



**APPLICATION FOR LICENCE FOR INTENTIONAL RELEASE OF GMOs INTO THE ENVIRONMENT: Application No. DIR 065/2006**

**SUMMARY INFORMATION**

Project Title:	Limited and controlled release of GM insect resistant (VIP3A and/or modified Cry1Ab) cotton
Applicant:	Deltapine Australia 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, 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>aph4</i> gene from <i>Escherichia coli</i> (antibiotic resistance)</li></ul>
Proposed Location(s)	One site in the Narrabri shire, New South Wales (NSW)
Proposed Release Size:	Up to 1.5 hectares
Proposed Release Dates:	Summer 2006/07

<sup>1</sup>The title of the licence application submitted by Deltapine was *Small scale seed increase of GM cottons containing the vip gene and cry1Ab gene alone and in stacks.*

**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 carry out a field trial of up to 11 GM cotton lines on one site on up to 1.5 hectares over summer 2006/07 in the shire of Narrabri, NSW.

The GM cotton lines proposed for release contain either one or two insect resistance genes (*vip3A* and/or modified *cry1Ab*). The VIP3A GM cotton line contains insect resistance (*vip3A*) and antibiotic resistance (*aph4*) genes. This GM cotton line is the same as the COT102 GM cotton line (ie COT102 event) released under DIR 058/2005. The five modified Cry1Ab GM cotton lines contain only an insect resistance gene (modified *cry1Ab*). The five VIP3A/modified Cry1Ab GM cotton lines contain two insect resistance genes (*vip3A* and modified *cry1Ab*) and one antibiotic resistance (*aph4*) gene. All of the introduced genes were derived from commonly occurring bacteria. Both insecticidal genes encode proteins that are toxic to the major lepidopteran caterpillar pests of cotton (*Helicoverpa amigera* and *H. punctigera*).

The VIP3A line was originally imported from the United States by CSIRO under an Australian Quarantine Inspection Service import permit. Similarly, the modified Cry1Ab and VIP3A/modified Cry1Ab lines have been imported from the United States by Deltapine.

The aim of the proposed release is to conduct early stage research to produce seed from the GM cotton lines for use in further studies in future trials (subject to additional assessments and 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 VIP3A line. Additional approvals would be required before oil from the other GM cotton lines could be used for human consumption. However, the applicant proposes to sell lint from the release for use as fibre in the textile industry. Lint does not contain genetic material or protein.

The applicant has proposed the following containment measures that will be considered in establishing the risk context for the assessment of this application and in determining any proposed risk management conditions:

- transportation of GM seed and plant materials in accordance with OGTR transportation guidelines
- surrounding the trial sites by a 20 m pollen trap of non-GM cotton and treating all plants in this area in the same way as the GM plants
- destruction of GM seed not required for further seed increase or breeding and all seed from the pollen trap plants by burning
- after harvest, destruction of all cotton plant materials on the site, including the pollen trap, by slashing and incorporation into the soil

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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.

- post harvest monitoring of trial site for 12 months and destroying any cotton volunteer plants.

Some details of the gene constructs, including the plasmid map and regulatory sequences, for the modified Cry1Ab lines have been declared as Confidential Commercial Information (CCI) under section 185 of the Act. However, the CCI will be made available to the prescribed experts and agencies that will be consulted on the preparation of the risk assessment and risk management plan for this application.

### **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 line (COT102) 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.

Two other limited and controlled release licences for the VIP3A line (COT102) were issued to Syngenta (DIR 034/2003) and CSIRO (DIR 036/2003), but no plantings took place.

There have been no previous releases of the modified Cry1Ab and VIP3A/modified Cry1Ab GM cotton lines in Australia. However, CSIRO conducted field trials of GM cotton lines containing the modified *cry1Ab* gene under the former voluntary system (PR-20, PR-20X, PR-138 and PR-138X). The Regulator also issued a licence approving limited and controlled release of GM cotton containing a similar *cry1Ab* gene to CSIRO under DIR 016/2002 in NSW.

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

### **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 Queensland (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.

### **Genetic modification and its effect**

Eleven GM cotton lines are proposed for release. The VIP3A GM cotton line contains an insecticidal gene, *vip3A*, derived from a common soil bacterium *Bacillus thuringiensis* (Bt). The five modified Cry1Ab GM cotton lines contain a different insecticidal gene, modified *cry1Ab*, also derived from Bt. The five VIP3A/modified Cry1Ab GM cotton lines contain both insecticidal genes (*vip3A* and modified *cry1Ab*).

The VIP3A line and the five VIP3A/modified Cry1Ab lines 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.

Short regulatory sequences that control expression of the introduced genes are also present in all the GM cotton lines. They are either derived from plants and/or a common soil bacterium (*Agrobacterium tumefaciens*). Although *A. tumefaciens* is a plant pathogen, the regulatory sequences comprise only a small part of its total genome, and are not in themselves 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 line) or the modified *cry1Ab* and *aph4* genes (modified Cry1Ab lines) along with regulatory sequences into the Coker 312 cotton variety on plasmid vectors carried by *Agrobacterium 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 five modified Cry1Ab lines. However, the *aph4* gene (and associated regulatory sequences) has been removed from the modified Cry1Ab GM cotton lines proposed for this release.

The five VIP3A/modified Cry1Ab GM cotton lines were produced by conventional crossing of the VIP3A (COT102) line with the five modified Cry1Ab lines.

### **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 065/2006.

In preparing the RARMP, the Regulator will seek input from a wide range of key stakeholders and expert groups 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 prescribed agencies and authorities, 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 **mid July 2006**. 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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