Australian Government
Department of Health and Ageing
Office of the Gene Technology Regulator

13 October 2006

TECHNICAL SUMMARY OF THE RISK ASSESSMENT AND RISK MANAGEMENT PLAN
for
APPLICATION NO. DIR 065/2006
from
DELTAPINE AUSTRALIA PTY LTD

INTRODUCTION

The Gene Technology Regulator (the Regulator) has decided to issue a licence (DIR 065/2006) to Deltapine Australia Pty Ltd (Deltapine) for dealings involving the intentional release of genetically modified (GM) cotton lines into the Australian environment, on a limited scale and under controlled conditions.

The DIR 065/2005 licence permits the limited and controlled release of up to 11 insect resistant GM cotton lines. The release will occur on one site in the shire of Narrabri on a maximum total area of 1.5 ha over one season (summer 2006/07).

The *Gene Technology Act 2000* (the Act), the Gene Technology Regulations 2001 (the Regulations) and corresponding state and territory law govern the comprehensive and highly consultative process undertaken by the Regulator before making a decision whether or not to issue a licence to deal with a GMO.

The Regulator's *Risk Analysis Framework* explains the approach used to evaluate licence applications and to develop the Risk Assessment and Risk Management Plans (RARMPs) that form the basis of her decisions[1].

This RARMP for DIR 065/2006 has been finalised in accordance with the gene technology legislation. Matters raised in the consultation process regarding risks to the health and safety of people and the environment from the proposed dealings were taken into account by the Regulator in deciding to issue a licence and the licence conditions that have been imposed.

[1] 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.

APPLICATION

*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:	*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) • modified *cry1Ab* gene from the bacterium *Bacillus thuringiensis* (insect resistance) • *aph4* gene from *Escherichia coli* (antibiotic resistance)
Proposed location(s):	One site in the Narrabri Shire, New South Wales (NSW)
Proposed release size:	Up to 1.5 hectares
Proposed time of release:	Summer 2006/07

*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*.

Deltapine applied for a licence to release 11 lines of insect resistant GM cotton into the environment on a limited scale and under controlled conditions. The release of the GM cotton lines is intended to take place at one site in the shire of Narrabri in NSW on a maximum area of 1.5 ha over one season (summer 2006/07).

The cotton lines have been genetically modified by insertion of the insect resistance genes *vip3A* and modified *cry1Ab* either alone, or in combination as a result of conventional crossing of cotton plants from lines containing the individual introduced genes. The insect resistance genes, isolated from a common soil bacterium, *Bacillus thuringiensis* subsp. *kurstaki*, encode for proteins that are specifically toxic to caterpillars of some lepidopterans including cotton bollworm (*Helicoverpa armigera*) and/or budworm (*H. punctigera*), the major pests of cotton crops in Australia.

Six of the GM cotton lines also contain a selectable marker gene, *aph4*, which confers resistance to the antibiotic hygromycin. The *aph4* gene was used to select modified GM plants during their early stages of development in the laboratory.

Some details of the gene construct, including the plasmid map and some of the regulatory sequences, have been declared Confidential Commercial Information (CCI) under section 185 of the Act. This information was considered during the preparation of the RARMP and was also made available to the prescribed expert groups and agencies that were consulted in its preparation.

The GM cotton lines were derived from the cotton cultivar Coker 312 which is not grown commercially in Australia. The purpose of the trial is to conduct early stage research and to produce seed from the GM cotton lines for use in further studies in future trials (subject to future applications and approvals). The applicant also requested approval to sell lint from the release.

The applicant proposed measures to limit the spread and persistence of the GM cotton in the environment. These were taken into account in establishing the risk assessment context for the proposed release and their suitability for limiting the release to the location, size and duration proposed by the applicant was considered as part of the risk assessment process. No products from the release will be used for human food or animal feed.

RISK ASSESSMENT

The risk assessment considered information contained in the application, previous GM cotton assessments, current scientific knowledge, and issues relating to risks to human health and safety and the environment raised in submissions received during consultation with a wide range of prescribed experts, agencies and authorities on the application (summarised in Appendix B). No further issues were raised in the comments received on the consultation version of the RARMP.

The consideration of advice received from a member of the public on the application and consultation on the RARMP is summarised in Appendices C and E respectively.

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

The hazard identification process considered the circumstances or events by which people or the environment may be adversely affected by exposure to the GMOs, GM plant materials, GM plant by-products, the introduced genes, or products of the introduced genes.

A hazard (source of potential harm) may be an event, substance or organism. 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.

Eighteen events were identified and assessed whereby the proposed release of the GM cotton lines might give rise to harm to people or the environment.

These 18 events included consideration of whether expression of the introduced genes could result in products that are toxic or allergenic to people or other organisms, produce unintended changes in the biochemistry or physiology of the GM plants, or alter characteristics that may impact on spread and persistence of the GMOs. In addition, consideration was given to the opportunity for gene flow to other organisms and its effects.

None of the 18 events are considered to give rise to an identified risk that requires further assessment. The principle reasons comprise:

- small scale of the trial that is limited in both area and duration
- none of the GM plant materials will be used in human food or animal feed
- widespread presence of the same or similar insect resistance proteins encoded by the introduced genes in the environment and their use in conventional agriculture for insect pest control
- very low toxicity of the proteins encoded by the introduced genes
- limited capacity of the GM cotton lines to spread and persist in the area proposed for release
- limited ability and opportunity for the GM cotton lines to transfer the introduced genes to other sexually related species or other organisms
- containment and disposal measures proposed by the applicant to limit the spread and persistence of GM cotton plants.

Therefore, as no risks to the health and safety of people or the environment were identified from the proposed limited and controlled release of the GM cotton lines, the level of risk is considered to be **negligible**.

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.

As none of the 18 events that were characterised in the risk assessment process are considered to give rise to an identified risk that requires further assessment, the level of risk to human health and safety and the environment from the release of GM cotton lines is considered to be **negligible** (ie insubstantial with no present need to invoke actions for their mitigation).

However, containment and disposal measures have been imposed to restrict the release to the size, duration and location requested by the applicant, as these were important parameters in establishing the context for assessing the risks.

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:

- implement measures to control the spread and persistence of the GMOs in the environment
- comply with the Regulator's guidelines and policies for the transport, supply, storage and disposal of GMOs (*Guidelines for the transport of GMOs, June 2001*; *Policy on transport and supply of GMOs, July 2005*)
- develop compliance and contingency plans and establish related reporting structures
- inform anyone covered by the licence of their obligations.

Other regulatory considerations

Australia's gene technology regulatory system operates as part of an integrated legislative framework. The Regulator sought input on the preparation of the RARMP from other agencies that also regulate GMOs or GM products including Food Standard Australia New Zealand (FSANZ), Australian Pesticides and Veterinary Medicines Authority (APVMA), Therapeutic Goods Administration, National Industrial Chemicals Notification and Assessment Scheme, National Health and Medical Research Council and Australian Quarantine Inspection Service. Dealings conducted under a licence issued by the Regulator may also be subject to regulation by one or more of these agencies[2].

AQIS is responsible for monitoring imports to prevent the introduction of exotic pests, weeds and diseases into the environment. An importer is required to notify AQIS if they are importing GMOs. Additionally, as the importation of the insect resistant GM cotton seed constituted a dealing under the *Gene Technology Act 2000*, the importer required an authorisation under this Act for the import to lawfully proceed. Seed from the insect resistant GM cotton lines has been imported by Deltapine under an AQIS seed import permit.

[2] More information on Australia's integrated regulatory framework for gene technology is contained in the *Risk Analysis Framework* available from the Office of the Gene Technology Regulator (OGTR). Free call 1800 181 030 or at <http://www.ogtr.gov.au/pdf/public/ raffinal2.2.pdf >.

FSANZ is responsible for human food safety assessment, including GM food. FSANZ has previously approved food (oil and linters) derived from GM cotton lines containing the VIP3A and Cry1Ac proteins in 2005 and 1999 respectively. The applicant does not intend materials from any of the GM cotton lines to be used in human food. Accordingly the applicant has not applied to FSANZ for evaluation of the modified Cry1Ab lines for use in human food and the applicant does not intend materials from any of the GM cotton lines proposed for release to be used in human food. FSANZ approval would need to be obtained before materials from cotton lines containing the modified Cry1Ab protein could be used in this way.

The GM cotton lines proposed for release meet the definition of an agricultural chemical product under the *Agricultural and Veterinary Chemicals Code Act 1994*, due to their production of insecticidal substances, and therefore these are subject to regulation by the APVMA. Deltapine has applied to the APVMA for a research permit for the proposed release. The regulator has liaised closely with APVMA to ensure the thorough and coordinated assessment of these parallel applications.

Identification of issues to be addressed for future releases

The risk assessment identified additional information that may be required to assess an application for a larger scale trial, reduced containment conditions or a commercial release of these GM cotton lines. This would include:

- specificity of the insecticidal activity of GM cotton lines containing the modified c*ry1Ab* gene
- toxicity of the modified Cry1Ab protein for non-target (including predators and beneficial insects) organisms
- specificity of the insecticidal activity of GM cotton lines containing both *vip3A* and modified *cry1Ab* genes
- toxicity of the GM cotton line containing the VIP3A in combination with modified Cry1Ab protein for non-target (including predators and beneficial insects) organisms
- data on the expression level of the introduced proteins in various parts of the plants (including pollen grains) encoded by the introduced insecticidal genes in the GM cotton lines
- molecular characterisation of the inserted genetic materials.

CONCLUSIONS OF THE RARMP

The risk assessment concludes that this limited and controlled release of up to 11 GM cotton lines on 1.5 ha in the shire of Narrabri in NSW poses **negligible** risks to the health and safety of people and the environment.

The risk management plan concludes that these negligible risks do not require specific risk treatment measures. However, licence conditions have been imposed to limit the release to the location, size and duration requested by the applicant.