



Office of the Gene Technology Regulator

RISK ASSESSMENT AND RISK MANAGEMENT PLAN FOR LICENCE FOR INTENTIONAL RELEASE OF GMOs INTO THE ENVIRONMENT:

Application No. DIR 012/2002

SUMMARY INFORMATION

Project Title:	Commercial release of Bollgard II [®] cotton
Applicant:	Monsanto Australia Ltd PO Box 6051 St. Kilda Road Central VIC 8008
Common name of the parent organism:	Cotton
Scientific name of the parent organism:	<i>Gossypium hirsutum</i>
Modified trait(s):	Insecticidal action, herbicide tolerance, antibiotic resistance, reporter gene expression
Identity of the gene(s) responsible for the modified trait(s):	<ul style="list-style-type: none">• <i>cry1Ac</i> and <i>cry2Ab</i> genes from the bacterium <i>Bacillus thuringiensis</i> (insecticidal genes)• EPSPS gene from <i>Agrobacterium</i> (herbicide tolerance gene)• <i>nptII</i> and <i>aad</i> genes from bacterial Tn5 and Tn7 transposons, respectively, (antibiotic resistance genes)• <i>uidA</i> gene from <i>Escherichia coli</i> (reporter gene)
Location:	Up to 80 shires in the current cotton growing areas in New South Wales (NSW) and Queensland (Qld), and potential cotton growing areas in Qld, northern Western Australia (WA) and the Northern Territory (NT) (see Appendix).
Release Size:	Approximately 5342 hectares of Bollgard II [®] and Bollgard II [®] / Roundup Ready [®] cotton in the first year with scale up to full production expected over 3 years, in the cotton growing areas in NSW and Qld south of latitude 22°S.

Limited and controlled release of Bollgard II[®] and Bollgard II[®]/ Roundup Ready[®] cotton up to a maximum of 800 hectares over up to 20 sites in potential cotton growing areas north of latitude 22° S in Qld, northern western WA and the NT.

Release Date:

First cotton growing season after issuing the Licence (September 2002 for southern Australia ; March 2003 for northern Australia).

Introduction

The Gene Technology Regulator (the Regulator) has made a decision to issue a licence in respect of the application (DIR 012/2002) of Monsanto Australia Ltd (Monsanto). The licence is for the commercial release of Bollgard II[®] and Bollgard II[®]/Roundup Ready[®] cotton south of latitude 22° South, and for a limited and controlled release of up to 800 hectares of these GM cottons in the Northern Territory, northern Queensland and northern Western Australia .

The decision was made after two rounds of extensive consultation on the risk assessment and risk management plan for this application with the public, State and Territory governments, relevant Commonwealth agencies, the Gene Technology Technical Advisory Committee, the Federal Environment Minister and relevant local councils, as required by the *Gene Technology Act 2000* (the Act).

Bollgard II[®] cotton is resistant to the major caterpillar pests that attack cotton. It contains two insecticidal genes that produce proteins toxic to specific insects and was derived from INGARD[®] cotton which contains one of the insecticidal genes. Bollgard II[®]/Roundup Ready[®] cotton was produced by conventional breeding of Bollgard II[®] cotton with genetically modified Roundup Ready[®] cotton that contains a gene for tolerance to the herbicide glyphosate (Roundup[®]). Bollgard II[®]/ Roundup Ready[®] cotton therefore contains the two insecticidal genes from Bollgard II[®] cotton as well as the glyphosate tolerance gene from Roundup Ready[®] cotton.

INGARD[®] and Roundup Ready[®] cotton were approved for commercial release in Australia in 1996 and 2000, respectively. These releases were restricted to south of latitude 22° South, because of concerns about the potential weediness of the cotton in tropical areas, as well as the potential for out-crossing to native cotton species in these areas.

Monsanto's application requested approval for the commercial cultivation of Bollgard II[®] and Bollgard II[®]/Roundup Ready[®] cotton in all current and potential Australian cotton growing areas, including areas north of latitude 22° South in the Northern Territory, Western Australia and Queensland, i.e. outside the area previously approved for commercial release of GM cotton. However, the risk assessment (see below, *Summary of risk assessment*) identified continuing concerns regarding a risk of weediness in northern Australia and the commercial release was not approved in this region.

Therefore, release of the GM cottons in areas above the latitude 22° South (northern Australia) will be subject to a number of specific licence conditions to limit the scale of planting and minimise the risk of weediness, by restricting the spread and persistence of the GM cotton in the environment (see below, *Summary of risk management plan*).

Following the two rounds of consultations, the Regulator revised the Risk Assessment and Risk Management Plan, to restrict the commercial release in southern Australia to south of 22° South rather than slightly further north (20° South) as initially proposed. The submissions received suggested that as some significant river systems in Queensland are located between 20° and 22° South and flow north-west from that area, they could potentially carry viable GM material into the area where it could persist in the environment.

The cotton plants and their by-products will be used in the same manner as conventional cotton, including for human food and stockfeed. Cotton seed is processed for oil that is used in a variety of food products (e.g. vegetable oils) and cotton linters (a type of fibre) are used as a cellulose base for several food products (e.g. ice-cream). Food Standards Australia New Zealand (FSANZ, formerly the Australia New Zealand Food Authority, ANZFA) has already approved the use in human food of oil and linters from INGARD® and Roundup Ready® cotton. In two previous assessments of Bollgard II® cotton, FSANZ indicated that it considers products from Bollgard II® cotton to be as safe for human consumption as those from conventional cotton.

Summary information about the genetically modified organisms (GMOs), the application and the regulatory system established by the Act is available in the document, *Summary information on application number DIR 012/2002*. More detailed information on the evaluation of the application is available in the Risk Assessment and Risk Management Plan that has been prepared in accordance with the requirements of the Act. Further background information is available in the document 'The biology and ecology of cotton (*Gossypium hirsutum*) in Australia'. All three documents are available from the Office of the Gene Technology Regulator (OGTR) website or from the OGTR (see contact details below).

This document summarises the conclusions of the risk assessment process and the risk management plan, including the specific licence conditions developed to manage the identified risks to human health and safety and the environment. The Regulator considers that these conditions are sufficient to manage any risks posed by the current release (see below, *Summary of risk management plan*).

Summary of risk assessment

A number of possible hazards that could arise as a direct result of the genetic modification of Bollgard II®, or Bollgard II®/Roundup Ready® cotton were considered. They include:

- whether the GM cotton can be harmful to organisms, because it may be more toxic or allergenic than non-GM cotton as a result of the novel gene products or because of unforeseen or unintended effects;
- whether the GM cotton can be harmful to the environment because of inherent weediness or increased potential for weediness, or whether inappropriate management of the crop-herbicide combination could lead to the development of herbicide resistant weeds; and
- whether the new genes introduced into the GM cotton can transfer to other cotton crops, feral or native cottons, or to other organisms, with adverse consequences for the environment.

Risk of toxicity or allergenicity

It is considered that the likelihood of adverse impacts on humans or other species (other than lepidopteran insects which includes the target pests), as a result of toxicity or allergenicity of Bollgard II® or Bollgard II®/Roundup Ready® cotton, is very low.

Evidence from previous limited and controlled releases and the available scientific literature suggest that Bollgard II[®] or Bollgard II[®]/Roundup Ready[®] cotton will not be more toxic or allergenic to humans or other organisms (other than lepidopteran insects) than conventional cotton varieties.

Risk of weediness

The risk of Bollgard II[®] or Bollgard II[®]/Roundup Ready[®] cotton spreading as a weed and causing environmental harm in the cotton-growing regions of New South Wales and Queensland is low, and unlikely to be greater than that for conventional cotton. In summary, the reasons for these conclusions are that cotton itself is not a problematic weed and that the introduced genes are unlikely to increase the weedy potential of the plants in the environment.

Bollgard II[®]/Roundup Ready[®] cotton would have a survival advantage in the presence of glyphosate. However, this herbicide is not used to control cotton plants in agricultural systems or in limited cases where it may occur in the natural environment (for example on roadsides).

In the cotton-growing regions of northern Western Australia, northern Queensland and the Northern Territory, it is possible that because of its insecticidal activity, the genetically modified cotton might have a survival advantage in regions where insect predation limits plant growth and regulates plant population density. However, the distribution of cotton appears to be determined by soil type, soil nutrients and water availability, rather than by insect pressure. More information is required on these issues to determine whether unrestricted release of the GM cotton in northern Australia would present a risk to the environment.

There is also potential for the development of herbicide-resistant weeds if the crop-herbicide combination is used inappropriately (see details below under *Summary of risk management plan and licence conditions*).

Risk of gene transfer

The likelihood of some gene transfer from the GM cotton to cultivated cotton is high, but the overall frequency of outcrossing would be very low. This would not pose any risks additional to negligible risks discussed in detail in the RARMP. Conventional farming practices, such as the use of certified (pure) seed will ensure any contamination is kept to a minimum.

The likelihood of gene transfer to feral cotton is low, because of its geographic distribution, and negligible for transfer to other plant species, including native Australian cottons, animals or microorganisms. The conclusions with respect to each transferred gene sequence are as follows:

Insecticidal genes

It is possible that if these genes were transferred to feral or native cotton, the plants might have a survival advantage in regions where insect predation limits their growth and regulates their population density (see above, *Risks of weediness*).

Herbicide tolerance gene

Outcrossing into species other than cotton is extremely unlikely. There would be no adverse consequences if outcrossing to cotton occurred, since cotton species are not regarded as weeds in Australia and are not controlled by glyphosate on the farm or in the natural environment. If gene transfer to animals or microorganisms did occur, there would be no adverse effects because herbicides are only used on plants.

Antibiotic resistance genes

Transfer of these genes to organisms other than bacteria would not present a hazard, since the antibiotics in question are only used to treat or prevent bacterial infections. Horizontal transfer from the genetically modified cotton to bacteria is also extremely unlikely and is considered to pose negligible risks to human health. The incidence of naturally occurring bacterial strains resistant to the antibiotics in question is already very high. If the resistance genes were transferred to a bacterium, this would be unlikely to have any detectable impact on the existing level of resistance in microbial populations. The antibiotics in question are not of major clinical or veterinary significance.

UidA (GUS) marker gene

There would be no adverse consequences even if outcrossing occurred. The GUS (β -glucuronidase) protein is not likely to be toxic or allergenic to other organisms, or to increase the weediness of the cotton.

Regulatory sequences

The GM cotton contains some regulatory sequences derived from a plant pathogen. These sequences only represent a very small proportion of the pathogen genome and are not in themselves infectious or pathogenic. The pathogens and the regulatory sequences are already present in the environment and in the human diet.

The likelihood of horizontal gene transfer from plants to microorganisms, including viruses, or to animals and humans is negligible, and it is considered that transfer of the regulatory sequences would in any case be unlikely to pose a hazard to human health and safety or the environment.

Risk of insecticide resistance

There is potential for development of insects resistant to the insecticidal proteins, but this will be limited by attributes of Bollgard II[®] cotton itself, since two, rather than one, insecticidal genes are present. Research indicates that the presence of two or more such genes significantly reduces the likelihood of developing populations of resistant insects. Bollgard II[®] cotton was developed with the aim of reducing the risk of developing resistant insects. It is intended that the planting of INGARD[®] cotton in Australia will be phased out over 3 years and replaced by Bollgard II[®] cotton.

Summary of risk management plan and specific licence conditions

Risk of toxicity or allergenicity

It is not considered necessary to include any management strategies in the risk management plan in relation to the potential toxicity or allergenicity of the cotton, since the risks are negligible. As noted above FSANZ (formerly ANZFA) has previously approved the use in food of oil and linters from Roundup Ready[®] and INGARD[®] cotton, and concluded in two previous assessments that products from Bollgard II[®] cotton are as safe as those from conventional cotton.

Risks of weediness or gene transfer

The risk of transfer of genes from the GM cotton to organisms other than cotton, including the risk of transfer to native Australian cottons, is considered to be negligible. The risk of it spreading as a weed in southern Australia is low and no management strategies will be required to manage this risk for releases in southern Australia. However, licence conditions have been included to manage the potential weediness of the GM cotton in northern Australia, by limiting the scale of planting and restricting gene flow and the spread and persistence of the GM cotton in the environment.

Management of the risk of development of herbicide-resistant weeds falls under the jurisdiction of the National Registration Authority for Agricultural and Veterinary Chemicals (NRA), which regulates the use of herbicides. The NRA will assess the new use pattern of glyphosate used in connection with Bollgard II®/Roundup Ready® cotton and will require the applicant to comply with a herbicide resistance management plan for the cotton industry as a whole.

No further conditions will be imposed in relation to herbicide resistance management in agriculture.

Risks of insecticide resistance

There is some potential for the development of insects resistant to the insecticidal proteins present in the Bollgard II® cotton. Bollgard II® or Bollgard II®/Roundup Ready® cotton fall into the Agricultural and Veterinary Chemicals Code (1994) definition of an agricultural chemical product, due to production of insecticidal substances, and are therefore subject to regulation by the NRA. The NRA will set requirements for an insect resistance management plan to manage the risk of development of insecticide resistance.

No further conditions will be imposed in relation to insect resistance management in agriculture.

Risk management conditions

As no significant risks to human health and safety and the environment were identified in relation to releasing Bollgard II® and Bollgard II®/Roundup Ready® cotton in the southern cotton-growing regions of Australia, no specific licence conditions will be imposed for cultivation in these areas.

However, the licence conditions require the applicant to undertake a research program to obtain more information on the potential environmental impacts of the GM cotton. In addition, the NRA sets limits on the total area of the release, and other conditions in relation to compliance with insecticide resistance and herbicide use management plans.

Since there remains a low risk that Bollgard II® and Bollgard II®/Roundup Ready® cotton may become a weed in northern Australia a number of specific conditions will be included in the licence relating to management of potential weediness in northern Australia. These conditions, which will apply only for releases north of latitude 22° South, will include requirements to:

- limit the area of all land planted to the GMOs north of latitude 22° South under this licence to 800 hectares in any one planting season (with a total cap of 1000 hectares for all licences);
- isolate the GM cottons from other cotton by at least 50 metres or to surround the release sites with 20 metre buffer rows of conventional cotton;
- prohibit the cultivation of the GM cotton within 100 metres of known feral cotton populations;
- destroy any viable material not required for subsequent trials (which would require separate licences), unless exported or used for stockfeed; and
- monitor for, and destroy, any cotton plants (volunteers) that germinate or regrow on the release site for a period of at least 12 months, during which no cotton can be grown on the site.

The licence will also contain other conditions relating to harvesting, cleaning of equipment and locations, transport and post-harvest use of the sites, including management practices specifically designed to reduce the seed bank of the GMOs. The proposed conditions also include a requirement for the applicant to have in place contingency plans to deal with any unintended release of the GMOs outside the release sites in northern Australia.

All licences issued by the Regulator are also subject to a number of general conditions. These include, for example, identifying the persons or classes of person covered by the licence, requiring the applicant to allow access to the release sites by the Regulator, or persons authorised by the Regulator for the purposes of monitoring or auditing, and informing the Regulator if the applicant becomes aware of any additional information about risks to human health or safety or to the environment.

Details of the proposed licence conditions are provided in the full risk assessment and risk management plan which can be obtained from the Office of the Gene Technology Regulator (OGTR) (see below).

Monitoring and enforcement of compliance by the OGTR

It should be noted that, as well as imposing licence conditions, the Regulator has additional options for risk management. The Regulator has the legislative capacity to enforce compliance with licence conditions and, indeed, to direct a licence holder to take any steps the Regulator deems necessary to protect the health and safety of people or the environment. The OGTR also independently monitors authorised trials. At least 20% of all trial sites are monitored on a rolling basis each year, to determine whether licence holders are complying with their licence conditions, or whether there are any unforeseen problems.

In identifying when to undertake routine monitoring visits, sites are selected on the basis of a risk profile. In assembling a risk profile of a site, a number of factors are taken into account, including the type of GMO(s) and biological, seasonal/geographical/ecological risk factors for both current and post-harvest field trial sites. For example, the critical periods for monitoring to occur in respect of GM field trials are when the trial is at its 'higher risk' points (ie when there may be a higher risk to the health and safety of people and/or the environment), for example during flowering of a crop, when the possibility of outcrossing is highest.

Contact details

Copies of the risk assessment and risk management plan, as well as this summary information, can be obtained from the OGTR at the address below or from the Office's website. Copies of the licence application are also available from the Office. Please quote application number DIR 012/2002.

**Office of the Gene Technology Regulator
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WODEN ACT 2600**

**Telephone: 1800 181 030
Facsimile: 02 6271 4202
Website: <http://www.ogtr.gov.au>
Email: ogtr@health.gov.au**

Appendix

Potential release shires for Licence DIR 012/2002*

NSW	QLD	WA	NT
Balranald	Aramac	Broome	Katherine
Barraba	Balonne	Wyndham- East Kimberley	
Berrigan	Banana		
Bingara	Bauhinia		
Bland	Belyando		
Bogan	Broadsound		
Bourke	Bungil		
Brewarrina	Cambooya		
Broken Hill	Chinchilla		
Carrathool	Clifton		
Central Darling	Dalby		
Cobar	Duaringa		
Conargo	Emerald		
Coolah	Fitzroy		
Coonabarabran	Flinders		
Coonamble	Gatton		
Deniliquin	Inglewood		
Dubbo	Jondaryan		
Forbes	Kingaroy		
Griffith	Milmeran		
Gunnedah	Monto		
Hay	Murilla		
Jerilderie	Murweh		
Lachlan	Peak Downs		
Manilla	Pittsworth		
Moree Plains	Quilpie		
Murray	Richmond		
Murrumbidgee	Rosalie		
Narrabri	Tara		
Narromine	Taroom		
Parkes	Toowoomba		
Parry	Waggamba		
Quirindi	Wambo		
Tamworth	Warroo		
Urana	Warwick		
Wakool	Wondai		
Walgett			
Warren			
Wellington			
Wentworth			
Yallaroi			

* Releases of Bollgard II® and Bollgard II®/Roundup Ready® will not necessarily occur in all nominated local government areas (LGAs).