



11 October 2006

**TECHNICAL SUMMARY OF THE
RISK ASSESSMENT AND RISK MANAGEMENT PLAN
for
APPLICATION NO. DIR 064/2006
from
MONSANTO AUSTRALIA LIMITED**

Introduction

The Gene Technology Regulator (the Regulator) has decided to issue a licence (DIR 064/2006) to Monsanto Australia Limited (Monsanto) for dealings involving the intentional release of up to 24 genetically modified (GM) cotton lines into the Australian environment.

The DIR 064/2006 licence permits the limited and controlled release of up to 24 cotton lines modified to enhance water use efficiency. The release will occur on up to 10 sites of up to 2 hectares (ie a maximum total area of 20 hectares) during each of the two summer growing seasons in 2006/07 and 2007/08 in a number of shires in New South Wales and Queensland.

The *Gene Technology Act 2000* (the Act), the *Gene Technology Regulations 2001* (the Regulations) and corresponding state and territory law govern the comprehensive and highly consultative process undertaken by the Regulator before making a decision on whether or not to issue a licence to deal with a GMO.

The Regulator's *Risk Analysis Framework* explains the approach used to evaluate licence applications and to develop the Risk Assessment and Management Plans (RARMPs) that form the basis of her decisions¹.

The RARMP for DIR 064/2006 has been finalised in accordance with the gene technology legislation. Matters raised in the consultation process regarding risks to the health and safety of people or the environment from the dealings proposed by the applicant were taken into account by the Regulator in deciding to issue a licence and the licence conditions that have been imposed.

¹ More information on the assessment of licence applications and copies of the Risk Analysis Framework are 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>> and <<http://www.ogtr.gov.au/pdf/public/raffinal2.2.pdf>>, respectively.

Application

Title:	Limited and controlled release of water-efficient GM cotton*
Applicant:	Monsanto Australia Limited
Common name of the parent organism:	Cotton
Scientific name of the parent organism:	<i>Gossypium hirsutum</i> L.
Modified traits:	Water use efficiency, herbicide tolerance, antibiotic resistance
Identity of the genes responsible for the modified traits:	<ul style="list-style-type: none"> • Each cotton line contains 1 of 24 different genes for water use efficiency derived from various plants including <i>Arabidopsis thaliana</i>, <i>Zea mays</i>, <i>Glycine max</i>, <i>Oryza sativa</i> and <i>Gossypium hirsutum</i>, or the bacterium <i>Escherichia coli</i>; and • <i>cp4 epsps</i> gene from <i>Agrobacterium</i> sp. strain CP4 (herbicide tolerance selectable marker); or • <i>nptII</i> from the bacterium <i>E. coli</i> (antibiotic resistance selectable marker).
Proposed locations:	Up to 10 sites per season in the NSW shires of Balranald, Bourke, Central Darling, Carathool, Coonamble, Hay, Lachlan, Moree Plains, Narrabri, Narromine, Walgett, Warren or Lake Tandou (an unincorporated area) and/or in the QLD shires of Paroo, Balonne, Murilla, Tara, Chinchilla, Waggamba, Wambo, Jondaryan or Pittsworth
Proposed release size:	Up to 2 hectares per site and a maximum of 20 hectares in total per growing season over 2 seasons
Proposed time of release:	Summer 2006/07 and 2007/08

* The original title of the licence application submitted by Monsanto was *Field testing of drought tolerance in cotton*.

Monsanto applied for a licence to release up to 24 cotton lines genetically modified to enhance water use efficiency² into the environment. The release of the GM cotton lines is intended to take place on up to 10 sites of up to 2 hectares (ie a maximum total area of 20 hectares) during each of the two summer growing seasons in 2006/07 and 2007/08³.

The release may take place in a number of shires in New South Wales and/or Queensland (refer to the application table).

The purpose of the trial is to conduct early stage ('proof of concept') research to assess the agronomic characteristics of the GM cotton lines in the field including water use efficiency, yield and fibre quality under different irrigation treatments. Seed will be collected for further studies and possible future releases of lines selected for further development (subject to additional applications and approvals).

The GM cotton lines were derived by transforming plants of the cotton cultivar Coker 130, which is not grown commercially in Australia. They contain 1 of 24 different introduced genes intended to improve water use efficiency in the field without unacceptable impacts on agronomic characteristics including fibre quantity. Twenty three of the genes are derived from the plants *Arabidopsis thaliana* (thale cress), *Zea mays* (corn), *Glycine max* (soybean), *Oryza sativa* (rice) and *Gossypium hirsutum* (cotton)⁴. One gene is derived from the gut bacterium *Escherichia coli*.

The introduced genes encode proteins that are intended to confer water use efficiency by modulating biochemical pathways, functioning as molecular chaperones, or regulating signal transduction and expression of endogenous genes in the cotton plants.

The GM cotton lines also contain either an *Agrobacterium* gene (*cp4 epsps*, conferring tolerance to the herbicide glyphosate) or an *E.coli* gene (*nptII*, conferring resistance to the

² Water use efficiency in cotton can be defined as the measure of total yield (lint) produced per unit of water supplied to the crop.

³ Monsanto varied its original request for sites up to 1 hectare and a total maximum area of 10 hectares per season to ensure experimental controls and containment measures could be accommodated.

⁴ In its initial application, Monsanto indicated all 24 introduced genes were derived from plants.

antibiotics kanamycin or neomycin) that were used to select modified plants during initial research and development work in the laboratory.

The applicant proposed measures to limit the spread and persistence of the GM cotton lines in the environment. These were taken into account in establishing the risk assessment context for the proposed release, and their suitability for limiting the release to the locations, size and duration proposed by the applicant was considered as part of the risk assessment process. No products from the GM cotton plants will be used for human food, animal feed or for the production of fabrics and/or other cotton commodities.

Some details including the names of the introduced genes, their encoded proteins and functions, and details of the gene constructs, including plasmid maps, and certain regulatory sequences, have been declared Confidential Commercial Information (CCI) under section 185 of the Act. This information was considered during the preparation of the RARMP and was also made available to the prescribed expert groups and agencies that were consulted on this application.

Risk assessment

The risk assessment considered information contained in the application, previous GM cotton assessments, current scientific knowledge, and issues relating to risks to human health and safety and the environment raised in submissions received during consultation with a wide range of prescribed experts, agencies and authorities on the application (summarised in Appendix B of the RARMP). No further issues were raised in the comments received on the consultation version of the RARMP (see Appendix D).

Advice received from members of the public on the application and consultation on the RARMP, and how it was considered, is summarised in Appendices C and E, respectively.

A reference document, *The Biology and Ecology of Cotton (Gossypium hirsutum) in Australia* (OGTR 2002), was produced to inform the risk assessment process for licence applications involving GM cotton plants. The document is available from the OGTR or from the website <<http://www.ogtr.gov.au>>.

The risk assessment first considered what harm to the health and safety of people or the environment could arise due to gene technology (hazard identification), and how it could happen during this release of GMOs, in comparison to the non-GM parent organism and in the context of the proposed receiving environment.

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.

The hazard identification process considered the circumstances by which the health and safety of people or the environment may be adversely affected by exposure to the GMOs, GM plant materials, GM plant by-products, the introduced genes, or products of the introduced genes.

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, alter characteristics that may impact on the spread and persistence of the GM plants or produce unintended

changes in their biochemistry or physiology. In addition, consideration was given to the opportunity for gene flow to other organisms and its effects.

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
- containment and disposal measures proposed by the applicant to limit the spread and persistence of the GM plants
- none of the GM plant materials will be used for any other purpose
- widespread presence of the same or similar proteins and enzymatic products in the environment and lack of evidence of harm from these proteins and their products
- the lack of known toxicity or allergenicity of the proteins (and enzymatic products) encoded by the introduced genes
- limited capacity of the GM cotton lines to spread and persist in the areas proposed for release
- limited ability and opportunity for the GM cotton lines to transfer the introduced genes to other sexually related species.

Therefore, as no risks to the health and safety of people or the environment were identified from the proposed limited and controlled release of GM cotton lines the level of risk is considered to be **negligible**.

Risk management

A risk management plan builds upon the risk assessment to consider whether any action is required to mitigate the identified risks, and what can be done to protect the health and safety of people and the environment.

As none of the 18 events that were characterised in the risk assessment process are considered to give rise to an identified risk that requires further assessment, the level of risk to human health and safety and the environment from the proposed release of GM cotton lines is considered to be **negligible** (ie insubstantial with no present need to invoke actions for their mitigation).

However, containment and disposal measures have been imposed to restrict the release to the locations, size and duration requested by the applicant, as these were important parameters in establishing the context for assessing the risks.

Licence conditions

A number of licence conditions have been imposed to limit and control the release, including requirements to:

- implement measures to control the spread and persistence of the GMOs in the environment
- comply with the Regulator's guidelines and policies for the transport, supply, storage and disposal of GMOs (*Guidelines for the transport of GMOs, June 2001; Policy on transport and supply of GMOs, July 2005*)
- develop compliance and contingency plans and establish related reporting structures

- inform anyone covered by the licence of their obligations.

Other regulatory considerations

Australia's gene technology regulatory system operates as part of an integrated legislative framework. The Regulator sought input on the preparation of the RARMP from other agencies that also regulate GMOs or GM products including Food Standard Australia New Zealand (FSANZ), Australian Pesticides and Veterinary Medicines Authority (APVMA), Therapeutic Goods Administration (TGA), National Industrial Chemicals Notification and Assessment Scheme (NICNAS), National Health and Medical Research Council (NHMRC) and Australian Quarantine Inspection Service (AQIS). Dealings conducted under a licence issued by the Regulator may also be subject to regulation by one or more of these agencies⁵.

FSANZ is responsible for human food safety assessment, including GM food. As the trial involves early stage research the applicant does not intend any material from the GM cotton lines proposed for release to be used in human food. Accordingly the applicant has not applied to FSANZ for evaluation of any of the GM cotton lines for use in human food. However, FSANZ approval would need to be obtained before they could be used in this way.

AQIS is responsible for monitoring imports to prevent the introduction of exotic pests, weeds and diseases into the environment. An importer is required to notify AQIS if they are importing GMOs. Additionally, as the importation of the water-efficient GM cotton seed constituted a dealing under the *Gene Technology Act 2000*, the importer required an authorisation under this Act for the import to lawfully proceed. Seed from the water-efficient GM cotton lines has been imported by Monsanto under an AQIS seed import permit.

Identification of issues to be addressed for future releases

In view of the very early stage of this research, the risk assessment identified additional information that may be required to assess an application for a larger scale trial, reduced containment conditions or a commercial release of any of these GM cotton lines. This would include:

- molecular characterisation of the introduced genetic materials in the GM cotton lines, genotypic stability, and expression levels of the introduced genes in the GM cotton lines
- data on the potential toxicity of plant material from the GM cotton lines including levels of endogenous toxins
- data on the allergenicity of the proteins encoded by the introduced genes for water use efficiency, and plant material from the GM cotton lines
- biochemical, physiological and agronomic characteristics of the GM cotton lines indicative of weediness including measurement of tolerance to environmental stresses (eg drought, cold and salt) and/or reproductive capacity (eg seed number and window of flowering).

Conclusions of the RARMP

The risk assessment concludes that this proposed limited and controlled release of up to 24 cotton lines modified to enhance water use efficiency into the areas proposed in New South

⁵ More information on Australia's integrated regulatory framework for gene technology is contained in the *Risk Analysis Framework* available from the Office of the Gene Technology Regulator (OGTR). Free call 1800 181 030 or at <<http://www.ogtr.gov.au/pdf/public/raffinal2.2.pdf>>.

Wales and Queensland 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, conditions have been imposed to contain the release to the locations, size and duration requested by the applicant.