

APPLICATION FOR LICENCE FOR INTENTIONAL RELEASE OF GMOs INTO THE ENVIRONMENT: Application No. DIR 064/2006

SUMMARY INFORMATION

Project Title:	Limited and controlled release of water-efficient GM cotton ¹
Applicant:	Monsanto Australia Limited
Common name of the parent organism:	Cotton
Scientific name of the parent organism:	<i>Gossypium hirsutum</i> L.
Modified trait(s):	Water use efficiency, herbicide tolerance, antibiotic resistance
Identity of the gene(s) responsible for the modified trait(s):	<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 Location(s)	Up to 10 sites per season may be trialled 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 20 hectares in total per growing season over 2 seasons
Proposed Release Dates:	Summer 2006/07 and 2007/08

¹The original title of the licence application submitted by Monsanto was *Field testing of drought tolerance in cotton*.

Introduction

The *Gene Technology Act 2000* (the Act) took effect on 21 June 2001. The Act, supported by the *Gene Technology Regulations 2001*, an inter-governmental agreement and corresponding legislation that is being enacted in each State and Territory, underpins 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).

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 licence².

The application and the proposed dealings

The OGTR has received an application from Monsanto Australia Ltd (Monsanto) for a licence for the intentional release of genetically modified (GM) cotton (*Gossypium hirsutum* L.) lines into the environment on a limited scale and under controlled conditions.

Up to 24 GM cotton lines are proposed for release. Each line contains 1 of 24 different introduced genes. 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). One gene is derived from the common gut bacterium *Escherichia coli*. The introduced genes encode proteins that are intended to confer enhanced water use efficiency by regulating expression of endogenous genes or modulating biochemical pathways in the cotton plants.

This is a proof of concept field trial. The purpose is to evaluate the agronomic characteristics, water use efficiency, yield and fibre quality of the GM cotton lines under optimum watering and water stress treatments. Seed will also be collected for further studies including possible future releases (subject to additional assessments and approvals).

The GM cotton lines proposed for release have been imported from the United States of America (USA) by Monsanto. The field trial will be conducted contra-season to similar trials in the USA to accelerate selection of GM cotton lines that exhibit the water use efficiency trait.

The release is proposed to take place at up to 10 sites per season on a maximum area of 2 hectares (ha) per site during each of the 2 summer growing seasons of 2006/07 and 2007/08. The sites may be located in the New South Wales shires of Balranald, Bourke, Central Darling, Carathool, Coonamble, Hay, Lachlan, Moree Plains, Narrabri, Narromine, Walgett, Warren or Lake Tandou (an incorporated area) and/or in the Queensland shires of Paroo, Balonne, Murilla, Tara, Chinchilla, Waggamba, Wambo, Jondaryan or Pittsworth.

The applicant has proposed the following containment measures:

- locating the proposed trial sites at least 50 m away from natural waterways
- surrounding the trial sites by a 20 m pollen trap of non-GM cotton or GM cotton that the Regulator has approved for commercial release (Bollgard II[®], Roundup Ready[®] or Roundup Ready Flex[®] cotton), or a 50 metre isolation zone where there are no cotton crops or naturalised cotton populations within 450 metres of the trial sites
- treatment of all plants including non-GM cotton grown at the trial sites, which includes the plants in the pollen trap, as if they were the GM cotton plants proposed for release in relation to harvesting and post harvest destruction
- harvesting all cotton plant materials (GM and non-GM) separately from other commercial cotton crops
- ginning of all harvested seed cotton from the proposed trial (GM and non-GM) in a certified PC2 facility or a facility approved in writing by the Regulator
- storage of plant materials from the proposed trial (required for future study or release) in certified PC2 facility or a facility approved in writing by the Regulator

² 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

- destruction of GM plant materials used in laboratory analysis and not required for future study or release
- after harvest destruction of all cotton plant materials, in and adjacent (eg equipment cleaning areas) to the trial sites, including the pollen trap, by stalk pulling, uprooting by ploughing, burning, treatment with herbicide, or hand weeding
- post harvest monitoring of trial sites for 12 months and destruction of any cotton volunteers
- transportation of GM cotton seed and plant materials in accordance with OGTR transportation guidelines.

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 will be made available to the prescribed expert groups and agencies that will be consulted in the preparation of the RARMP.

None of the cotton plants from the release, or their by-products, are proposed to be used for animal or human food.

Previous releases of the GMOs

There have been no previous releases of these, or other, water-efficient GM cotton lines in Australia.

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 24 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.

Genetic modification and its effect

The GM cotton lines contain 1 of 24 different introduced genes that have demonstrated the capacity to produce a water-efficient phenotype in cotton and/or other plants. Twenty three of the genes are derived from the plants *A. thaliana*, *Z. mays*, *G. max*, *O. sativa* and *G. hirsutum*. One gene is derived from the gut bacterium *Escherichia coli*. The introduced genes may also confer tolerance to other abiotic and biotic stresses. However, at this early stage of research the potential tolerance of the GM cotton to other abiotic and biotic stresses is not known.

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 for the enzyme neomycin phosphotransferase type II enzyme, was originally derived from the common gut bacterium *E. 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 during the initial stage of selection of GM plants in the laboratory. The applicant does not intend to apply these antibiotics or glyphosate during the field trial.

Short regulatory sequences that control expression of the introduced genes are also present in the GM cotton lines. These are derived from the plants *A. thaliana*, *Petunia x hybrida* and *Pisum sativum* (field pea), *G. max*, the plant viruses CaMV and Figwort Mosaic Virus (FMV), and the bacteria *A. tumefaciens* and *E. coli*. Although *A. tumefaciens*, CaMV and FMV are

plant pathogens, and *E. coli* is a facultative human pathogen, the regulatory sequences comprise only a small part of their total respective genomes, and are not infectious or capable of causing disease.

Method of genetic modification

Twenty four different plasmid vectors were prepared. Each contained a plant gene that is expected to confer water use efficiency, either a *cp4 epsps* herbicide tolerance gene or *nptII* antibiotic resistance gene, and regulatory sequences. The individual vectors were introduced into plant tissues of the cotton cultivar Coker 130 by *A. tumefaciens*-mediated transformation. The vectors 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 was the result of an independent transformation event with one type of plasmid vector.

Consultation on preparation of the Risk Assessment and Risk Management Plan

The Regulator has made an initial assessment as to whether the proposed release may pose significant risks to human health and safety or the environment, in accordance with section 49 of the Act. Based on the characteristics of the GM cotton lines and the introduced genes, and the limited scale and scope of the dealings, **the Regulator has decided that the proposed release does not pose a significant risk to human health and safety or the environment.**

This means that the Regulator is **not required to seek public comment** on the assessment of this proposal until after a risk assessment and risk management plan (RARMP) has been prepared for consultation. In the interim, copies of the application are available on request from the OGTR. Please quote application number DIR 064/2006.

In preparing the RARMP, the Regulator will seek input from a wide range of key stakeholders and expert groups including State and Territory Governments, Australian Government agencies, the Minister for the Environment and Heritage, the Gene Technology Technical Advisory Committee and relevant local councils. The Regulator will consult again with these prescribed agencies and authorities, as well as the public, in finalising the RARMP, which then forms the basis of her decision whether or not to issue a licence.

The consultation version of the RARMP will be released for a six week consultation period by **early August 2006**. 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 from the OGTR, or on the OGTR website.

If you have any questions about the application or the assessment process, please contact the OGTR at:

The Office of the Gene Technology Regulator
MDP 54
PO Box 100
WODEN ACT 2606
Tel: 1800 181 030
Fax: 02 6271 4202
Email: ogtr@health.gov.au
Website <http://www.ogtr.gov.au>