



**APPLICATION FOR LICENCE FOR INTENTIONAL RELEASE OF GMOs INTO THE ENVIRONMENT: Application No. DIR 087**

**SUMMARY INFORMATION**

Project Title:	Limited and controlled release of cotton genetically modified for insect resistance and herbicide tolerance <sup>1</sup>
Applicant:	Bayer CropScience Pty Ltd
Common name of the parent organism:	Cotton
Scientific name of the parent organism:	<i>Gossypium hirsutum</i> L.
Modified trait(s):	Insect resistance and herbicide tolerance
Identity of the gene(s) responsible for the modified trait(s):	<ul style="list-style-type: none"><li>• <i>cry1Ab</i> (encoding a Bt toxin) from the bacterium <i>Bacillus thuringiensis</i></li><li>• <i>cry2Ae</i> (encoding a Bt toxin) from the bacterium <i>Bacillus thuringiensis</i></li><li>• <i>bar</i> (encoding phosphinothricin acetyltransferase) from the bacterium <i>Streptomyces hygrosopicus</i></li></ul>
Proposed Location(s):	One site at Narrabri, NSW
Proposed Release Size:	0.1 ha
Proposed Release Dates:	Summer growing season 2008 – 2009

**Introduction**

The *Gene Technology Act 2000* (the Act) in conjunction with the *Gene Technology Regulations 2001*, an inter-governmental agreement and corresponding legislation that is being enacted in each State and Territory, comprise Australia's nationally consistent regulatory system for gene technology. Its objective is to protect the health and safety of people, and the environment, by identifying risks posed by or as a result of gene technology, and managing those risks by regulating certain dealings with genetically modified organisms (GMOs).

The Act establishes a statutory officer, the Gene Technology Regulator (the Regulator), to administer the legislation and make decisions under the legislation. The Regulator is supported by the Office of the Gene Technology Regulator (OGTR), an Australian Government regulatory agency located within the Health and Ageing portfolio.

The legislation sets out the requirements for considering applications for licences for dealings with GMOs and the matters that the Regulator must take into account before deciding whether, or not, to issue a licence. The Regulator's *Risk Analysis Framework*<sup>2</sup> outlines the assessment process that will be followed.

<sup>1</sup> The title of the licence application submitted by Bayer CropScience Pty Ltd is 'Preliminary Field Efficacy Assessment of Insect Resistant and Herbicide Tolerant Cotton – TwinLink (*Gossypium hirsutum* L.)'

<sup>2</sup> More information on the assessment of licence applications is available from the Office of the Gene Technology Regulator (OGTR). Free call 1800 181 030 or at

<http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/process-1>.

## The application and the proposed dealings

The Acting Regulator has received an application from Bayer CropScience Pty Ltd (Bayer) for a licence for dealings involving the intentional release of genetically modified (GM) cotton (*Gossypium hirsutum* L.) into the Australian environment on a limited scale under controlled conditions.

The GM cotton plants contain two introduced genes for insect resistance (*cry1Ab* and *cry2Ae*) as well as the herbicide tolerance gene, *bar*.

The aims of the proposed field trial are to conduct research to:

- assess the agronomic performance of the GM cotton (known as TwinLink<sup>®</sup>)
- assess the efficacy of the insecticidal proteins against the target pest, *Helicoverpa armigera* (cotton bollworm), under Australian conditions
- produce seed for use in further studies or releases (subject to additional approvals).

Bayer proposes to limit the release to one site in the local government area of Narrabri on a maximum area of 0.1 ha over the summer cotton growing season 2008 -2009.

The applicant has also proposed a number of control measures to restrict the dissemination or persistence of the GM plants and their introduced genetic material that will be considered in the assessment of this application including:

- locating the trial site at least 50 metres away from natural waterways
- surrounding the site with a 20 metre pollen trap
- harvesting and ginning seed cotton from the release separately from any other cotton crop
- not permitting any materials from the release to be used in human food, or animal feed or for the production of fabrics and/or other cotton products
- destroying all plant materials not required for further analysis or future release
- cleaning the site after harvest by slashing and incorporating all plant material into the soil
- monitoring the trial site for at least 12 months and destroying any cotton volunteers
- transporting GM seed and plant materials in accordance with OGTR transportation guidelines.

## Confidential Commercial Information

Some details, including details of the GM cotton breeding program, expression levels of the three introduced genes, toxicity of the insecticidal proteins against target organisms, details of the plasmid vector and construct used for the *cry2Ae* transformation event and some details of the *cry2Ae* gene, have been declared Confidential Commercial Information (CCI) under section 185 of the Act. The confidential information will be made available to the prescribed experts and agencies that will be consulted on the Risk Assessment and Risk Management Plan (RARMP) for this application.

## Parent organism

The parent organism is cultivated cotton (*Gossypium hirsutum* L.), which is exotic to Australia and is grown as an agricultural crop in NSW and southern and central Qld and on a trial basis in northern Qld, north western WA and the NT.

The GM cotton plants proposed for release were produced using the Coker cultivars 312 and 315. These Coker cultivars are often used as a starting point of research as they can be easily genetically modified in the laboratory. They are not grown commercially in Australia.

### **The genetic modifications and their effect**

The GM cotton contains three introduced genes. Two of these genes, *cry1Ab* and *cry 2Ae*, were originally derived from the bacterium *Bacillus thuringiensis* and encode proteins that confer resistance to lepidopteran insect pests. The genes have been modified for expression in plants.

The GM cotton also contains the herbicide tolerance gene, *bar*, isolated from *Streptomyces hygroscopicus*, which was used as a marker to select for modified plants. The *bar* gene encodes the phosphinothricin acetyltransferase (PAT) enzyme, which provides tolerance to herbicides containing glufosinate ammonium. The applicant intends to apply glufosinate ammonium during the field trial.

The GM cotton also contains short regulatory sequences that control expression of the introduced genes. These are derived from a soil bacterium (*Agrobacterium tumefaciens*) and plant viruses (Cauliflower mosaic virus and Subterranean clover stunt virus). The regulatory sequences of the plant pathogens comprise only a small part of their total respective genome and are not capable of causing disease.

### **Method of genetic modification**

The gene constructs were introduced into cotton on a plasmid vector carried by *A. tumefaciens*. The vector is 'disarmed' since it lacks the genes that encode the tumorigenic functions of *A. tumefaciens*. This method has been widely used in Australia and overseas for introducing new genes into plants.

A GM cotton line expressing the *cry1Ab* and *bar* genes was conventionally bred with a GM cotton line expressing the *cry2Ae* and *bar* genes to produce plants containing all three genes. These plants were then backcrossed to homogeneity to produce the TwinLink<sup>®</sup> GM cotton plants proposed for release in this field trial.

### **Previous releases of the same or similar GMOs**

There has been no previous release of this GM cotton in Australia. However, there have been a number of trials of GM cotton lines containing a modified *cry1Ab* gene or the *bar* gene under the former voluntary system overseen by the Genetic Manipulation Advisory Committee (GMAC) and the current regulatory system.

GM cotton containing introduced genes for insect resistance and/or herbicide tolerance have been approved for commercial release in Australia under the trade names Bollgard II<sup>®</sup>, Roundup Ready<sup>®</sup>, Roundup Ready Flex<sup>®</sup>, and Liberty Link<sup>®</sup>.

Plants derived from the individual transformation events used to breed TwinLink<sup>®</sup> cotton, as well as TwinLink<sup>®</sup> cotton itself, have undergone preliminary field trials in the US

### **Suitability of Applicant**

Section 43(2)(f) of the Act requires the Regulator to be satisfied regarding the suitability of the applicant to hold a licence as a pre-requisite for considering DIR applications. The matters to be considered are outlined in Section 58 of the Act and include relevant convictions, revocation of a licence or permit relating to the health and safety of people, and capacity to meet the conditions of the licence.

The Acting Regulator has determined that Bayer currently meets the suitability requirements and will verify this continues to be the case prior to making any decision regarding the issuing of a licence.

## **Consultation process for this DIR application**

The Acting Regulator has made an assessment of whether the application should be considered as a limited and controlled release, under with Section 50A of the Act. As its principal purpose is to enable the conduct of experiments, and the applicant has proposed limits on the size and duration of the release and controls to restrict the dissemination and persistence of both the GMO and its genetic material in the environment, **the Acting Regulator has decided that the application qualifies as a limited and controlled release.**

This means that the Acting Regulator is not required to consult on the assessment of this application until after a RARMP has been prepared in accordance with section 51 of the Act. In the interim, copies of the application are available on request from the OGTR. Please quote application number DIR 087.

The Acting Regulator will seek comment on the consultation RARMP from the public as well as a wide range of experts, agencies and authorities including the Gene Technology Technical Advisory Committee, State and Territory Governments, Australian Government agencies and the Minister for the Environment, Heritage and the Arts. The RARMP will then be finalised, taking into account matters raised relating to risks to human health and safety and the environment, and form the basis of her decision whether or not to issue a licence.

At this stage, **the RARMP is expected to be released for comment in October 2008.** The public will be invited to provide submissions on the RARMP via advertisements in the media and direct mail to anyone registered on the OGTR mailing list. The RARMP and other related documents will be available on the OGTR website, or in hard copy from the OGTR.

If you have any questions about the application or the assessment process, or wish to register on the mailing list, please contact the OGTR at:

**The Office of the Gene Technology Regulator, MDP 54 GPO Box 9848 Canberra ACT 2601**  
**Telephone: 1800 181 030 Facsimile: 02 6271 4202 E-mail: [ogtr@health.gov.au](mailto:ogtr@health.gov.au)**  
**Website <http://www.ogtr.gov.au>**