



**APPLICATION FOR LICENCE FOR INTENTIONAL RELEASE OF GMOs INTO THE ENVIRONMENT: Application No. DIR 063/2005**

**SUMMARY INFORMATION**

Project Title:	Field trial of GM cotton expressing natural plant genes for fungal control <sup>1</sup>
Applicant:	Hexima Limited
Common name of the parent organism:	Cotton
Scientific name of the parent organism:	<i>Gossypium hirsutum</i> L.
Modified trait(s):	Fungal resistance, antibiotic resistance
Identity of the gene(s) responsible for the modified trait(s):	<ul style="list-style-type: none"><li>• <i>NaD1</i> (<i>Nicotiana glauca</i> defensin), from ornamental tobacco (fungal resistance gene)</li><li>• <i>nptII</i> (neomycin phosphotransferase type II) from the bacterium <i>Escherichia coli</i> (antibiotic resistance selectable marker)</li></ul>
Proposed Location(s)	Up to a total of 3 sites per season in the shires of Pittsworth (QLD), Narrabri or Moree Plains (NSW)
Proposed Release Size:	Up to 1.0 hectare per season over 3 seasons
Proposed Release Dates:	September 2006 to May 2009

<sup>1</sup>The title of the licence application submitted by Hexima is *Assessment of transgenic cotton expressing natural plant genes for fungal control*.

## **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 licence<sup>2</sup>.

<sup>2</sup>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.

## The application and the proposed dealings

The OGTR has received an application from Hexima Limited Ltd (Hexima) 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.

The three GM cotton lines proposed for release contain one of two versions of the fungal resistance gene *NaD1* derived from a common plant, ornamental tobacco. The introduced fungal resistance gene encodes a plant defensin protein (NaD1) which has inhibitory activity against major fungal diseases of cotton, including Fusarium wilt, black root rot and Verticillium wilt. Many conventional (non-GM), commercial cotton cultivars are susceptible to these fungal diseases.

This is a proof of concept field trial. The purpose is to conduct early stage research to evaluate the efficacy of three GM cotton lines for enhanced resistance to fungal diseases as compared to non-GM cotton lines; to assess their agronomic performance under field conditions; to measure the expression levels of the defensin protein and to test for adverse impacts on selected beneficial microorganisms (mycorrhiza). Seed will also be collected for future studies including further releases (subject to additional applications and approval processes).

The release is proposed to take place at two sites in the shire of Pittsworth, Queensland (QLD) and one site in the shire of Narrabri or Moree Plains, New South Wales (NSW) on a maximum total area of 1.0 ha during each of the three growing seasons (September 2006 – May 2009).

The applicant has proposed the following containment measures:

- transportation of GM 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;
- destruction of GM plant materials used in laboratory analysis by autoclaving;
- locating the proposed trial sites 50 m away from natural waterways or 3 km away from a nature reserve, national park or state forest;
- 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 as the GM plants;
- 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 cotton volunteer plants.

Details of the gene constructs, including the plasmid map and regulatory sequences, preliminary molecular characterisation of the genetic modifications and inhibition studies have been declared as Confidential Commercial Information (CCI) under section 185 of the Act. However, the CCI will be made available to the prescribed experts and agencies that will be consulted on the preparation of the risk assessment and risk management plan for this application.

## Previous releases of the GMOs

There have been no previous releases of these GM cotton lines.

## Parent organism

The parent organism is cultivated cotton (*Gossypium hirsutum* L.), which is exotic to Australia and is grown as an agricultural crop in NSW and southern and central QLD. The cultivar Coker was used to produce the three 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 one of two versions of the fungal resistance gene, *NaD1*, which was derived from ornamental tobacco (*Nicotiana glauca*) and encodes a plant defensin protein (NaD1). The plant defensin has inhibitory activity against major fungal diseases of cotton.

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 bacterium *Escherichia coli*, and confers kanamycin or neomycin resistance on the GM plant. The *nptII* gene was used 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 soil bacterium, *Agrobacterium tumefaciens* and Cauliflower Mosaic Virus. Although *A. tumefaciens* and the 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 *NaD1* 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, fungal resistance was assessed and the best performing plants were selected for further characterisation. Each of the three GM cotton lines proposed for release is the result of an independent 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 low risk potential of the GMOs, the control measures that will be imposed, 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 063/2005.

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 relevant local councils. 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 May 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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