



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 083/2007

SUMMARY INFORMATION

Project Title:	Limited and controlled release of cotton genetically modified for enhanced waterlogging tolerance ¹
Applicant:	CSIRO
Common name of the parent organisms:	Cotton
Scientific name of the parent organisms:	<i>Gossypium hirsutum</i> L.
Modified trait(s):	Enhanced tolerance to waterlogging stress, antibiotic resistance
Identity of the gene(s) responsible for the modified trait(s):	<ul style="list-style-type: none">• <i>Pdc2</i> (pyruvate decarboxylase) from <i>Arabidopsis thaliana</i>• <i>Adh</i> (alcohol dehydrogenase) from <i>Gossypium hirsutum</i>• <i>Ahb1</i> (plant haemoglobin 1) from <i>Arabidopsis thaliana</i>• <i>nptII</i> (neomycin transferase type II) from the bacterium <i>E.coli</i> (antibiotic resistance selectable marker)• <i>hpt</i> (hygromycin phosphotransferase) from the bacterium <i>E.coli</i> (antibiotic resistance selectable marker)
Proposed Location(s)	One site in the shire of Narrabri (NSW)
Proposed Release Size:	Up to 0.1 ha per growing season
Proposed Release Dates:	October 2008 to May 2011

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).

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

¹ The title of the licence application submitted by CSIRO is *Limited and controlled release of waterlogging tolerant GM cotton*.

issue a licence. The Regulator's *Risk Analysis Framework*² outlines the assessment process that will be followed.

The application and the proposed dealings

The Regulator has received a licence application from CSIRO 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 20 GM cotton lines³ are proposed for release. They contain genes derived from cotton and *Arabidopsis* that are expected to enhance tolerance to waterlogging. The proposed trial would involve experiments to assess the tolerance of the GM cotton plants to waterlogging stress under simulated conditions in the field. Cotton seed will also be collected for further studies and possible future trials (subject to further approvals). The GM cotton plants will not be used for either human or animal consumption.

The applicant proposes to limit the release to one site in the shire of Narrabri (NSW) on an area of 0.1 ha per growing season between October 2008 and May 2011.

The applicant has also proposed a number of controls 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 site at least 50 metres from the closest cotton breeding sites and commercial cotton crops
- surrounding the trial site with a 20 metre pollen trap
- analysing GM plant materials from the trial in a certified PC2 facility and then destroying the materials (except saved seed)
- destroying all (GM and non-GM) plant materials from the field trial by slashing and incorporating the material into the soil for microbial degradation
- post harvest monitoring of the trial site for 12 months and destroying any volunteers
- transporting GM plant materials to and from the proposed trial site in accordance with OGTR transportation guidelines
- not using the GMO in human food or animal feed

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 315 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 GM cotton lines will contain one or more of three introduced genes encoding proteins expected to enhance tolerance to waterlogging. These genes include *Pdc2* from *Arabidopsis* encoding the enzyme pyruvate decarboxylase, *Adh* from cotton encoding the enzyme alcohol dehydrogenase and *Ahb1* from *Arabidopsis* encoding the plant haemoglobin 1 protein. Up to 10 lines will contain the

² Available on the 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.

³ The term 'line' is used to denote plants derived from a single plant containing a specific genetic modification made by one transformation event.

Pdc2 gene, up to 6 lines will contain both the *Pdc2* and *Adh* gene and up to 4 lines will contain the *Pdc2*, *Adh* and *Ahb1* genes.

In addition, the GM cotton lines contain the antibiotic resistance marker gene, *hpt*, and some lines also contain the *nptII* gene. The *hpt* gene encodes hygromycin phosphotransferase which confers resistance to the antibiotic hygromycin, and the *nptII* gene encodes the enzyme neomycin phosphotransferase, which confers kanamycin or neomycin resistance. Both genes are derived from the bacterium, *Escherichia coli* and were used during the initial development of the GM plants in the laboratory. The antibiotics will not be applied to the plants during the proposed field trial. While the *hpt* and *nptII* genes are derived from a bacterium capable of causing illness in humans, they comprise only a small part of the *E. coli* genome and are not capable of causing disease.

The GM cotton lines also contain short regulatory sequences that control expression of the introduced genes. These are derived from a plant (*Flaveria bidentis*), a soil bacterium (*Agrobacterium tumefaciens*) and two plant viruses (Cauliflower mosaic virus and Subterranean clover virus). The regulatory sequences of the plant pathogens comprise only a small part of their total respective genome and are not capable of causing disease.

Method of genetic modification

The GM cotton lines were produced using *Agrobacterium tumefaciens* mediated transformation. This technique introduces the gene and associated regulatory sequences into immature cotton embryos via the vector *A. tumefaciens*. The vector is 'disarmed' since it lacks the genes which encode the tumorigenic functions of *A. tumefaciens*. Transformed plant tissues were identified using expression of the marker genes and grown into plants in the laboratory.

GM lines containing a single waterlogging tolerance gene (plus a selectable marker gene) were produced via separate genetic modification events. The GM lines containing multiple waterlogging tolerance genes were generated via conventional crossing of the single gene GM cotton lines.

Previous releases of the same or similar GMOs

The GM cotton lines proposed for release were developed in Australia and have not been previously trialled.

The Regulator has previously issued a licence to conduct a field trial of waterlogging tolerant cotton containing the *Ahb1* gene (DIR 067/2006). One of these lines was used for crossing to generate some of the GM lines proposed for this field trial. Under the former voluntary system overseen by the Genetic Manipulation Advisory Committee (GMAC) there have been previous field trials of waterlogging tolerant cotton lines containing the *Adh* gene and/or a rice *Pdc* gene under PR99(1998), PR99X(1999), PR99X2(2000) and PR99X3(2001). One of these lines containing the *Adh* gene only was used for crossing to generate some of the GM lines proposed for this field trial.

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 CSIRO 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 083/2007.

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 and the Minister for the Environment, Heritage and the Arts and the relevant local council(s). 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 early June 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:

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