



**APPLICATION FOR LICENCE FOR INTENTIONAL RELEASE OF GMOs INTO THE ENVIRONMENT: Application No. DIR 073/2007**

**SUMMARY INFORMATION**

Project Title:	Limited and controlled release of GM insect resistant and insect resistant/herbicide tolerant cotton <sup>1</sup>
Applicant:	Deltapine Australia Pty Ltd
Common name of the parent organism:	Cotton (cv Coker 312)
Scientific name of the parent organism:	<i>Gossypium hirsutum</i> L.
Modified trait(s):	Insect resistance, herbicide tolerance, antibiotic resistance
Identity of the gene(s) responsible for the modified trait(s):	<ul style="list-style-type: none"><li>• <i>vip3A</i> gene from the bacterium <i>Bacillus thuringiensis</i> (insect resistance)</li><li>• modified <i>cry1Ab</i> gene from the bacterium <i>Bacillus thuringiensis</i> (insect resistance)</li><li>• <i>cp4 epsps</i> gene from the bacterium <i>Agrobacterium</i> sp. strain CP4 (herbicide tolerance)</li><li>• <i>aph4</i> gene from the bacterium <i>Escherichia coli</i> (antibiotic resistance)</li></ul>
Proposed Location(s)	Up to 50 sites in the NSW shires of Bourke, Brewarrina, Gwydir, Liverpool Plains, Moree Plains, Narrabri, Narromine, Walgett and Warren, and/or the Qld shires of Balonne, Banana, Chinchilla, Dalby, Emerald, Jondaryan, Millmeran, Pittsworth, Waggamba, Wambo and Wondai.
Proposed Release Size:	Maximum total area of 500 hectares
Proposed Release Dates:	Summers 2007/08, 2008/09 and 2009/10

<sup>1</sup>The title of the licence application submitted by Deltapine was Cotton field trials of insect resistant cotton expressing the VIP3A and Cry1Ab genes, either alone or in combination, and both insect genes together with the Roundup Ready Flex herbicide tolerance trait (Cry1Ab alone, VIP3A alone, Cry1Ab + VIP3A, Cry1Ab + VIP3A + Roundup Ready Flex).

**Introduction**

The *Gene Technology Act 2000* (the Act) took effect on 21 June 2001. The Act, supported by the *Gene Technology Regulations 2001*, an inter-governmental agreement and corresponding legislation that is being enacted in each State and Territory, underpins 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<sup>2</sup>.

### **The application and the proposed dealings**

The Regulator has received an application from Deltapine Australia Pty Ltd (Deltapine) for a licence for the intentional release of genetically modified (GM) cotton (*Gossypium hirsutum* L.) lines into the environment on a limited scale and under controlled conditions.

Deltapine proposes to trial up to four GM cotton lines on up to 50 sites (of no more than 10 hectares each) on a maximum total area of 500 hectares, over 3 summer growing seasons (2007/08, 2008/09 and 2009/10). The sites are located in the New South Wales (NSW) shires of Bourke, Brewarrina, Gwydir, Liverpool Plains, Moree Plains, Narrabri, Narromine, Walgett and Warren, and/or the Queensland (Qld) shires of Balonne, Banana, Chinchilla, Dalby, Emerald, Jondaryan, Millmerran, Pittsworth, Waggamba, Wambo and Wondai.

The four GM cotton lines contain introduced genes for insect resistance (*vip3A* and modified *cryIAb*) alone, and in combination, and together with the herbicide tolerance gene, *cp4 epsps*. The aims of the proposed field trial are to conduct early stage research to:

- evaluate the agronomic performance and efficacy of the GM cotton lines;
- collect data for future applications to the OGTR and other regulators (including investigating the impact of the GM cotton on non-target organisms);
- breed, select and test new cotton lines; and
- produce seed for use in further studies or future trials, subject to additional approvals.

None of the cotton plants from the release, or their by-products, would be used for animal or human food. Food Standards Australia New Zealand (FSANZ) has previously approved food (oil and linters) derived from the GM cotton lines containing *vip3A* and *cp4 epsps* genes. Additional approvals would be required before oil and linters from the other GM cotton lines could be used for human consumption.

The applicant proposes to sell lint from the release for use as fibre in the textile industry. Lint does not contain detectable genetic material or protein.

Deltapine has proposed a number of containment measures for the conduct of the field trial that will be considered in the assessment of this application, including:

- locating the proposed trial sites 50 m away from natural waterways
- surrounding the trial sites with a 20 m pollen trap of non-GM or commercially released GM cotton (Bollgard II<sup>®</sup> and/or Roundup Ready Flex<sup>®</sup>) and treating all plants in this area in the same way as the GM cotton plants proposed for release
- destruction of all GM cotton plant materials (excluding lint and some seed), including the pollen trap plants, by burning and destruction of excess seed by burial
- transportation of GM cotton seed and plant materials in accordance with OGTR transportation guidelines

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<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.

- storage of GM cotton seed and plant materials required for further study or future release in certified PC2 facilities
- after harvest, monitor each site for 12 months and destroy any volunteer GM cotton plants.

Some details of the gene construct, including the plasmid map and regulatory sequences, for the modified Cry1Ab line were previously declared as Confidential Commercial Information (CCI) under DIR 065/2006. However, the applicant requested that this CCI be revoked. The information is contained in the application and will be considered in the assessment process.

## 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 American cultivar Coker 312 was used to produce the GM cotton lines proposed for release. This cultivar is often used as a starting point of research as it can be easily genetically modified in the laboratory. It is not grown commercially in Australia.

## The genetic modifications and their effect

Four GM cotton lines are proposed for release. The VIP3A GM cotton line (sometimes described by its event transformation number COT102) contains an insect resistance gene, *vip3A*, derived from a common soil bacterium *Bacillus thuringiensis*. The modified Cry1Ab GM cotton line contains a different insect resistance gene, modified *cryIAb*, based on the *cryIAb* gene derived from *B. thuringiensis*. This gene is modified relative to *cryIAb* by the addition of a sequence coding for 26 amino acids derived from the *cryIAa* gene. The insect resistance genes encode proteins that are selectively toxic to the major lepidopteran caterpillar pests of cotton (*Helicoverpa armigera* and *H. punctigera*). The VIP3A/modified Cry1Ab GM cotton line contains both insect resistance genes (*vip3A* and modified *cryIAb*).

The VIP3A/modified Cry1Ab/Roundup Ready Flex<sup>®</sup> GM cotton line contains both insect resistance genes (*vip3A* and modified *cryIAb*) and two copies of the herbicide tolerance gene, *cp4 epsps*, which is commercially known as the Roundup Ready Flex<sup>®</sup> herbicide tolerance trait. The *cp4 epsps* gene is derived from another common soil bacterium, *Agrobacterium tumefaciens*. Roundup Ready Flex<sup>®</sup> GM cotton is currently approved for commercial release in Australia (see below).

Unlike the plant *cp4 epsps* gene, the CP4 EPSPS protein encoded by the bacterial gene can function in the presence of glyphosate, the active constituent in Roundup Ready<sup>®</sup> Herbicide. Expression of two copies of the herbicide tolerance gene present in Roundup Ready Flex<sup>®</sup> GM cotton confers tolerance to glyphosate throughout the growing season, so herbicide can be applied to the crop to kill weeds without damaging the cotton plants.

In addition, the GM cotton lines which contain the *vip3A* gene, also contain a commonly used selectable marker gene, *aph4*, from the gut bacterium *Escherichia coli* that confers resistance to the antibiotic hygromycin B. The marker gene enabled identification of genetically modified plant tissues during the initial laboratory stage of development of the GMOs.

The GM cottons also contain short regulatory sequences derived from plant pathogens (cauliflower mosaic virus, figwort mosaic virus, *A. tumefaciens*) and/or plants, (*Pisum sativum* (pea) and *Arabidopsis thaliana*). The regulatory sequences from plant pathogens, comprise only a small part of their total respective genome and are not capable of causing disease.

## Method of genetic modification

The GM cotton lines were produced by introducing gene constructs containing the *vip3A* and *aph4* genes (VIP3A GM cotton line), the modified *cry1Ab* and *aph4* genes (modified Cry1Ab GM cotton line), or two copies of the *cp4 epsps* gene (the Roundup Ready Flex<sup>®</sup> herbicide tolerance trait), along with regulatory sequences into the Coker 312 cotton variety on plasmid vectors carried by *A. tumefaciens*. These vectors are ‘disarmed’ since they lack the genes that encode the tumour-inducing functions of *A. tumefaciens*.

The modified *cry1Ab* and *aph4* genes were introduced on two separate vectors to produce the modified Cry1Ab GM cotton line. However, the *aph4* gene and associated regulatory sequences are not present in the modified Cry1Ab GM cotton line proposed for this release, as a result of a breeding programme which selected for its absence.

The VIP3A/modified Cry1Ab and VIP3A/modified Cry1Ab/Roundup Ready Flex<sup>®</sup> GM cotton lines were produced by the conventional crossing of the VIP3A GM cotton line with the modified Cry1Ab GM cotton line, and the VIP3A/modified Cry1Ab GM cotton line with Roundup Ready Flex<sup>®</sup> GM cotton, respectively.

## Previous releases of the GMOs

Under the former voluntary system overseen by the Genetic Manipulation Advisory Committee (GMAC), CSIRO conducted a field trial with the VIP3A (COT 102) GM cotton line in NSW (PR-151). In addition, the Regulator issued licences approving the limited and controlled release of the VIP3A (COT102) GM cotton line to:

- CSIRO under DIR 017/2002 in NSW and under DIR 025/2002 in north-western Western Australia
- Deltapine under DIR 058/2005 in NSW and Qld, and DIR 065/2006 in NSW

Two other limited and controlled release licences for the VIP3A GM cotton line (COT102) were issued to Syngenta (DIR 034/2003) and CSIRO (DIR 036/2003), but no plantings took place because of a change in the commercial licensing arrangements between Syngenta and CSIRO.

There has been one previous release of the modified Cry1Ab and VIP3A/modified Cry1Ab GM cotton lines in Australia, under the licence DIR 065/2006 (issued to Deltapine). Previously, CSIRO conducted field trials with GM cotton lines containing the unmodified *cry1Ab* gene under the former voluntary system (PR-20, PR-20X, PR-138 and PR-138X). The Regulator also issued licence DIR 016/2002 to CSIRO, approving a limited and controlled release of GM cotton containing the unmodified *cry1Ab* gene in NSW.

Roundup Ready Flex<sup>®</sup> GM cotton was released on a commercial scale throughout Australia under DIR 059/2005 (southern Australia) and DIR 066/2006 (northern Australia).

There have been no reports of adverse effects on human health or the environment resulting from any of these releases.

There have been no previous releases of VIP3A and modified Cry1Ab in combination with the Roundup Ready Flex<sup>®</sup> herbicide tolerance trait.

## Consultation on preparation of the Risk Assessment and Risk Management Plan

The Regulator has made an initial assessment as to whether the proposed release may pose significant risks to human health and safety or the environment, in accordance with section 49 of the Act. Based on the characteristics of the GM cotton lines and the introduced genes, and

the limited scale and scope of the dealings, **the Regulator has decided that the proposed release does not pose a significant risk to human health and safety or the environment.**

This means that the Regulator is **not required to seek public comment** on the assessment of this proposal until after a risk assessment and risk management plan (RARMP) has been prepared for consultation. In the interim, copies of the application are available on request from the OGTR. Please quote application number DIR 073/2007.

In preparing the RARMP, the Regulator will seek input from a wide range of experts, agencies and authorities including State and Territory Governments, Australian Government agencies, the Minister for the Environment and Heritage, the Gene Technology Technical Advisory Committee and relevant local councils. The Regulator will consult again with these key stakeholders and expert groups, as well as the public, in finalising the RARMP, which then forms the basis of her decision whether or not to issue a licence.

At this stage, the consultation version of the RARMP is expected to be released for a six week consultation period in **late May 2007**. 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 from the OGTR, or on the OGTR website.

If you have any questions about the application or the assessment process, please contact the OGTR at:

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