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

APPLICATION FOR LICENCE FOR INTENTIONAL RELEASE OF GMOs INTO THE ENVIRONMENT: Application No. DIR 081/2007

SUMMARY INFORMATION

Project Title:	Limited and controlled release of cotton genetically modified for enhanced water use efficiency[1].
Applicant:	Monsanto Australia Limited
Common name of the parent organism:	Cotton
Scientific name of the parent organism:	*Gossypium hirsutum* L.
Modified trait(s):	Enhanced water use efficiency, herbicide tolerance, antibiotic resistance
Identity of the gene(s) responsible for the modified trait(s):	Each cotton line[2] contains: • one of fifty-six different genes[3] for water use efficiency derived from various plants, bacteria, yeast and fungi • *cp4 epsps* gene from *Agrobacterium* sp. strain CP4 (herbicide tolerance selectable marker); or • *nptII* from the bacterium *Escherichia coli* (antibiotic resistance selectable marker)
Proposed Location(s)	Up to 20 sites per year in the New South Wales shires of Balranald, Bourke, Central Darling, Carathool, Coonamble, Hay, Lachlan, Lake Tandou, Moree Plains, Narrabri, Narromine, Walgett and Warren; Queensland shires of Balonne, Brisbane, Chinchilla, Jondaryan, Murilla, Paroo, Pittsworth, Tara, Toowoomba, Waggamba and Wambo; and the Western Australia shire of Wyndham-East Kimberley
Proposed Release Size:	Up to 40 ha in total per year
Proposed Release Dates:	2008/09 to 2009/10

Introduction

The *Gene Technology Act 2000* (the Act) in conjunction with the *Gene Technology Regulations 2001*, an inter-governmental agreement and corresponding legislation that is being enacted in each State and Territory, comprise Australia's nationally consistent regulatory system for gene technology. Its objective is to protect the health and safety of people, and the environment, by identifying risks posed by or as a result of gene technology, and managing those risks by regulating certain dealings with genetically modified organisms (GMOs).

[1]The original title of the licence application submitted by Monsanto was *Field testing of water use efficient cotton.*
[2] The term 'line' is used to denote plants derived from a single plant containing a specific genetic modification made by one transformation event.
[3] Some details of the gene constructs used for the genetic modification have either been declared, or are the subject of an application for, Confidential Commercial Information (CCI) under section 185 of the Act.

The Act establishes a statutory officer, the Gene Technology Regulator (the Regulator), to administer the legislation and make decisions under the legislation. The Regulator is supported by the Office of the Gene Technology Regulator (OGTR), an Australian Government regulatory agency located within the Health and Ageing portfolio.

The legislation sets out the requirements for considering applications for licences for dealings with GMOs and the matters that the Regulator must take into account before deciding whether, or not, to issue a licence. The Regulator's *Risk Analysis Framework*[4] outlines the assessment process that will be followed.

The application and the proposed dealings

The Regulator has received a licence application from Monsanto Australia Limited (Monsanto) for a licence for dealings involving the intentional release of genetically modified (GM) cotton (*Gossypium hirsutum* L.) into the Australian environment on a limited scale under controlled conditions.

Up to 504 GM cotton lines are proposed for release. Each line contains one of 56 different genes derived from various plants, bacteria, yeast or fungi. The introduced genes encode proteins that are intended to confer enhanced water use efficiency.

The purpose of the trial is to conduct proof of concept experiments to evaluate agronomic characteristics including water use efficiency, yield and fibre quality of the GM cotton lines under optimal and water stress conditions. Seed would be collected for further studies, including possible future releases (subject to additional assessments and approvals).

The applicant proposes to limit the release to up to 20 sites totalling no more than 40 hectares (ha) per annum over a two year period between 2008 and 2010. The sites may be located in the New South Wales shires of Balranald, Bourke, Central Darling, Carathool, Coonamble, Hay, Lachlan, Lake Tandou (unincorporated), Moree Plains, Narrabri, Narromine, Walgett and Warren; the Queensland shires of Balonne, Brisbane, Chinchilla, Jondaryan, Murilla, Paroo, Pittsworth, Tara, Toowoomba, Waggamba and Wambo; and the Western Australia shire of Wyndham-East Kimberley. Glasshouses in Brisbane and Toowoomba would be producing the seed for planting at field sites.

The applicant has also proposed a number of control measures to restrict the dissemination or persistence of the GM plants and their introduced genetic material, that will be considered in the assessment of this application, including:

- locating the proposed trial sites at least 50 m away from natural waterways
- surrounding the trial sites (except glasshouses) by a 20 m pollen trap of non-GM (conventional) cotton or GM cotton that the Regulator has approved for commercial release (eg Bollgard II®, Roundup Ready® or Roundup Ready Flex® cotton)
- the glasshouses are located at least 20 km from the nearest commercial cotton crop
- adopting an insect control program within the glasshouses
- harvesting and ginning all cotton plant materials (GM and non-GM) separately from other commercial cotton crops
- removing and/or destroying all cotton plant materials from the trail site and adjacent areas (eg pollen trap, equipment cleaning areas) after harvest, except for materials required for future research or release

[4] Available on the Office of the Gene Technology Regulator (OGTR) website at <http:www.ogtr.gov.au/pubform/riskassessments.htm>. Information on the assessment of licence applications is also available at <http://www.ogtr.gov.au/ir/process.htm> or Freecall 1800 181 030.

- transporting GM seed and plant materials in accordance with OGTR transportation guidelines
- storing GM plant materials (required for further study or future release) in certified PC2 facilities
- monitoring trial sites after harvest for a minimum of 12 months and destroying any cotton volunteers
- restricting personnel with access to the site to authorised Monsanto staff only
- not using the GM plant material, including cotton seed, cotton seed oil and meal for human food or animal feed

Confidential Commercial Information

Some details of 21 of the 56 genes, including the names of the introduced genes and their encoded proteins, and the gene constructs, including plasmid maps and certain regulatory sequences, have previously been declared Confidential Commercial Information (CCI) under section 185 of the Act (in relation to limited and controlled release Licence DIR064/2006). The applicant has submitted a request that details of the other 35 genes and their gene constructs be similarly protected which is still under consideration. All CCI will be made available to the prescribed experts and agencies that will be consulted on the Risk Assessment and Risk Management Plan (RARMP) for this application.

Parent organism

The parent organism is cultivated cotton (*Gossypium hirsutum* L.), which is exotic to Australia and is grown as an agricultural crop in New South Wales and southern and central Queensland. The cultivar Coker 130 was used to produce the GM cotton lines proposed for release. This cultivar is often used as a starting point of research as it can be easily genetically modified in the laboratory. It is not grown commercially in Australia.

The genetic modifications and their effect

The cotton lines were genetically modified using one of 56 different genes that have demonstrated the capacity to produce a water use efficient phenotype in cotton and other plants by regulating expression of endogenous genes, or modulating biochemical pathways in the cotton plants. Most of the introduced genes were derived from the plants *Arabidopsis thaliana* (thale cress), *Zea mays* (corn), *Glycine max* (soybean), *Oryza sativa* (rice), *Gossypium hirsutum* (cotton), *Beta vulgaris* (beetroot), *Cucurbita ficifolia* (figleaf gourd), *Triticum aestivum* (wheat) and the moss, *Physcomitrella patens*. The remainder of the introduced genes were derived from the bacteria *Agrobacterium tumefaciens*, *Bacillus haloduras*, *B. subtillius*, and *Escherichia coli*; or the fungus (*Saccharomyces cervisiae*). The introduced genes may also confer tolerance to other abiotic and biotic stresses. However, at this early stage of research, the nature and extent of such stress tolerance is not known. This uncertainty will be taken into account in the risk analysis process.

Additionally, the GM cotton lines contain the antibiotic resistance selectable marker gene, *nptII* or the herbicide tolerance selectable marker gene, *cp4 epsps*. The *nptII* gene, encoding a neomycin phosphotransferase type II enzyme, was originally derived from the common gut bacterium *Escherichia coli* and confers kanamycin or neomycin resistance on the GM plant. The *cp4 epsps* gene, which encodes the 5-enolpyruvylshikimate-3-phosphate synthase enzyme, is from the common soil bacterium *Agrobacterium* sp. strain CP4 and confers tolerance to the herbicide glyphosate. The *nptII* gene and *cp4 epsps* genes were used in the laboratory to select modified plant tissues during the initial development of the plants from which the GM lines are derived.

Short regulatory sequences that control expression of the introduced genes are also present in all the GM cotton lines. These are derived from the plants *Arabidopsis thaliana* (thale cress), *Petunia x hybrida* (petunia), *Gossypium barbadense* (cotton) and *Pisum sativum* (field pea), the bacterium

Agrobacterium tumefaciens, and Cauliflower Mosaic Virus (CaMV) and Figwort Mosaic Virus (FMV). Although *A. tumefaciens*, CaMV and FMV are plant pathogens, the regulatory sequences comprise only a small part of their respective total genomes and are not in themselves capable of causing disease.

Method of genetic modification

Individual gene constructs were introduced into plant tissues of the cotton cultivar Coker 130 by *Agrobacterium tumefaciens*-mediated transformation. The constructs are 'disarmed' since they lack the genes that encode the tumorigenic functions of *A. tumefaciens*. This method has been widely used in Australia and overseas for introducing new genes into plants without causing any biosafety problems. Each GM cotton line resulted from an independent transformation event with one gene construct.

Previous releases of the same or similar GMOs

The Regulator has previously issued a licence to Monsanto for the limited and controlled release of GM cotton lines containing 21 of the same genes for enhanced water use efficiency (Licence DIR064/2006). There have been no previous releases of the GM cotton lines containing the other 35 genes for water use efficiency in Australia.

GM cotton lines containing some of the same genes have been trialled in the United States of America. There have been no reports of adverse effects on human health or the environment resulting from any of these releases.

Suitability of Applicant

Section 43(2)(f) of the Act requires the Regulator to be satisfied regarding the suitability of the applicant to hold a licence as a pre-requisite for considering DIR applications. The matters to be considered are outlined in section 58 of the Act and include relevant convictions, revocation of a licence or permit relating to the health and safety of people, and capacity to meet the conditions of the licence.

The Regulator has determined that Monsanto Australia Limited currently meets the suitability requirements and will verify this continues to be the case prior to making any decision regarding the issuing of a licence.

Consultation process for this DIR application

The Regulator has made an assessment of whether the application should be considered as a limited and controlled release, under section 50A of the Act. As its principal purpose is to enable the conduct of experiments, and the applicant has proposed limits on the size and duration of the release and controls to restrict the dissemination and persistence of both the GMO and its genetic material in the environment, **the Regulator has decided that the application qualifies as a limited and controlled release.**

This means that the Regulator is not required to consult on the assessment of this application until after a Risk Assessment and Risk Management Plan (RARMP) has been prepared in accordance with section 51 of the Act. In the interim, copies of the application are available on request from the OGTR. Please quote application number DIR 081/2007.

The Regulator will seek comment on the consultation RARMP from the public as well as a wide range of experts, agencies and authorities including the Gene Technology Technical Advisory Committee, State and Territory Governments, Australian Government agencies, the Australian Minister for the Environment, Heritage and the Arts and relevant local councils. The RARMP will then be finalised, taking into account matters raised relating to risks to human health and safety and the environment, and form the basis of her decision whether or not to issue a licence.

At this stage, **the RARMP is expected to be released for comment in mid May 2008.** The public will be invited to provide submissions on the RARMP via advertisements in the media and direct mail to anyone registered on the OGTR mailing list. The RARMP and other related documents will be available on the OGTR website, or in hard copy from the OGTR.

If you have any questions about the application or the assessment process, or wish to register on the mailing list, please contact the OGTR at:

The Office of the Gene Technology Regulator
MDP 54
GPO Box 9848
Canberra ACT 2601
Tel: 1800 181 030
Fax: 02 6271 4202
Email: ogtr@health.gov.au
Website http://www.ogtr.gov.au