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

13 October 2006

EXECUTIVE 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 made a decision to issue a licence for dealings involving the intentional release of insect resistant genetically modified (GM) cotton lines into the Australian environment, in respect of application DIR 065/2006 from Deltapine Australia Pty Ltd (Deltapine).

The DIR 065/2006 licence permits the release of up to 11 GM cotton lines on a limited scale and under controlled conditions.

The *Gene Technology Act 2000* (the Act) and the *Gene Technology Regulations 2001* (the Regulations) govern the process undertaken by the Regulator before a decision is made on whether or not to issue a licence. The decision is based upon a Risk Assessment and Risk Management Plan (RARMP) prepared by the Regulator in consultation with a wide range of experts, agencies and authorities and the public.

More information on the comprehensive assessment required for licence applications to release a genetically modified organism (GMO) into the environment is 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>.

THE APPLICATION

Deltapine applied for a licence to conduct a small scale field trial, of up to 11 lines of insect resistant cotton, on 1.5 ha at one site in the shire of Narrabri in NSW over one season (summer 2006/07). The GM cotton lines have been modified to contain either the *vip3A* or a modified *cry1Ab* gene (insect resistance genes isolated from a common soil bacterium) or both genes through conventional crossing of lines containing the individual introduced genes.

The insect resistance proteins encoded by the introduced genes are specifically toxic to caterpillars of some lepidopterans (butterflies and moths) including cotton bollworm (*Helicoverpa armigera*) and/or budworm (*H. punctigera*), major pests of cotton crops in Australia.

Six of the GM cotton lines also contain a selectable marker gene (*aph4*) which provides resistance to the antibiotic hygromycin. The marker gene was used to select modified plants during initial research and development work in the laboratory.

The purpose of the trial is to conduct early stage research 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.

Deltapine proposed a number of measures to limit the spread and persistence of the GMOs and the introduced genetic materials that were considered during the evaluation of the application. None of the GM plants or their by-products will be used for human food or for animal feed.

RISK ASSESSMENT

The hazard identification process considered the circumstances by which people or the environment may be exposed 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 their spread and persistence. In addition, consideration was given to the potential for gene flow to other organisms and its effect.

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, any risks of harm to the health and safety of people, or the environment, from the proposed release of the GM cotton lines into the environment is considered to be **negligible**.

RISK MANAGEMENT

The risk management process builds upon the risk assessment to determine whether measures are required in order to protect people and/or the environment. As none of the 18 events identified and characterised in the risk assessment are considered to give rise to an identified risk that requires further assessment, the level of risk is considered to be **negligible**.

The *Risk Analysis Framework* defines negligible risks as insubstantial, with no present need to invoke actions for their mitigation. However, containment and disposal measures have been imposed to restrict the release in location, size and duration to those requested by the applicant, as these were an important part of establishing the context for assessing the risks.

The licence conditions, detailed in Chapter 3 of the RARMP, require the applicant to limit the duration of the release to one cotton growing season (summer 2006/07) at one site on a maximum total area of 1.5 hectares; prevent the use of the GMOs, or materials from the GMOs, in food and animal feed; maintain physical isolation of the release site; and conduct post-harvest monitoring of the release site to ensure all GM plants are destroyed[1].

CONCLUSIONS OF THE RARMP

The risk assessment concludes that this limited and controlled release of up to 11 GM cotton lines into 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 contain the release to the location, size and duration requested by the applicant.

[1] The licence and conditions for DIR 065/2006 are now available on the OGTR website (<http://www.ogtr.gov.au/gmore/ir.htm#table> following the path to DIR 065/2006).