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

12 December 2006

TECHNICAL SUMMARY OF THE RISK ASSESSMENT AND RISK MANAGEMENT PLAN (CONSULTATION VERSION)

for

APPLICATION NO. DIR 067/2006

from **CSIRO**

INTRODUCTION

The Gene Technology Regulator (the Regulator) has decided to issue a licence (DIR 067/2006) to the Commonwealth Scientific and Industrial Research Organisation (CSIRO) for dealings involving the intentional release of genetically modified (GM) cotton lines into the Australian environment, on a limited scale and under controlled conditions.

The DIR 067/2006 licence permits the limited and controlled release of up to 30 GM cotton lines with tolerance to waterlogging. The release will occur on one site in the shire of Narrabri on a maximum total area of 0.1 ha during each of the three summer growing seasons of 2006/07, 2007/08 and 2008/09.

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 whether 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 Risk Management Plans (RARMPs) that form the basis of her decisions[1].

This RARMP for DIR 067/2006 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 and the environment from the proposed dealings 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 waterlogging tolerant cotton*
Applicant:	CSIRO
Common name of the parent organism:	Cotton
Scientific name of the parent organism:	*Gossypium hirsutum* L.
Modified traits:	Waterlogging tolerance, antibiotic resistance
Identity of the genes responsible for the modified traits:	• *AHb1* (non symbiotic haemoglobin), from *Arabidopsis thaliana* (waterlogging tolerance gene); • *nptII* (neomycin phosphotransferase type II) from the bacterium *Escherichia coli* (antibiotic resistance selectable marker)
Proposed location:	One site per season in the shire of Narrabri (NSW)
Proposed release size:	Up to 0.1 hectare per season over 3 seasons
Proposed time of release:	Summer seasons 2006/07, 2007/08 and 2008/09

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

CSIRO applied for a licence to release up to 30 GM cotton lines with tolerance to waterlogging into the environment on a limited scale and under controlled conditions. The trial of the GM cotton lines is intended 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 of 2006/07, 2007/08 and 2008/09.

The GM cotton lines contain between one and eight copies of the non-symbiotic phytohaemoglobin gene (*AHb1*), derived from thale cress (*Arabidopsis thaliana)* in different positions in the genome. This gene encodes a protein (AHB1) which is induced under conditions of oxygen deficit (hypoxia) and that is expected to provide tolerance to waterlogging. Non-symbiotic haemoglobins are common in many food plants such as barley, maize, wheat, rice, soybean and tomato.

The GM cotton lines also contain an antibiotic resistance gene, *nptII* (derived from *Escherichia coli*) conferring resistance to the antibiotics kanamycin and neomycin, that was used to select successfully modified plants during initial research and development work in the laboratory.

The GM cotton lines were derived from the cotton cultivar Coker 315 which is not grown commercially in Australia. The purpose of the release is to conduct early stage ('proof of concept') research to measure the expression levels of the *AHb1* gene; to evaluate the tolerance of the GM cotton plants to waterlogging stress under simulated conditions; and to conduct a preliminary assessment of their agronomic performance in the field. Cotton seed will also be collected for further studies and possible future releases (subject to additional approvals).

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 release, and their suitability for limiting the release to the location, 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 products.

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 from consultation with a wide range of prescribed experts, agencies and authorities on the application (summarised in Appendix B of the RARMP). No issues were raised in the comments received on the consultation version of the RARMP that required further analysis or consideration (Appendix D of RARMP).

The consideration of advice received from a member of the public on the application is summarised in Appendix C.

A reference document, *The Biology and Ecology of Cotton* (Gossypium hirsutum) *in Australia*, 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 hazard identification process considered the circumstances or events by which 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.

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.

Eighteen events were identified and assessed whereby the 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 human food, animal feed or for the production of fabrics and/or other cotton products
- widespread presence of the same or similar proteins encoded by the introduced genes in the environment and lack of known toxicity or allergenicity from these proteins
- limited capacity of the GM cotton lines to spread and persist in the area 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 limited and controlled release of the 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 release of GM cotton lines is considered to be **negligible** (ie insubstantial with no present need to invoke actions for their mitigation).

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

Licence conditions to manage this limited and controlled release

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

- surround the release site with a pollen trap
- locate the release site at least 50 m away from natural waterways
- harvest and gin seed cotton from the release separately from any other cotton crop
- not permit cotton seed or other materials from the release to be used in human food, animal feed or for the production of fabrics and/or other cotton products
- destroy all plant materials remaining at the site after harvest
- clean the site and any equipment used on the site
- conduct regular inspections of the release site following harvest for at least 12 months (and until six consecutive months have passed without any volunteer cotton plants) and destroy any volunteers prior to flowering.

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 agencies[2].

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

[2] 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>.

lines to be used in human food. Accordingly the applicant has not applied to FSANZ to evaluate any of the GM cotton lines. FSANZ approval would need to be obtained before they could be used in human food.

Identification of issues to be addressed for future releases

In recognition of the very early stage of 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 *AHb1* gene in the GM cotton lines
- data on the potential toxicity of plant material from the GM cotton lines including levels of known endogenous toxins
- data on the allergenicity of the protein encoded by the introduced *AHb1* gene for waterlogging tolerance
- details of the survival of the waterlogging tolerant GM cotton lines compared with non-GM cotton in the environment, particularly in habitats such as natural waterways, wetland areas and areas affected by high rainfall or flooding where the GM cotton may have a selective advantage
- biochemical, physiological and agronomic characteristics of the GM cotton lines indicative of weediness including measurement of tolerance to environmental stresses (eg drought or pathogen infection) and reproductive capacity (eg growth rate and window of flowering).

CONCLUSIONS OF THE RARMP

The risk assessment concludes that this limited and controlled release of up to 30 GM cotton lines with tolerance to waterlogging stress on a maximum of 0.1 ha per annum for 3 years in the shire of Narrabri, NSW poses **negligible** risks to the health and safety of people and the environment posed by or as a result of gene technology.

The risk management plan concludes that these **negligible** risks do not require specific risk treatment measures. However, licence conditions have been imposed to limit the release to the size, duration and location requested by the applicant.