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

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EXECUTIVE SUMMARY OF THE RISK ASSESSMENT AND RISK MANAGEMENT PLAN
for
APPLICATION NO. DIR 058/2005
from
DELTAPINE AUSTRALIA PTY LTD

EXECUTIVE SUMMARY

INTRODUCTION

The Gene Technology Regulator (the Regulator) has made a decision to issue a licence for dealings involving the intentional release (DIR) 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) 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 prepared by the Regulator in consultation with a wide range of expert groups and authorities and the public.

More information on the process required for the comprehensive assessment of licence applications to release a genetically modified organism (GMO) into the environment is available from the Office of the Gene Technology Regulator (OGTR) (Freecall 1800 181 030) or at <http://www.ogtr.gov.au/ir/process.htm>.

THE APPLICATION

Deltapine has applied for a licence to grow three GM cotton lines on one or two sites of half a hectare each for one summer season (2005–06). The proposed release sites are in the Shires of Narrabri, NSW, and Emerald, QLD.

The GM cotton lines contain an insect resistance gene (*vip3A*) isolated from *Bacillus thuringiensis*, a common soil bacterium. The gene expresses an insect resistance protein (VIP3A) that is toxic to caterpillars of some lepidopterans (butterflies and moths), including cotton bollworm (*Helicoverpa armigera*) and native budworm (*Helicoverpa punctigera*).

One of the GM cotton lines also contains a bacterial gene (*aph4*, conferring resistance to the antibiotic hygromycin B) that was used to select successfully modified plants during initial research and development work in the laboratory.

The purpose of the proposed release is to produce pure seed from the GM cotton lines. This seed may be used in future releases, which would require separate assessments and approval processes. The applicant also requested permission to sell lint from the cotton plants grown during this release. Lint (cellulose fibres removed from the surface of the cotton seed during ginning) does not contain protein or genetic material after it has been processed.

RISK ASSESSMENT

Background

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 OGTR by free call 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.

The risk assessment considered what harm to the health and safety of people or the environment could arise as a result of gene technology, and how it could happen, during the proposed release of GMOs into the environment (**hazard identification** refer to Chapter 2 for more information).

Thirty one hazards were identified for this proposed release. These hazards are particular sets of circumstances (**events**) that might give rise to adverse outcomes (ie cause harm). When an event was considered to have some chance of causing harm, it was identified as posing a risk that required further assessment.

Eight events were selected for further assessment. The potential adverse outcomes associated with these events were: allergic reactions in people, toxicity for non-target invertebrates and weediness. The remaining 23 events compiled during the hazard identification were not assessed further as they were considered not to give rise to an identified risk.

Each event associated with an **identified risk** was then assessed to determine the seriousness of harm (**consequence**—ranging from marginal to major) and the chance of harm (**likelihood**—ranging from highly unlikely to highly likely)). The **level of risk** (ranging from negligible to high), was then estimated using a risk estimate matrix (refer to Chapter 2 for more information). A brief summary of the conclusions of the risk assessment is provided below.

The GM cotton lines proposed for release have been approved previously for limited and controlled releases under DIR licences 017/2002, 025/2002, 034/2003 and 036/2003. release (PR-151) occurred under the former voluntary system overseen by the Genetic Manipulation Advisory Committee.

The risks to people and the environment from this limited and controlled release were assessed in comparison to non-GM cotton and in the context of the intended agronomic management practices of the applicant, and the environmental conditions in the regions proposed for the release.

Risks of allergic reactions in people

Three events were considered that might cause allergic reactions in people as a result of the release of the GM cotton lines.

- Contact with GM plant materials containing the insect resistance or hygromycin resistance proteins
- Exposure of people to the insect resistance or hygromycin resistance proteins as a result of spread and persistence of the GM cotton in the environment
- Exposure of people to the insect resistance or hygromycin resistance proteins as a result of gene transfer to other cultivated or naturalised cotton plants (GM or non-GM).

The risk assessment considered the consequence and likelihood of harm that might result from each of the above events. The estimate of risk for each event is **negligible**.

Risks of toxicity to non-target invertebrates

Three events were considered that might cause toxicity in non-target invertebrates, in particular some non-target lepidopteran insects, as a result of the release of the GM cotton lines.

- Direct or indirect ingestion of the insect resistance proteins by non-target invertebrates as a result of this release
- Exposure of non-target invertebrates to the insect resistance protein as a result of spread and persistence of the GM cotton in the environment.
- Exposure of non-target invertebrates to the insect resistance protein as a result of gene transfer to other cultivated or naturalised cotton plants (GM or non-GM).

The risk assessment considered the consequence and likelihood of harm that might result from each of the above events. The estimate of risk for each event is **negligible**.

Risks of weediness

Two events were considered that might cause weediness as a result of the release of the GM cotton lines.

- Expression of the insect resistance gene increasing spread and persistence of the GM cotton plants through reduced insect attack on the plants.
- Expression of the insect resistance gene in other cultivated or naturalised cotton plants (GM or non-GM).

The risk assessment considered the consequence and likelihood of harm that might result from each of the above events. The estimate of risk for each event is **negligible**.

RISK MANAGEMENT

The level of risk to the health and safety of people or the environment was assessed for eight events. The risk estimates for the adverse outcomes associated with all eight events were **negligible**. The *Risk Analysis Framework* defines negligible risks as insubstantial, with no present need to invoke actions for their mitigation. However, as the small size and short duration of the release were important parts of the context for assessing the risks, containment measures have been imposed to limit the size and duration of the release to that requested by the applicant.

The licence conditions, detailed in Chapter 7 of the RARMP, require the applicant to limit the area and duration of the release to 1 hectare for a single season; prevent use of the GMOs, or materials from the GMOs, in human food or animal feed; maintain physical isolation of the release sites; and conduct post-harvest monitoring to ensure all GMOs are destroyed.

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.