



26 October 2005

**TECHNICAL SUMMARY OF THE RISK ASSESSMENT AND RISK
MANAGEMENT PLAN**

for

APPLICATION NO. DIR 058/2005

from

DELTAPINE AUSTRALIA PTY LTD

INTRODUCTION

The Gene Technology Regulator (the Regulator) has made a decision to issue a licence for dealings involving the intentional release of genetically modified (GM) insect resistant cotton lines into the environment, in respect of application DIR 058/2005 from Deltapine Australia Pty Ltd (Deltapine).

The DIR 058/2005 licence permits Deltapine to conduct a limited and controlled release of GM insect resistant (COT102, COT202 and COT203) cotton lines. The small scale trial may take place on a maximum of two sites in the Shires of Narrabri, New South Wales and Emerald, Queensland during the 2005–06 summer growing season. Each site must not exceed half a hectare in size.

The *Gene Technology Act 2000* (the Act), the *Gene Technology Regulations 2001* (the Regulations) and corresponding state and territory law govern the process undertaken by the Regulator before a decision is made on whether or not to issue a licence.

While the gene technology legislation provides the scope and boundaries for assessment under the Act and Regulations, it is not explicit in directing how the evaluator should undertake a risk analysis. The Regulator's *Risk Analysis Framework* explains the approach used to evaluate applications for licences to deal with GMOs. The *Risk Analysis Framework* has been revised based on the recently published Australia and New Zealand Standard 4360:2004 on Risk Management (AS/NZS 4360:2004), which is recognised internationally as reflecting best practice in this field.

This is the first time that the revised *Risk Analysis Framework* has been fully applied to the preparation of a RARMP. Copies of the *Risk Analysis Framework* can be obtained from the Office of the Gene Technology Regulator (OGTR) (Freecall 1800 181 030, or at <http://www.ogtr.gov.au/pdf/public/raffinal2.1.pdf>). The restructured RARMP aims to explain the risk analysis process in greater detail and introduces new terminology to differentiate the steps involved.

SECTION 1 APPLICATION

Title: Limited and controlled release of insect resistant (VIP) GM cotton*
Applicant: Deltapine Australia Pty Ltd
Common name of the parent organism: Cotton
Scientific name of the parent organism: *Gossypium hirsutum* L.
Modified trait(s): Insect resistance, antibiotic resistance
Identity of the gene(s) responsible for the modified trait(s):

- *vip3A* gene from the bacterium *Bacillus thuringiensis* (insect resistance)
- *aph4* gene from the bacterium *Escherichia coli* (antibiotic resistance)

Proposed location(s): Shires of Narrabri, NSW and Emerald, QLD
Proposed release size: 1 hectare
Proposed time of release: September/October 2005–July 2006
*The title of the licence application submitted by Deltapine is *Small scale seed increase of VIP cotton*

Deltapine has applied for a licence to release three insect resistant GM cotton lines (COT102, COT202 and COT203) into the environment. The trial is proposed on one or two sites of up to half a hectare each, ie a maximum total planting area of 1 hectare, over one summer planting season (2005–06) in the Shires of Narrabri, NSW and Emerald, QLD.

Some details of the gene constructs, including plasmid maps and some of the regulatory sequences, were previously declared Confidential Commercial Information (CCI) under section 185 of the Act, in connection with licence applications DIR 017/2002, DIR 034/2003 and DIR 036/2003. This information was made available to the prescribed expert groups and authorities that were consulted in the preparation of the RARMP.

The purpose of the proposed release is to produce and store pure seed from the GM cotton lines for possible future releases. To obtain pure seed from the trial, the applicant intends to treat the GM cotton plants with insecticide sprays to prevent any insects carrying pollen onto the release sites.

The GM cotton lines have one or two introduced genes. The COT102 line contains both the *vip3A* gene (encoding the Vegetative Insecticidal Protein) and the *aph4* selectable marker gene (encoding the hygromycin resistance protein), while the COT202 and COT203 lines contain only the *vip3A* gene. The insect resistance protein, VIP3A, is toxic to caterpillars of some lepidopterans (butterflies and moths), including *Helicoverpa armigera* and *H. punctigera*, major pests of cotton in Australia.

The applicant intends to transport GM cottonseed to the release sites for planting and harvested GM seed cotton from the release sites for ginning and de-linting. The applicant also intends to sell lint (cellulose fibres removed from the surface cotton seed during ginning) from the cotton plants grown during the release. Processed lint does not contain protein or genetic material.

SECTION 2 RISK ASSESSMENT

The risk assessment for Deltapine's application, DIR 058/2005, has been prepared in accordance with the Act and the Regulations. The risk assessment considered information contained in the application, current scientific knowledge, and issues relating to risks to human health and safety and the environment raised in submissions received during

consultation on the application with a wide range of prescribed agencies and authorities (see Appendix B).

The Regulator notified the public that a RARMP had been prepared and invited written submissions in relation to the RARMP. Advice on the RARMP was also sought from those consulted on the application. Issues relating to the assessment of risk to the health and safety of people or the environment raised during the consultation period are summarised in Appendices D and E. These appendices also indicate where the issues were addressed in the RARMP.

In addition, a reference document, *The Biology and Ecology of Cotton (Gossypium hirsutum) in Australia*, is used to inform the risk assessment process for licence applications involving GM cotton plants. This is available from the OGTR or from the website <<http://www.ogtr.gov.au>>.

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 (OGTR 2005). The hazard identification process resulted in the compilation of a list of 31 events that describe sets of circumstances (events) by which the proposed release could potentially give rise to adverse outcomes as a result of gene technology.

A risk is identified when a hazard is considered to have some chance of causing harm. 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 or 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	Moderate	High
	Unlikely	Negligible	Negligible	Low	Moderate
	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.

Eight events were identified as requiring further assessment. The potential adverse outcomes associated with these events were: allergic reactions in people, toxicity for non-target

invertebrates and weediness. These identified risks were then assessed in further detail in comparison to the parent organism, in the context of the intended agronomic management practices, and the environmental conditions in the regions where the proposed release would occur.

The consequence and likelihood assessments used to derive risk estimates from these eight events are summarised in Table 1 (the detailed risk assessments are in Chapters 3–5). More information on the remaining 23 events is provided in Chapter 2. These 23 events were considered not to give rise to an identified risk.

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. However, all risks were estimated to be **negligible** for this proposed release.

Table 1 Summary table for the risk assessment

Potential adverse outcome	Event that may give rise to the adverse outcome	Consequence assessment	Likelihood assessment	Risk estimate	Risk evaluation
Allergic reactions for people (see Ch 3)	Event 1 Contact with GM plant materials containing the VIP3A or hygromycin resistance proteins by: <ul style="list-style-type: none"> • contact with plants damaged during handling • inhalation of pollen • inhalation of cotton dust. 	Marginal <ul style="list-style-type: none"> • The VIP3A and hygromycin resistance proteins lack several characteristics typical of allergens. • Exposure to natural sources of the introduced proteins already occurs without evidence of allergic reactions. 	Highly unlikely <ul style="list-style-type: none"> • Exposure to the VIP3A and hygromycin resistance proteins is expected to be restricted to few people due to low expression of the proteins and the small size and short duration of the proposed release. 	Negligible	No specific treatment options are required, however, some conditions proposed to limit the release in time and space are given below.
	Event 2 Exposure of people to the VIP3A or hygromycin resistance proteins as a result of spread and persistence of the GM cotton in the environment	Marginal <ul style="list-style-type: none"> • The VIP3A and hygromycin resistance proteins lack several characteristics typical of allergens. • Exposure to natural sources of the introduced proteins already occurs without evidence of allergic reactions. 	Highly unlikely <ul style="list-style-type: none"> • Exposure to the VIP3A and hygromycin resistance proteins is expected to be restricted to few people due to low expression of the proteins and the small size and short duration of the proposed release. • GM cotton volunteers emerging after harvest are expected to be considerably less numerous than the GM cotton plants grown during the release. 	Negligible	No specific treatment options are required, however, some conditions proposed to limit the release in time and space are given below.

Potential adverse outcome	Event that may give rise to the adverse outcome	Consequence assessment	Likelihood assessment	Risk estimate	Risk evaluation
	<p>Event 3 Exposure of people to the VIP3A or hygromycin resistance proteins as a result of gene transfer to <i>G. hirsutum</i> or <i>G. barbadense</i> plants</p>	<p>Marginal</p> <ul style="list-style-type: none"> The VIP3A and hygromycin resistance proteins lack several characteristics typical of allergens. Exposure to natural sources of the introduced proteins already occurs without evidence of allergic reactions. 	<p>Highly unlikely</p> <ul style="list-style-type: none"> Cotton is primarily in-breeding and gene transfer to other cotton plants is expected to occur at low frequencies. The numbers of recipient plants containing the VIP3A protein as a result of gene transfer are expected to be considerably less than the number of GM cotton plants grown during the release. The proposed release is limited to a small size and short duration. 	Negligible	No specific treatment options are required, however, some conditions proposed to limit the release in time and space are given below.
<p>Toxicity for non-target invertebrates (see Ch 4)</p>	<p>Event 4 Direct or indirect ingestion of the VIP3A protein by non-target invertebrates.</p>	<p>Minor</p> <ul style="list-style-type: none"> Toxicity of the VIP3A protein is specific to a subset of lepidopteran insects. 	<p>Highly unlikely</p> <ul style="list-style-type: none"> Exposure to the VIP3A protein is expected to be restricted to few non-target invertebrates due to low expression of the proteins and the small size and short duration of the proposed release. Agronomic practices proposed for the release, specifically pesticide use, are expected to have a greater impact on invertebrate survival than the expression of the VIP3A protein in the GM cotton plants. 	Negligible	No specific treatment options are required, however, some conditions proposed to limit the release in time and space are given below.
	<p>Event 5 Exposure of non-target invertebrates to the VIP3A protein as a result of spread and persistence of the GM cotton in the environment.</p>	<p>Minor</p> <ul style="list-style-type: none"> Toxicity of the VIP3A protein is specific to a subset of lepidopteran insects. 	<p>Highly unlikely</p> <ul style="list-style-type: none"> Exposure to the VIP3A protein is expected to be restricted to few non-target invertebrates due to low expression of the proteins and the small size and short duration of the proposed release. GM volunteers are expected to be considerably less numerous than the GM cotton plants grown during the release. 	Negligible	No specific treatment options are required, however, some conditions proposed to limit the release in time and space are given below.

Potential adverse outcome	Event that may give rise to the adverse outcome	Consequence assessment	Likelihood assessment	Risk estimate	Risk evaluation
	<p>Event 6 Exposure of non-target invertebrates to the VIP3A protein as a result of gene transfer to <i>G. hirsutum</i> or <i>G. barbadense</i> plants.</p>	<p>Minor</p> <ul style="list-style-type: none"> • Toxicity of the VIP3A protein is specific to a subset of lepidopteran insects. 	<p>Highly unlikely</p> <ul style="list-style-type: none"> • Cotton is primarily in-breeding and gene transfer to other cotton plants is expected to occur at low frequencies. • The numbers of recipient plants containing the VIP3A protein as a result of gene transfer are expected to be considerably less than the number of GM cotton plants grown during the release. • The proposed release is limited to a small size and short duration. 	Negligible	No specific treatment options are required, however, some conditions proposed to limit the release in time and space are given below.
<p>Weediness (see Ch 5)</p>	<p>Event 7 Expression of the <i>vip3A</i> gene increasing spread and persistence of the GM cotton plants through reduced lepidopteran herbivory</p>	<p>Marginal</p> <ul style="list-style-type: none"> • Cotton is not a serious weed in southern Australia because of limitations placed on it by temperature, water, nutrients, light, frost and herbivory by a range of insects. • The expression of the <i>vip3A</i> gene is not expected to alter the environmental limitations on the spread and persistence of cotton in the regions proposed for the release. 	<p>Highly unlikely</p> <ul style="list-style-type: none"> • The limited area and duration of this proposed release would result in the introduction of a relatively small number of GM cotton lines into the environment. • The chance of volunteer GM plants establishing as weeds by finding suitable ecological niches, would be no greater than for the non-GM parent. 	Negligible	No specific treatment options are required, however, some conditions proposed to limit the release in time and space are given below.

Potential adverse outcome	Event that may give rise to the adverse outcome	Consequence assessment	Likelihood assessment	Risk estimate	Risk evaluation
	Event 8 Expression of the <i>vip3A</i> gene in other <i>G. hirsutum</i> or <i>G. barbadense</i> cotton plants as a result of gene transfer	Minor <ul style="list-style-type: none"> Cotton is not a serious weed in southern Australia because of limitations placed on it by temperature, water, nutrients, light, frost and herbivory by a range of insects. The expression of the <i>vip3A</i> gene is not expected to alter the environmental limitations on the spread and persistence of cotton in the regions proposed for the release. 	Highly unlikely <ul style="list-style-type: none"> The limited size and duration of this proposed release would result in the introduction of a relatively small number of GM cotton lines into the environment. Cotton is primarily in-breeding and gene transfer to other cotton plants is expected to occur at low frequencies. Following transfer of the <i>vip3A</i> gene to any of these cotton plants, the likelihood of it causing weediness in these plants is expected to be the same as for the GM cotton plants. 	Negligible	No specific treatment options are required, however, some conditions proposed to limit the release in time and space are given below.

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 eight events that might lead to risks to the health and safety of people or the environment. The risk estimates for the adverse outcomes associated with all eight events are **negligible** ie insubstantial with no present need to invoke actions for their mitigation.

However, containment measures have been imposed to restrict the release in size, duration and regions to those requested by the applicant, as these were important considerations in establishing the context of the consequence and likelihood assessments used to estimate the level of risk.

3.1 Licence conditions to manage this limited and controlled release

A number of licence conditions have been imposed to limit and control the release, including requirements to:

- surround each release site with a pollen trap
- locate the release sites at least 50 m away from natural waterways
- harvest and gin seed cotton from the release separately from other cotton

- prohibit cotton seed and other materials from the release to be used in human food or animal feed
- clean the sites and any equipment used on the sites
- inspect the sites following harvest, any areas used to clean equipment and any irrigation channels associated with the release
- destroy any volunteers prior to flowering
- conduct regular inspections of the release sites and other areas following harvest for at least 12 months and until six consecutive months have passed without any volunteer cotton plants.

To obtain pure seed, the applicant proposes to spray the GM cotton crop with insecticides targeting pollinators, to minimise gene flow from the adjoining non-GM cotton used as a pollen trap. This will further reduce the frequency of gene flow from the GM cotton beyond the release site.

The Regulator has issued guidelines and policies for the transport, supply and storage of GMOs (*Guidelines for the transport of GMOs, June 2001; Policy on transport and supply of GMOs, July 2005; and Policy on storage of genetically modified organisms, July 2004*). Licence conditions based on these guidelines and policies have also been imposed to control possession, use or disposal of the GMOs for the purposes of, or in the course of, the authorised dealings.

3.2 Other regulatory considerations

Some of the dealings conducted under a licence issued by the Regulator may also be subject to regulation by other agencies. The GM cotton lines proposed for release produce an insecticidal substance and, therefore, could be subject to regulation by the Australian Pesticides and Veterinary Medicines Authority (APVMA). Deltapine has made an application to the APVMA for a permit to undertake the proposed release.

The possibility of insects developing resistance to the VIP3A protein as a result of this proposed release was considered in the risk assessment. However, no chance of harm to the health and safety of people or the environment was identified. No conditions have been imposed in relation to management of insecticide resistance, as this relates to product efficacy and is considered by the APVMA.

3.3 Identification of issues to be addressed for future releases

The risk assessment identified additional information that may be required to evaluate an application requesting a larger scale release of these GM cotton lines or a reduction in containment conditions. This would include the following:

- expression levels of the VIP3A protein in the COT202 and COT203 GM cotton lines
- the toxicity of the VIP3A protein for a range of organisms in Australia

- Australian field studies addressing the biodiversity of insect populations in unsprayed VIP3A crops compared with conventional cotton crops.

SECTION 4 CONCLUSIONS OF THE RARMP

The risk assessment concludes that this limited and controlled release of insect resistant GM cotton lines into the Shires of Narrabri, NSW and Emerald, QLD poses **negligible** risks to the health and safety of people and the environment as a result of gene technology.

The risk management plan concludes that these negligible risks do not require specific risk treatment measures. Licence conditions have been imposed to contain the release to the proposed size, duration and regions requested by the applicant.