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

26 October 2006

EXECUTIVE SUMMARY OF THE RISK ASSESSMENT AND RISK MANAGEMENT PLAN
for
APPLICATION NO. DIR 066/2006
from
MONSANTO AUSTRALIA LTD

INTRODUCTION

The Gene Technology Regulator (the Regulator) has made a decision to issue a licence for dealings involving the intentional release (DIR) of five herbicide tolerant and/or insect resistant genetically modified (GM) cotton lines into the Australian environment, in respect of application DIR 066/2006 from Monsanto Australia Ltd (Monsanto).

The DIR 066/2006 licence permits the commercial release of the GM cotton lines on an unrestricted basis in northern Australia, north of latitude 22° South. It should be noted that cultivation of these GMOs may require additional approvals under State or Territory legislation that restrict the commercial release of GM crops on marketing grounds.

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 the 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 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) (Free call 1800 181 030) or at <http://www.ogtr.gov.au/>.

THE APPLICATION

Monsanto applied for a licence to release the following GM cotton lines, without specific containment measures, north of latitude 22ºSouth:

- insect resistant Bollgard II® cotton (also known as MON15985)
- herbicide tolerant Roundup Ready® cotton (also known as MON1445)
- herbicide tolerant Roundup Ready Flex® cotton (also known as MON88913)
- herbicide tolerant/insect resistant Roundup Ready®/Bollgard II® cotton (also known as MON1445/MON15985)
- herbicide tolerant/insect resistant Roundup Ready Flex®/Bollgard II® cotton (also known as MON88913/MON15985).

The Regulator comprehensively assessed the GM cotton lines proposed for release prior to issuing licences for their unrestricted commercial release south of latitude 22ºS (under DIRs 012/2002, 023/2002 and 059/2005) and for field trials under limited and controlled conditions north of latitude 22° S (under DIRs 006/2001, 009/2001, 012/2002, 035/2003 and 055/2004).

Monsanto intends to conduct plant breeding, agronomic trials and seed production, and to cultivate the GM cotton lines in areas suitable for cotton growing in northern Australia. Monsanto indicates that commercial scale plantings are not planned at this stage as a range of industry, community and infrastructure issues would need to be resolved before commercial cotton production could take place in northern Australia.

Monsanto intends to use the GM cotton plants and their products in the same manner as non-GM cotton and GM cotton lines commercially approved north and south of latitude 22ºS, including use in human food and stockfeed, transportation and sale of lint.

Under Australia's integrated framework for the regulation of genetically modified organisms, regulatory decisions by relevant agencies are coordinated as far as possible. Monsanto has received approval from Food Standards Australia New Zealand for the use of oil and linters derived from Bollgard II® cotton, Roundup Ready® cotton and Roundup Ready Flex® cotton in food (FSANZ reports A436, A355 and A553). No additional approvals are required from FSANZ for the stacked GM cotton lines.

The Agricultural Pesticides and Veterinary Medicines Authority (APVMA) has registered Roundup Ready® Herbicide by Monsanto for use on Roundup Ready® and Roundup Ready Flex® cotton varieties. The APVMA has also registered the use of the insecticidal proteins as produced by the insecticidal genes (*cry1Ac* and *cry2Ab*) in GM Bollgard II® cotton as insecticidal products for New South Wales (NSW) and Queensland (QLD) south of latitude 22ºS. It is currently assessing an application from Monsanto to vary the label for Bollgard II® to remove the condition for restriction on planting Bollgard II® north of latitude 22°S.

RISK ASSESSMENT

Background

The risk assessment first 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 the GM cotton lines into the environment (**hazard identification** refer to Chapter 2 for more information).

The risks to people and the environment from the proposed commercial release were assessed in comparison to non-GM cotton and GM Liberty Link® Cotton (previously approved for commercial release by the Regulator in northern Australia under DIR 062/2005), in the context of information gained from growing the GM cotton lines commercially in southern Australia, intended agronomic management practices, and the environmental conditions in the regions proposed for the release.

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.

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).

Hazard identification

Of the 35 events compiled during the hazard identification process, six were selected for further assessment. The potential adverse outcomes to the environment associated with these events were increased toxicity to non-target invertebrates and enhanced spread and persistence (weediness). The remaining 29 events were not assessed further as they were considered not to give rise to an identified risk to human health and safety or the environment (refer to Chapter 2 for more information).

Risk of increased toxicity to non-target invertebrates

One event was considered that might result in the insect resistant GM cotton lines exhibiting greater toxicity to non-target invertebrates than non-GM cotton.

- Direct or indirect ingestion of the Cry1Ac and Cry2Ab proteins by non-target invertebrates (Identified Risk 1).

Risk of weediness

Five events were considered that might result in the introduced genes causing greater weediness in the GM cotton lines or in related species following gene transfer, than non-GM cotton or GM Liberty Link® cotton.

- Tolerance to glyphosate due to expression of the *cp4 epsps* gene(s) in the GM cotton plants (Identified Risk 2)

- Reduced lepidopteran herbivory due to expression of the *cry1Ac* and *cry2Ab* genes in the GM cotton plants (Identified Risk 3)

- Tolerance to glyphosate and reduced lepidopteran herbivory due to expression of the *cp4 epsps*, *cry1Ac* and *cry2Ab* genes in combination in the GM cotton plants (Identified Risk 4)

- Expression of the *cp4 epsps*, and/or *cry1Ac* and *cry2Ab* genes in naturalised *G. hirsutum* or *G. barbadense* cotton plants providing glyphosate tolerance and/or reduced lepidopteran herbivory resulting from vertical gene transfer (Identified Risk 5)

- Expression of the *cp4 epsps*, and/or *cry1Ac* and *cry2Ab* genes in combination with the *bar* gene (from Liberty Link® Cotton) providing dual herbicide tolerance and reduced lepidopteran herbivory resulting from vertical gene transfer (Identified Risk 6).

The risk assessment considered the consequence and likelihood of harm that might result from each of the above events. The estimate of risk for all six Identified Risks is **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. The level of risk to health and safety of people or the environment for the six Identified Risks that were assessed was estimated as **negligible**.

The *Risk Analysis Framework* defines negligible risks as insubstantial, with no present need to invoke actions for their mitigation. Therefore, no risk treatment measures are required and no specific risk management conditions have been imposed. However, as part of the Regulator's oversight of licensed dealings involving the release of genetically modified organisms, the licence contains a number of general conditions relating to ongoing licence holder suitability, auditing and monitoring provisions; and reporting requirements, including a compliance plan, annual report and other relevant information[1].

CONCLUSIONS OF THE RARMP

The risk assessment concludes that this commercial release of five herbicide tolerant and/or insect resistant GM cotton lines in northern Australia 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 the negligible risks do not require risk treatment measures and no specific risk management conditions have been imposed. The licence contains general conditions that enable the Regulator to maintain oversight of the licensed dealings in accordance with her statutory obligations.

[1] The licence and conditions for DIR 066/2006 are available on the OGTR website (http://www.ogtr.gov.au/gmorec/ir.htm#table, following the path to DIR 066/2006).