



16 February 2006

**EXECUTIVE SUMMARY OF THE RISK ASSESSMENT
AND RISK MANAGEMENT PLAN**
for
APPLICATION NO. DIR 059/2005
from
MONSANTO AUSTRALIA PTY LTD

INTRODUCTION

The Gene Technology Regulator (the Regulator) has made a decision to issue a licence for dealings involving the intentional release (DIR) of herbicide tolerant and herbicide tolerant/insect resistant genetically modified (GM) cotton into the Australian environment, in respect of application DIR 059/2005 from Monsanto Australia Ltd (Monsanto).

The DIR 059/2005 licence permits the commercial release of the two GM cotton lines on an unrestricted basis south of latitude 22° South. The licence also permits the use of seed from the GM cotton plants as stockfeed, including in northern Australia where measures to limit spread and persistence of the GMOs have been imposed.

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 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/ir/process.htm>>.

THE APPLICATION

Monsanto applied for a licence to release herbicide tolerant and herbicide tolerant/insect resistant GM cotton, Roundup Ready Flex[®] MON 88913 (referred to as Roundup Ready Flex[®]) and Roundup Ready Flex[®]/Bollgard II[®], into the environment. Monsanto is seeking approval for unrestricted, commercial scale planting of the two GM cotton lines in all areas south of latitude 22° South in Australia.

The GM cotton lines have either one or five introduced genes. Roundup Ready Flex[®] cotton contains two copies of a herbicide tolerance gene (*cp4 epsps*) isolated from a common soil bacterium, *Agrobacterium* sp. strain CP4. The gene expresses a protein that provides tolerance to glyphosate, the active ingredient in Roundup Ready[®] Herbicide, and enables the herbicide to be applied for weed control in the GM cotton crop.

Roundup Ready[®] cotton, which was approved for commercial release south of latitude 22° South in 2000 (refer DIR 023/2002) and is now widely grown, contains only one copy of the *cp4 epsps* gene. Glyphosate can only be applied to Roundup Ready[®] cotton plants up to the four-leaf stage of growth (ie prior to flower formation, approximately 3 to 5 weeks after planting) because later application can lead to yield loss. If weather conditions prevent spraying in this short window, then farmers must use more intensive methods of weed management (eg inter-row cultivation, hand weeding, shielded/spot spraying). As Roundup Ready Flex[®] cotton has increased and prolonged expression of the protein from the two herbicide tolerance genes, it is tolerant to glyphosate application throughout the growing season (approximately 24 to 28 weeks) and will provide greater flexibility in the timing of spraying.

Roundup Ready Flex[®]/Bollgard II[®] cotton was produced by conventional crossing of Roundup Ready Flex[®] cotton with Bollgard II[®] cotton (approved for commercial release south of latitude 22° South in 2002 under DIR 012/2002) and contains all the genes introduced into each of the parent GMOs. This means that (in addition to the two copies of the herbicide tolerance gene) the plants contain two insect resistance genes (*cryIAc* and *cry2Ab*) from a common soil bacterium, *Bacillus thuringiensis*. The genes express two insect resistance proteins that are specifically toxic to caterpillars of some lepidopterans (butterflies and moths), including *Helicoverpa armigera* and *H. punctigera*. These are the two major pests of cotton in Australia.

Roundup Ready Flex[®]/Bollgard II[®] cotton also contains three bacterial genes from the latter parent (*nptII*, *aad*, and *uidA*) that were used to select modified plants in the laboratory.

Roundup Ready Flex[®] and Roundup Ready Flex[®]/Bollgard II[®] cotton have been approved previously for limited and controlled releases under DIR licences 035/2003 and 055/2004.

The application requests approval for commercial scale cultivation without containment measures south of latitude 22° South, and the use of the GM cotton plants and their by-products in the same manner as non-GM or other commercially released GM cotton. This would include sale of seed for commercial planting, use in human food and stockfeed, sale of lint, export of seed and unrestricted transport south of latitude 22° South. Monsanto also proposes restricted transport of ginned cotton seed from the release to areas north of latitude 22° South for use only as stockfeed.

Under Australia's integrated framework for the regulation of genetically modified organisms Monsanto will also require approval from Food Standards Australia New Zealand for the use of oil and linters from the Roundup Ready Flex[®] cotton in food. In addition, Monsanto will require approval from Australian Pesticides and Veterinary Medicines Authority to extend the current registration of Roundup Ready[®] Herbicide to allow its application to Roundup Ready Flex[®] cotton (including application beyond the seedling stage).

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 cotton lines previously approved for commercial release by the Regulator, in the context of the 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 (i.e. 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 41 events compiled during the hazard identification process, eight were selected for further assessment. The potential adverse outcomes to the environment associated with these events were: toxicity for non-target invertebrates and weediness. The remaining 33 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 3 for more information).

Risk of toxicity to non-target invertebrates

One event was considered that might cause toxicity in non-target invertebrates via direct or indirect ingestion of the insect resistance proteins in the GM cotton lines as a result of this release (event 1).

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

Risk of weediness

Seven events were considered that might result in the GM cotton lines exhibiting greater weediness than non-GM cotton or other GM cotton lines previously approved for commercial release:

- Expression of the herbicide tolerance gene increasing spread and persistence of the GM cotton plants through tolerance to glyphosate (event 2)
- Expression of the herbicide tolerance and insect resistance genes in combination increasing spread and persistence of the GM cotton plants through tolerance to glyphosate and reduced insect attack on the plants (event 3)
- Dispersal of GM seed during transport or storage north of latitude 22° South (event 4)
- Dispersal of seed via use of GM cotton seed as stockfeed in areas north of latitude 22° South (event 5)
- Dispersal of GM seed via flooding north of latitude 22° South (event 6)

- Expression of the herbicide tolerance gene in other cultivated (non-GM or commercially released GM) or naturalised cotton plants increasing spread and persistence through providing glyphosate tolerance (event 7)
- Expression of the herbicide tolerance and insect resistance genes in combination in other cultivated (non-GM or commercially released GM) or naturalised cotton plants increasing spread and persistence through providing glyphosate tolerance and reduced insect attack on the plants (event 8).

The risk assessment considered the consequence and likelihood of harm that might result from each of the above events. The estimates of risk for events 2, 3, 6, 7 and 8 are **negligible** and for events 4 and 5 are **low**.

RISK MANAGEMENT

The *Risk Analysis Framework* defines negligible risks as insubstantial, with no present need to invoke actions for their mitigation. Low risks are defined as minimal but may invoke actions for mitigation beyond normal practices.

The level of risk to the health and safety of people or the environment for six of the eight events that were assessed was estimated as negligible. Therefore, no risk management measures have been imposed. The risk estimate for the two remaining events was low. Hence, treatment measures have been imposed to manage these risks.

The licence conditions, detailed in Chapter 6 of the RARMP, require the applicant to minimise dissemination of GM cotton seed, and spread and persistence of GM cotton plants, in areas north of latitude 22° South.

CONCLUSIONS OF THE RARMP

The risk assessment concludes that this commercial release of herbicide tolerant and herbicide tolerant/insect resistant GM cotton lines poses **low to 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 specific risk treatment measures. However, licence conditions have been imposed to treat the low risks to the environment which relate to the use of GM cotton seed as stockfeed in northern Australia. Therefore, licence conditions have been imposed to minimise spread and persistence of the GMOs north of latitude 22° South.