



## Office of the Gene Technology Regulator

### APPLICATION FOR LICENCE FOR INTENTIONAL RELEASE OF GMOs INTO THE ENVIRONMENT: Application No. DIR 039/2003

#### SUMMARY INFORMATION

Project Title:	Field Evaluation of Genetically Modified High Oleic (HO) Cotton
Applicant:	CSIRO GPO Box 225 Dickson ACT 2602
Common name of the parent organism:	Cotton
Scientific name of the parent organism:	<i>Gossypium hirsutum</i> L.
Modified trait(s):	Modified fatty acid content in cottonseed oil Resistance to kanamycin related antibiotics
Identity of the gene(s) responsible for the modified trait(s):	<i>ghFAD2-1</i> gene from cotton (increased oleic acid, decreased linoleic and palmitic acids) <i>nptII</i> gene from the bacterial Tn5 transposon (antibiotic resistance) <i>lec1</i> gene regulatory sequences from soybean (seed specific expression)
Proposed Location	Narrabri, NSW
Proposed Release Size:	2 hectares (about 15,000 plants)
Proposed Time of Release	Oct 2003 – May 2004

#### Introduction

The *Gene Technology Act 2000* (the Act) took effect on 21 June 2001. The Act, supported by the *Gene Technology Regulations 2001*, underpins Australia's national regulatory system for gene technology and is designed 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), a Commonwealth regulatory agency located within the Health and Ageing portfolio.

The legislation also sets out the requirements for considering applications for licences for dealings with GMOs and the matters that the Regulator must take into account before issuing a licence.

## The application and the proposed dealings

The OGTR has received an application from the Commonwealth Scientific and Industrial Research Organisation (CSIRO) for a licence for the limited and controlled release into the environment of genetically modified (GM) cotton using a cotton gene to down regulate conversion of oleic acid to linoleic acid in the seed. This change has been demonstrated to elevate oleic fatty acid content in cottonseed from GM cotton plants grown in contained glasshouse experiments.

The applicant proposes to release two GM cotton lines ( $\Delta 12$ -IR\*23 and  $\Delta 12$ -IR\*124) that correspond to independent transformation events with the same DNA construct. The main aims of the proposed release are to conduct agronomic evaluation of the GM cotton lines and to test for maintenance of the high oleic (HO) phenotype under field conditions.

Oil derived from conventional cottonseed is used in food applications around the world, following processing to remove gossypol and other toxic or anti-nutritional compounds such as cyclopropenoid fatty acids. The high levels of polyunsaturated fatty acids present in most non-GM cotton seed often necessitates additional processing through partial hydrogenation to obtain oil with higher stability and more resistant to oxidation (ie to avoid becoming rancid). However, hydrogenation results in fatty acid structural forms (*trans*, rather than the *cis* arrangement of hydrogen atoms more commonly found in nature) that may increase cholesterol levels upon consumption. HO cotton has an altered ratio of fatty acids in cottonseed oil, with increased oleic acid levels (monounsaturated fatty acid) and decreased levels of linoleic (polyunsaturated fatty acid with low stability) and palmitic acids (saturated fatty acid associated with blood cholesterol-raising properties). Oil from GM HO cottonseed is expected to have a greater stability than other seed oils. This may enable direct use in frying or for margarine hard stock, without the need for hydrogenation that current oils require.

CSIRO is proposing to carry out a limited and controlled release up to 2 hectares at one site (about 15,000 plants) at the Australian Cotton Research Centre (ACRI) Narrabri, NSW. None of the cotton plants from the release, or their by-products, will be used for animal or human consumption. The applicant is proposing to sell lint from non-GM cotton used as pollen trap rows surrounding the release site, but not from the release. Lint does not contain genetic material or protein.

The applicant proposes to store seed from the release and analyse it for the HO trait. Seed from the non-GM pollen trap rows will be destroyed.

CSIRO state post-harvest management conditions and monitoring would be in accordance with the recommendations of the OGTR.

## Previous releases of the GMO

There have been no previous releases of the GM HO cotton under either the voluntary system or the current regulatory system.

Field trials have been approved in other countries for GM soybean, canola and sunflower with high oleic acid. Food Standards Australia New Zealand (FSANZ) has recently approved oil from GM HO soybean for human consumption.

## 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 Queensland and on a trial basis in Western Australia and the Northern Territory.

## Genetic modification and its effect

Both GM cotton lines contain an additional copy of the *ghFAD2-1* gene followed by an inverted partial repeat of the first 850 base pairs of the gene. The *ghFAD2-1* gene is derived from cotton (*Gossypium hirsutum* L.). The 1½ copy inverted repeat gene construct is intended to induce post-

transcriptional gene silencing (ie suppression) of the endogenous *ghFAD2-1* gene, resulting in the down regulation of conversion of oleic acid to linoleic acid and leading to a higher content of oleic acid in the cottonseed.

Short regulatory sequences that control expression of the modified *ghFAD2-1* gene are also present in the GM cotton. These seed specific regulatory sequences are the 5' promoter and 3' terminator sequences from soybean lectin gene *lec1*. These sequences serve as gene regulatory sequences to direct seed specific expression of the gene construct. Therefore, the linoleic acid content in other parts of the GM cotton plants should remain unchanged.

The HO cotton also contains the *nptII* gene from the bacterial Tn5 transposon that confers resistance to kanamycin. It was used as a marker to select modified cotton plants containing the *ghFAD2-1* gene in the initial laboratory screenings. Short regulatory sequences from the nopaline synthase (*nos*) gene from a common soil bacterium, *Agrobacterium tumefaciens*, regulate expression of the *nptII* gene. Although this organism is a plant pathogen, the regulatory sequences comprise only a small part of their total genome and are not in themselves capable of causing disease.

### **Method of gene transfer**

The gene construct was introduced into cotton on a plasmid vector carried by *Agrobacterium tumefaciens*. The vector is 'disarmed' since it lacks 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.

### **Consultation on draft 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 low risk potential of the GMO and 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 a risk assessment and risk management plan (RARMP) has been prepared.

In preparing the RARMP, the Regulator will seek input from a wide range of key stakeholders and expert groups comprising State and Territory Governments, relevant Commonwealth agencies, the Environment Minister, the Gene Technology Technical Advisory Committee and appropriate local councils, as required by section 50 of the Act.

As required by section 52 of the Act, the Regulator will again consult with these prescribed agencies and authorities and the public in finalising the RARMP that is expected to be issued for comment in **mid July 2003**. The public will be invited to provide submissions on the RARMP over a six week consultation period, via advertisements in the media and direct mail to anyone registered on the OGTR mailing list. Summaries and copies of the RARMP 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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