



EXECUTIVE SUMMARY OF THE RISK ASSESSMENT AND RISK MANAGEMENT PLAN

for
APPLICATION NO. DIR 073/2007
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) cotton lines into the environment, in respect of application DIR 073/2007 from Deltapine Australia Pty Ltd (Deltapine).

The DIR 073/2007 licence permits the release of up to four GM cotton lines on a limited scale and under controlled conditions.

The *Gene Technology Act 2000*¹ (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. The decision is based upon a Risk Assessment and Risk Management Plan (RARMP) prepared by the Regulator in accordance with the *Risk Analysis Framework* and in consultation with a wide range of experts, agencies, authorities and the public.

More information on the comprehensive assessment undertaken 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>>.

THE APPLICATION

Deltapine applied for a licence to conduct a small scale release of GM cotton lines² on up to 50 sites of no more than 10 hectares each (ie maximum total area of 500 hectares) over 3 summer growing seasons (2007/08, 2008/09 and 2009/10). The release is authorised to take place in the New South Wales (NSW) shires of Bourke, Brewarrina, Gwydir, Liverpool Plains, Moree Plains, Narrabri, Narromine, Walgett and Warren, and the Queensland (QLD) shires of Balonne, Banana, Chinchilla, Dalby, Emerald, Jondaryan, Millmerran, Pittsworth, Waggamba, Wambo and Wondai.

Four GM cotton lines are approved for release into the environment. Two of the lines contain different insect resistance genes, VIP3A or modified Cry1Ab, derived from a common soil bacterium (*Bacillus thuringiensis*), which express proteins that are selectively toxic to the major lepidopteran caterpillar pests of cotton (*Helicoverpa armigera* and *H. punctigera*). A third line contains copies of both insect resistance genes, and the fourth line will contain both insect resistance genes and two copies of a herbicide tolerance gene (*cp4 epsps*), which is also derived from a soil bacterium (*Agrobacterium tumefaciens*).

The presence of two copies of the herbicide tolerance gene is commercially known as the Roundup Ready Flex[®] herbicide tolerance trait and confers tolerance to glyphosate, which can be applied to

¹ None of the amendments arising from a recent statutory review of the Act that came into effect on 1 July 2007 apply directly to the processing of this application which commenced prior to this date.

² The GM cotton lines proposed for release are all cotton species with the scientific name *Gossypium hirsutum*.

the crop to kill weeds without damaging the cotton plants. Roundup Ready Flex[®] GM cotton is currently licensed for commercial release in Australia.

In addition, the GM cotton lines containing the *vip3A* gene, also contain an antibiotic resistance marker gene, *aph4*, from the gut bacterium *Escherichia coli* which enabled identification of GM plant tissues during the initial laboratory stage of development of the GMOs.

The aims of the release are to conduct early stage research to breed and evaluate the agronomic performance of the GM cotton lines; produce seed for further trials (subject to additional approvals); and collect data for future regulatory requirements.

Deltapine proposed a number of measures to limit the spread and persistence of the GM cotton lines and the introduced genetic materials that were considered during the evaluation of the application. The GM plant material is not permitted for use in human food or animal feed. However, the applicant has approval to sell lint from the release.

Some details of the gene construct, including the plasmid map and regulatory sequences, for the modified Cry1Ab line were previously declared as Confidential Commercial Information (CCI) under DIR 065/2006. However, this CCI has now been revoked at the request of the applicant. The previously declared CCI information was contained in the application and was considered in the assessment process.

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.

Seventeen events were identified and assessed whereby the release of the GM cotton lines might give rise to harm to people or the environment (see Chapter 2).

These 17 events included consideration of whether expression of the introduced genes could result in products that are toxic or allergenic to people, or toxic to other organisms; alter characteristics that may impact on the spread and persistence of the GM plants; or produce unintended changes in biochemistry or physiology. In addition, consideration was given to the potential for gene flow to other organisms and its effect if this occurred.

All events were characterised in relation to both the magnitude and probability of harm in the context of the controls proposed by the applicant to limit the spread and persistence of the GMOs in both time and space. This detailed consideration concluded that none of the 17 events gave rise to an identified risk that required further assessment. The principal reasons comprise:

- the scale of the release is limited in both area and duration
- containment, monitoring and disposal measures proposed by the applicant will limit the spread and persistence of the GM cotton plants
- none of the GM plant materials or products will be used in human food or animal feed
- widespread presence of the same or similar proteins encoded by the introduced genes in the environment and lack of known toxicity or allergenicity from these proteins

- limited capacity of the GM cotton plants to spread and persist outside the release sites
- limited ability and opportunity for the GM cotton lines to transfer the introduced genes to commercial cotton crops or other sexually compatible species.

Therefore, any risk to the health and safety of people, or the environment, from the limited and controlled 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 17 events characterised in the risk assessment are considered to give rise to an identified risk that required further assessment, the level of risk is considered to be **negligible**.

The Regulator's *Risk Analysis Framework* defines negligible risks as insubstantial, with no present need to invoke actions for their mitigation. However, licence conditions have been imposed to restrict the release to the size, duration and locations requested by the applicant, as these were an important part of establishing the context for assessing the risks (see Chapter 1).

The licence conditions require the applicant to limit the size and duration of the release to 50 sites of no more than 10 hectares each (ie maximum total area of 500 hectares) over 3 summer growing seasons (2007/08, 2008/09 and 2009/10) and prevent the use of the GMOs, or materials from the GMOs in human food or animal feed. Containment measures include limiting the spread and persistence of the GMOs through use of pollen traps; transport requirements; and the conduct of post-harvest monitoring of the release sites to ensure all GMOs are destroyed³.

CONCLUSIONS OF THE RARMP

The risk assessment concluded that this limited and controlled release of up to four lines of GM cotton modified for insect resistance and insect resistance in combination with herbicide tolerance, in up to 20 shires in NSW and QLD, poses **negligible** risks to the health and safety of people and the environment as a result of gene technology.

The risk management plan concluded that these **negligible** risks do not require specific risk treatment measures. However, licence conditions have been imposed to contain the release to the size, duration and locations requested by the applicant as these were important considerations in establishing the context for assessing the risks.

³ The licence for DIR 073/2007 is available on the OGTR website (<<http://www.ogtr.gov.au/gmorec/ir.htm#table>>, via the link to DIR 073/2007).