



Australian Government

Department of Health

Office of the Gene Technology Regulator

APPLICATION FOR LICENCE FOR INTENTIONAL RELEASE OF GMOs INTO THE ENVIRONMENT: Application No. DIR 085/2008

SUMMARY INFORMATION

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| Project Title: | Limited and controlled release of cotton genetically modified for altered fatty acid composition of the cottonseed oil ¹ |
| Applicant: | CSIRO |
| Common name of the parent organism: | Cotton |
| Scientific name of the parent organism: | <i>Gossypium hirsutum</i> L. |
| Modified trait(s): | Altered fatty acid composition of the cottonseed oil |
| Identity of the gene(s) responsible for the modified trait(s): | Partial sequences of three genes all derived from <i>G. hirsutum</i> : <ul style="list-style-type: none">• <i>ghFatB-1</i> (<i>palmitoyl-ACP thioesterase</i>)• <i>ghFAD2-1</i> (<i>microsomal Δ12-desaturase</i>)• <i>ghCPA-FAS-2</i> (<i>cyclopropane fatty acid synthase</i>)• <i>nptII</i> (<i>neomycin phosphotransferase type II</i>) gene from the bacterium <i>Escherichia coli</i> (antibiotic resistance selectable marker) |
| Proposed Location(s): | One site in the local government area of Narrabri, NSW |
| Proposed Release Size: | Up to 2 ha |
| Proposed Release Dates: | October 2008 – June 2009 |

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

¹ The title of the licence application submitted by CSIRO is Field Evaluation of MonoCott Cotton

² More information on the assessment of licence applications is available from the Office of the Gene Technology Regulator (OGTR). Free call 1800 181 030 or at [How are licence applications for environmental release of GMOs evaluated?](#)

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 (*G. hirsutum*) into the Australian environment on a limited scale under controlled conditions.

A single line³ of GM cotton (line DCS9-34, also called MonoCott cotton) is proposed for release. Partial sequences from three genes derived from cotton have been introduced into the GM cotton line. Expression of the gene sequences is expected to suppress the function of the corresponding genes in the parent plant and result in altered composition of the fatty acids in oil derived from the cotton seeds.

The proposed trial would involve experiments to assess a range of agronomic characteristics of the GM cotton line including seed germination rate, fibre yield and quality, seed yield, oil content and fatty acid composition. The trial will also produce cottonseed oil for quality evaluation by industry.

The applicant proposes to limit the release to one site in Narrabri, NSW on a maximum area of 2 ha between October 2008 and June 2009.

The applicant has also proposed a number of control measures 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 above the normal flood plain and at least 50 m away from natural waterways and other cotton breeding areas;
- surrounding the trial sites by a 20 m pollen trap of non-GM cotton and treating all plants in this area in the same way GM cotton plants;
- managing the GM cotton in the same manner as non-GM cotton, including application of insecticides;
- cleaning and inspecting all equipment prior to removal from the release site;
- harvesting and ginning all cotton plant materials (GM and non-GM) separately from other commercial cotton crops;
- cleaning the site and adjacent areas (eg pollen trap) after harvest by removing and/or destroying all cotton plant materials, except for materials required for future research or release;
- monitoring the trial site after harvest for a minimum of 12 months and destroying any cotton volunteers;
- transporting GM seed and plant materials in accordance with OGTR transportation guidelines;
- storing GM plant materials (required for further study or future release) in certified PC2 facilities;
- restricting personnel with access to the site to authorised CSIRO staff only; and
- not using the GM plant material, including cotton seed, cottonseed oil and meal for 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 cotton cultivar, Coker 315, was used to produce the GM cotton lines proposed for release. This cultivar has been adapted to tissue culture conditions and can be readily modified by standard genetic technologies. However, it is not commercially grown in Australia.

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

The genetic modifications and their effect

The cotton line contains the partial sequences of three genes: *palmitoyl-ACP thioesterase* (*ghFatB-1*), *microsomal $\Delta 12$ -desaturase* (*ghFAD2-1*) and *cyclopropane fatty acid synthase* (*ghCPA-FAS-2*). These sequences were derived from *G. hirsutum* and are intended to suppress the expression of the corresponding endogenous genes. Transcription of the introduced partial gene sequences is regulated by a seed specific promoter and terminator derived from the soybean *lec* gene.

The applicant has presented data indicating that cottonseed oil derived from the GM cotton line has increased levels of oleic acid and reduced levels of palmitic, linoleic and cyclopropenoid fatty acids compared to the untransformed parental line. The changes in the composition of fatty acids are intended to improve the properties of cottonseed oil for food uses (eg greater stability and longer shelf life; potential for use as frying oil without the need for hydrogenation).

The GM cotton line also contains the *nptII* gene, encoding a neomycin phosphotransferase type II enzyme, was originally derived from the common gut bacterium *Escherichia coli* and confers kanamycin or neomycin resistance on the GM plant. The *nptII* gene is regulated by the SC1 promoter and SC3 termination sequences derived from subterranean clover stunt virus (SCSV). Although SCSV is a plant pathogen, the regulatory sequences comprise only a small part of its total genome, and are not in themselves capable of causing disease. The *nptII* gene was used in the laboratory to select modified plant tissues during the initial development of the plants from which the GM line was derived

Method of genetic modification

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 and is not known to cause any adverse effects for people or the environment.

Previous releases of the same or similar GMOs

There has been no previous release of this GM cotton line.

The Regulator has previously issued Licence DIR039/2003 to CSIRO for the limited and controlled release of cotton modified for high oleic acid levels in the cottonseed oil. The GM cotton lines authorised for release under this licence contain one of the same introduced, partial gene sequences (*ghFAD2-1*) present in the GM cotton line proposed for release in the current application, which also contains two other introduced, partial gene sequences.

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 with 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 085/2008.

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 August 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:

The Office of the Gene Technology Regulator, MDP54 GPO Box 9848 Canberra ACT 2601

Telephone: 1800 181 030 Facsimile: 02 6271 4202 E-mail: ogtr@health.gov.au

[OGTR Website](#)