



APPLICATION FOR LICENCE FOR INTENTIONAL RELEASE OF GMOs INTO THE ENVIRONMENT: Application No. DIR 067/2006

SUMMARY INFORMATION

Project Title:	Limited and controlled release of GM cotton lines with tolerance to waterlogging stress ¹
Applicant:	CSIRO
Common name of the parent organism:	Cotton
Scientific name of the parent organism:	<i>Gossypium hirsutum</i> L.
Modified trait(s):	Waterlogging tolerance, antibiotic resistance
Identity of the gene(s) responsible for the modified trait(s):	<ul style="list-style-type: none">• <i>AHb1</i> (non-symbiotic phytohaemoglobin), from <i>Arabidopsis thaliana</i> (waterlogging tolerance)• <i>nptII</i> (neomycin phosphotransferase type II) from the bacterium <i>Escherichia coli</i> (antibiotic resistance selectable marker)
Proposed Location(s)	One site per season over three summer growing seasons in the shire of Narrabri (NSW)
Proposed Release Size:	Up to 0.1 hectare per season over three summer growing seasons
Proposed Release Dates:	September 2006 to May 2009

¹The title of the licence application submitted by CSIRO is *Evaluation under field conditions of cotton plants expressing a phytohaemoglobin protein*.

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.

²More 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.

The application and the proposed dealings

The OGTR has received an application from CSIRO 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.

This is a proof of concept field trial. The GM cotton lines proposed for release contain a waterlogging tolerance gene, *AHb1*, derived from a common plant, thale cress. The introduced gene encodes a protein (AHb1) which is thought to provide tolerance to waterlogging stress, a significant problem in global cotton production, particularly on clay soils. In Australia, a significant proportion of cotton production occurs on clay soils, especially in New South Wales.

As clay soils drain poorly they are susceptible to waterlogging which decreases the amount of oxygen available to the cotton plants. This in turn leads to poor root growth and nutrient uptake resulting in leaf chlorosis, reduced boll number and thus reduced lint yields.

The purpose of the proposed release is to conduct early stage research with up to 30 GM cotton lines to measure the expression levels of the waterlogging tolerance gene; to evaluate the tolerance of the GM cotton plants to waterlogging stress under simulated conditions; and to assess their agronomic performance in the field. Cotton seed will also be collected for further studies and possible future releases (subject to additional applications and assessments).

The release is proposed to take place at one site in the shire of Narrabri, New South Wales (NSW) on a maximum total area of 0.1 ha during each of the three summer growing seasons between September 2006 and May 2009.

The applicant has proposed a number of containment measures including:

- locating the proposed trial sites 50 m away from natural waterways or other cotton breeding areas
- surrounding the trial sites by a 20 m pollen trap of non-GM or commercially released GM cotton (Bollgard II[®]) cotton and treating all plants in this area in the same way as the GM cotton plants proposed for release
- managing the GM cotton in the same manner as non-GM cotton, including application of insecticides
- after harvest, destruction of all cotton plant materials on the sites including the pollen trap by burning
- post harvest monitoring of trial sites for 12 months and destroying any volunteer cotton plants
- transportation of GM cotton seed and plant materials in accordance with OGTR transportation guidelines
- storage of GM plant materials (required for further study or future release) in certified PC2 facilities

Previous releases of the same or similar GMOs

There have been no previous releases of these GM cotton lines. However, CSIRO has performed four small (0.5 ha each) field trials of cotton, using genes other than *AHb1*, for tolerance to waterlogging. These were carried out under the former voluntary system that was overseen by the Genetic Manipulation Advisory Committee (GMAC): PR99 (1998), PR99X (1999), PRX2 (2000) and PRX3 (2001).

Parent organism

The parent organism is cultivated cotton (*Gossypium hirsutum* L.), which is exotic to Australia and is currently grown as an agricultural crop in NSW, and southern and central QLD. The cultivar Coker 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.

Genetic modification and its effect

The GM cotton lines contain the waterlogging tolerance gene, *AHb1*, which was derived from thale cress (*Arabidopsis thaliana*) and encodes a waterlogging tolerance protein (AHb1). The expression of this protein is induced during oxygen deficit (hypoxia) and other species of plants which over-express the *AHb1* gene have been shown to have improved tolerance to waterlogging stress.

Additionally, the GM cotton lines contain an antibiotic resistance selectable marker gene, neomycin phosphotransferase type II (*nptII*). The *nptII* gene encoding for the enzyme neomycin phosphotransferase was originally derived from the common gut bacterium *Escherichia coli*, and confers kanamycin or neomycin resistance on the GM plant. The *nptII* gene was used only as a selective marker during early stages of development of GM plants in the laboratory.

Short regulatory sequences that control expression of the genes are also present in all the GM cotton lines. These are derived from a plant (*Flavaria bidentis*), a soil bacterium (*Agrobacterium tumefaciens*) and two viruses (Subterranean clover stunt virus and Cauliflower mosaic virus). Although *A.tumefaciens*, Subterranean clover stunt virus and Cauliflower mosaic virus 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

Gene constructs containing the *AHb1* and *nptII* genes along with the regulatory sequences were introduced into cells from plants of the cotton cultivar Coker by *Agrobacterium*-mediated transformation. Tissue cultured plantlets were grown to mature plants in contained laboratory conditions, expression of the *AHb1* gene was assessed and plants with different levels of the AHb1 protein were selected for further characterisation. Each of the 30 GM cotton lines proposed for release is the result of a different genetic modification event.

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. Due to the characteristics of the GM cotton lines, the control measures that have been proposed, 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 067/2006.

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 the relevant local council. 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.

At this stage, the consultation version of the RARMP is expected to be released for a six week consultation period in **late September 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:

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