of latitude 22° S (under DIRs 006/2001, 009/2001, 012/2002, 035/2003 and 055/2004).

Monsanto intends to conduct plant breeding, agronomic trials and seed production, and to cultivate the GM cotton lines in areas suitable for cotton growing in northern Australia. Monsanto indicates that commercial scale plantings are not planned at this stage as a range of industry, community and infrastructure issues would need to be resolved before commercial cotton production could take place in northern Australia.

Monsanto intends to use the GM cotton plants and their products in the same manner as non-GM cotton and GM cotton lines commercially approved north and south of latitude 22°S, including use in human food and stockfeed, transportation and sale of lint.

SECTION 2 RISK ASSESSMENT

The risk assessment considered information contained in the application, previous GM cotton assessments, current scientific knowledge, and issues relating to risks to human health and safety or 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), and on the RARMP (see Appendix D), including every Local Council north of latitude 22°S.

Similarly, advice received from the public on the application and from consultation on the RARMP, and how it was considered is summarised in Appendices C and E, respectively. A total of fifty-five public submissions were received. A variety of views were expressed regarding the release, ranging from strong opposition to substantial support.

The risk assessment first considered what harm to the health and safety of people or the environment could arise due to gene technology, and how it could happen during this release of GMOs into the environment (hazard identification).

A hazard (source of potential harm) may be an event, substance or organism. The hazard identification process resulted in the compilation of a list of 35 events that describe sets of circumstances by which the proposed release could potentially give rise to adverse outcomes.

A risk is identified when a hazard is considered to have some chance of causing harm to people and/or the environment. 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).

		RISK ESTIMATE			
		Low	Moderate	High	High
LIKELIHOOD	Highly likely	Negligible	Low	High	High
	Likely	Negligible	Low	High	High
	Unlikely	Negligible	Low	Moderate	High
	Highly unlikely	Negligible	Negligible	Low	Moderate
		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.

Six of the 35 events characterised in the hazard identification process for the proposed release were identified as requiring further assessment. The potential adverse outcomes associated with these events were: toxicity to non-target invertebrates and increased spread and persistence (weediness). These identified risks were assessed in comparison to non-GM cotton and GM Liberty Link[®] Cotton (previously approved for commercial release by the Regulator in northern Australia under DIR 062/2005), in the context of information provided from growing the GM cotton lines commercially in southern Australia and field trials in northern Australia, intended agronomic management practices, and the environmental conditions in the regions proposed for the release.

The consequence and likelihood assessments used to derive risk estimates for these six Identified Risks are summarised in Table 1 (the detailed risk assessments are in Chapters 3 and 4). More information on the remaining 29 events that were considered not to give rise to an identified risk is provided in Chapter 2.

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.

Table 1 Summary table for the risk assessment

Event that may give rise to toxicity for non-target invertebrates	Consequence assessment	Likelihood assessment	Risk estimate	Does risk require treatment?
Identified Risk 1 Direct or indirect ingestion of the Cry1Ac and Cry2Ab proteins by non-target invertebrates.	Minor <ul style="list-style-type: none"> The Cry1Ac and Cry2Ab proteins are toxic only to lepidopteran insects. Field studies indicated that growing Bollgard II[®] cotton plants has no significant effect on non-target invertebrate populations when compared to unsprayed non-GM cotton. 	Highly Unlikely <ul style="list-style-type: none"> Exposure to the GM cotton lines and the Cry proteins would occur mostly to those non-target invertebrates consuming the GM cotton within the cotton field. Non-target invertebrates are insensitive to the levels of Cry1Ac and Cry2Ab proteins expressed in the Bollgard II[®] plants. 	Negligible	No

Event that may give rise to weediness	Consequence assessment	Likelihood assessment	Risk estimate	Does risk require treatment?
<p>Identified Risk 2 Tolerance to glyphosate due to expression of the <i>cp4 epsps</i> gene(s) in the GM cotton plants</p>	<p>Minor</p> <ul style="list-style-type: none"> • Cotton does not have weedy characteristics and is not considered a serious weed anywhere in Australia. • Although glyphosate is the most widely used herbicide in Australia today, it is not generally used to control established cotton plants as the herbicide is not effective on cotton beyond the seedling stage. • In the presence of glyphosate, the small competitive advantage of the GM cotton is offset by susceptibility to the abiotic and biotic factors (such as water and nutrient availability, plant competition and herbivory by non-lepidopteran insects) that limit the spread and persistence of all cotton in northern Australia. 	<p>Highly unlikely</p> <ul style="list-style-type: none"> • Glyphosate tolerant cotton volunteers are effectively controlled by mechanical means or, if still at the seedling stage, by the use of alternative herbicides. • The chance of volunteer GM plants arising from unintended seed dispersal (eg transportation, use as stockfeed, via animals or flooding) finding suitable ecological niches and establishing as weeds would be no greater than for non-GM cotton. • Glyphosate tolerant cotton is not likely to be cultivated as extensively as lepidopteran resistant cotton in northern Australia (unless stacked with lepidopteran resistant cotton) due to the requirement for multiple insecticide applications. 	<p>Negligible</p>	<p>No</p>
<p>Identified Risk 3 Reduced lepidopteran herbivory due to expression of the <i>cry1Ac</i> and <i>cry2Ab</i> genes in the GM cotton plants</p>	<p>Minor</p> <ul style="list-style-type: none"> • Cotton does not have weedy characteristics and is not considered a serious weed anywhere in Australia. • While lepidopteran herbivory impacts adversely on productivity in commercial cotton crops, it is not an important limiting factor on the spread and persistence of cotton in northern Australia. • In the presence of lepidopteran herbivory, the small competitive advantage of the GM cotton is offset by susceptibility to the abiotic and biotic factors (such as water and nutrient availability, plant competition and herbivory by non-lepidopteran insects) that limit the spread and persistence of all cotton in northern Australia. 	<p>Highly unlikely</p> <ul style="list-style-type: none"> • Lepidopteran resistant cotton volunteers are effectively controlled by mechanical means or, if still at the seedling stage, by the use of herbicides. • The chance of volunteer GM plants arising from unintended seed dispersal (eg transportation, use as stockfeed, via animals or flooding) finding suitable ecological niches and establishing as weeds would be no greater than for non-GM cotton. 	<p>Negligible</p>	<p>No</p>

Event that may give rise to weediness	Consequence assessment	Likelihood assessment	Risk estimate	Does risk require treatment?
<p>Identified Risk 4 Tolerance to glyphosate and reduced lepidopteran herbivory due to expression of the <i>cp4 epsps</i>, <i>cry1Ac</i> and <i>cry2Ab</i> genes in combination in the GM cotton plants</p>	<p>Minor</p> <ul style="list-style-type: none"> • Cotton does not have weedy characteristics and is not considered a serious weed anywhere in Australia. • Although glyphosate is the most widely used herbicide in Australia today, it is not generally used to control established cotton plants as the herbicide is not effective on cotton beyond the seedling stage. • While lepidopteran herbivory impacts adversely on productivity in commercial cotton crops, it is not an important limiting factor on the spread and persistence of cotton in northern Australia. • In the presence of both glyphosate and lepidopteran herbivory, the small competitive advantage of the GM cotton is offset by susceptibility to the abiotic and biotic factors (such as water and nutrient availability, plant competition and herbivory by non-lepidopteran insects) that limit the spread and persistence of all cotton in northern Australia. • The herbicide tolerance and insect resistance genes operate through independent, unrelated biochemical mechanisms and there is no evidence of any interaction. 	<p>Highly unlikely</p> <ul style="list-style-type: none"> • Glyphosate tolerant and lepidopteran resistant cotton volunteers are effectively controlled by mechanical means or, if still at the seedling stage, by the use of alternative herbicides. • The chance of volunteer GM plants arising from unintended seed dispersal (eg transportation, use as stockfeed, via animals or flooding) finding suitable ecological niches and establishing as weeds would be no greater than for non-GM cotton. 	<p>Negligible</p>	<p>No</p>

Event that may give rise to weediness	Consequence assessment	Likelihood assessment	Risk estimate	Does risk require treatment?
<p>Identified Risk 5 Expression of the <i>cp4 epsps</i>, and/or <i>cry1Ac</i> and <i>cry2Ab</i> genes in naturalised <i>G. hirsutum</i> or <i>G. barbadense</i> cotton plants providing glyphosate tolerance and/or reduced lepidopteran herbivory</p>	<p>Minor</p> <ul style="list-style-type: none"> • Cotton does not have weedy characteristics and is not considered a serious weed anywhere in Australia. • Although glyphosate is the most widely used herbicide in Australia today, it is not generally used to control established cotton plants as the herbicide is not effective on cotton beyond the seedling stage. • While lepidopteran herbivory impacts adversely on productivity in commercial cotton crops, it is not an important limiting factor on the spread and persistence of cotton in northern Australia. • In the presence of glyphosate and/or lepidopteran herbivory, the small competitive advantage of the GM cotton is offset by susceptibility to the abiotic and biotic factors (such as water and nutrient availability, plant competition and herbivory by non-lepidopteran insects) that limit the spread and persistence of all cotton in northern Australia. • The herbicide tolerance and insect resistance genes operate through independent, unrelated biochemical mechanisms and there is no evidence of any interaction. 	<p>Highly unlikely</p> <ul style="list-style-type: none"> • Cotton is primarily self-pollinating and gene transfer to other cotton plants is only expected to occur in close proximity and at low frequencies. • Glyphosate tolerant and/or lepidopteran resistant cotton volunteers are effectively controlled by mechanical means or, if still at the seedling stage, by the use of alternative herbicides. • The chance of volunteer GM plants finding suitable ecological niches and establishing as weeds would be no greater than for the non-GM parent. 	<p>Negligible</p>	<p>No</p>

Event that may give rise to weediness	Consequence assessment	Likelihood assessment	Risk estimate	Does risk require treatment?
<p>Identified Risk 6 Expression of the <i>cp4 epsps</i>, and/or <i>cry1Ac</i> and <i>cry2Ab</i> genes in combination with the <i>bar</i> gene (from Liberty Link[®] Cotton) providing dual herbicide tolerance and reduced lepidopteran herbivory</p>	<p>Minor</p> <ul style="list-style-type: none"> • Cotton does not have weedy characteristics and is not considered a serious weed anywhere in Australia. • Neither glyphosate nor glufosinate ammonium are effective in controlling established cotton plants. • While lepidopteran herbivory impacts adversely on productivity in commercial cotton crops, it is not an important limiting factor on the spread and persistence of cotton in northern Australia. • In the presence of glufosinate ammonium, and glyphosate and/or lepidopteran herbivory, the small competitive advantage of the GM cotton is offset by susceptibility to the abiotic and biotic factors (such as water and nutrient availability, plant competition and herbivory by non-lepidopteran insects) that limit the spread and persistence of all cotton in northern Australia. • The herbicide tolerance and insect resistance genes operate through independent, unrelated biochemical mechanisms and there is no evidence of any interactions. 	<p>Highly unlikely</p> <ul style="list-style-type: none"> • Cotton is primarily self-pollinating and gene transfer to other cotton plants is only expected to occur in close proximity and at low frequencies. • If Liberty Link[®], Roundup Ready[®] or Roundup Ready[®] Flex cotton lines were to be cultivated in northern Australia, they will require multiple insecticide applications resulting in limited gene flow because of the reduced numbers of insect pollinators. • Cotton volunteers with glufosinate ammonium tolerance in combination with glyphosate tolerance and/or lepidopteran resistance would be effectively controlled by mechanical means or, if still at the seedling stage, by the use of alternative herbicides. 	<p>Negligible</p>	<p>No</p>

SECTION 3 RISK MANAGEMENT

A risk management plan builds upon the risk assessment to consider whether any action is required to mitigate the identified risks, and what can be done to protect the health and safety of people and the environment.

The risk assessment considered six events that might lead to risks to the environment. The risk estimates for the adverse outcomes associated with all six Identified Risks are **negligible** (ie insubstantial with no present need to invoke actions for their mitigation). Therefore, no risk treatment measures for identified risks were required and no specific risk management conditions have been imposed. However, as part of the Regulator's oversight of licensed dealings involving the release of genetically modified organisms, the licence contains a number of general conditions relating to ongoing licence holder suitability, auditing and monitoring provisions; and reporting requirements, including a compliance plan, annual report and other relevant information².

3.2 Other regulatory considerations

Australia's gene technology regulatory system operates as part of an integrated legislative framework. Other agencies that also regulate GMOs or GM products include FSANZ, APVMA, Therapeutic Goods Administration (TGA), National Industrial Chemicals Notification and Assessment Scheme (NICNAS), National Health and Medical Research Council (NHMRC) and Australian Quarantine Inspection Service (AQIS). Dealings conducted under any licence issued by the Regulator may also be subject to regulation by one or more of these agencies³.

FSANZ is responsible for human food safety assessment, including GM food. FSANZ has approved the use of food (oil and linters) derived from Bollgard II[®] cotton, Roundup Ready[®] cotton and Roundup Ready Flex[®] cotton (FSANZ reports A436, A355 and A553). No additional approvals are required by FSANZ for the stacked GM cotton lines.

The APVMA has regulatory responsibility for the use of agricultural chemicals, including herbicides and insecticidal products, in Australia. Roundup Ready[®] Herbicide by Monsanto is currently registered for use on Roundup Ready[®] and Roundup Ready Flex[®] cotton varieties. The APVMA registered the use of the insecticidal proteins as produced by the insect resistance genes (*cryIAc* and *cry2Ab*) in GM Bollgard II[®] cotton as insecticidal products for New South Wales (NSW) and Queensland (QLD) south of latitude 22°S in 2003. It is currently assessing an application from Monsanto to vary the label for Bollgard II[®] to remove the condition for restriction on planting Bollgard II[®] north of latitude 22°S.

SECTION 4 CONCLUSIONS OF THE RARMP

The risk assessment concludes that this commercial release of five herbicide tolerant and/or insect resistant GM cotton lines in northern Australia poses **negligible** risks to the health and safety of people and the environment as a result of gene technology.

² The licence and conditions for DIR 066/2006 are available on the OGTR website (<http://www.ogtr.gov.au/gmorec/ir.htm#table>, following the path to DIR 066/2006).

³ 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> >.

The risk management plan concludes that the negligible risks do not require risk treatment measures and no specific risk management conditions have been imposed. The licence contains general conditions that enable the Regulator to maintain oversight of the licensed dealings in accordance with her statutory obligations.