APPLICATION FOR LICENCE FOR INTENTIONAL RELEASE OF GMOs INTO THE ENVIRONMENT: Application No. DIR 048/2003

SUMMARY INFORMATION

Project Title:	**Field trial to assess transgenic cotton expressing natural plant genes for insect control**
Applicant:	Hexima Limited 200 Queen Street MELBOURNE VIC 3000
Common name of the parent organism:	Cotton
Scientific name of the parent organism:	*Gossypium hirsutum* L.
Modified trait(s):	Insecticidal action, antibiotic resistance
Identity of the gene(s) responsible for the modified trait(s):	• *NaPI* genes from the ornamental tobacco *Nicotiana alata* (insect resistance) • *PotI* gene from potato *Solanum tuberosum* (insect resistance) • *nptII* gene from *Escherichia coli* (antibiotic resistance) (Details of the gene construct including the full identity of the genes, gene products, and the transgenic cotton lines have been declared as Confidential Commercial Information)
Proposed Location(s)	Shires of Wambo, Pittsworth and Jondaryan in Queensland;
Proposed Release Size:	A maximum of 2 sites covering up to a total of 0.5 hectares per season
Proposed Time of Release	October 2004 – May 2007

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 to issue a licence.

The application and the proposed dealings

The OGTR has received an application from Hexima Limited (Hexima) for a licence for the intentional release of genetically modified (GM) insecticidal cotton into the environment, on a limited scale and under controlled conditions.

Some details of the gene construct including the full identity of the insecticidal genes and the identity of the transgenic cotton lines have been declared as Confidential Commercial Information (CCI) under section 185 of the Act. However, the CCI will be made available to the various prescribed expert groups that will be consulted on the preparation of the risk assessment and risk management plan for this application.

The GM cotton contains genes that produce protease inhibitors that are expected to inhibit digestion in the gut of the major caterpillar pests of cotton. The lines also contain regulatory sequences that control the level of expression of the introduced genes and an antibiotic resistance marker gene.

The trials would take place on a maximum of 2 sites selected from 3 shires, totalling an area less than 0.5 hectares per season in Queensland during the 2004/5, 2005/6 and 2006/7 cotton-growing seasons. The purpose of the release is to evaluate the agronomic performance of the GM cotton and the efficacy of the introduced insecticidal proteins.

None of the cotton plants from the release, or their by-products, would be used for animal and human food.

Previous releases of the GMO

There have been no previous releases of these GMOs in Australia or overseas. The technology on which this application is based was developed in laboratory research conducted under notifiable low risk dealing (NLRD) 740/2003, held by the University of Melbourne.

Parent organism

The parent organism, cultivated cotton (*Gossypium hirsutum* L.), 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

The GM cotton contains insecticidal genes, *NaPI*, derived from ornamental tobacco (*Nicotiana alata*) and *PotI* from potato (*Solanum tuberosum*) that code for protease inhibitors. These modifications may provide possible alternatives against insect attack to the *cry1Ac* genes present in other types of insecticidal GM cotton (e.g. INGARD®). Proteases are enzymes, which are essential for the digestion of proteins. The protease inhibitors produced by the introduced genes are expected to act by binding to the main proteases in the gut of the major lepidopteran caterpillar pests of cotton, inhibiting the digestive capacity and leading to reduced growth of larvae feeding on the GM cotton.

Short regulatory sequences that control expression of the *NaPI* and *PotI* genes are also present in the GM cotton. These are derived from a plant pathogen, Cauliflower Mosaic Virus (CaMV) and a common bacterium *Agrobacterium tumefaciens*. Although CaMV and *A. tumefaciens* are plant pathogens, the regulatory sequences comprise only a small part of the total genome, and are not in themselves capable of causing disease.

In addition to the *NaPI* and *PotI* genes and the various promoters, the plants contain a commonly used selectable bacterial marker gene (*nptII*) from *Escherichia coli* that confers resistance to the antibiotic kanamycin. The marker gene enabled identification of plant tissues in which the insecticidal gene is being expressed during the breeding of the GM plants.

Method of gene transfer

The *NaPI* and *PotI* genes were introduced into cotton on a plasmid vector carried by *A. tumefaciens*. The vector is 'disarmed' since it lacks the genes that encode the tumour-inducing functions of *A. tumefaciens*.

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 of the GMOs spreading or persisting, 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 a risk assessment and risk management plan (RARMP) has been prepared. In the interim, copies of the application are available on request from the OGTR. Please quote application number DIR 048/2003.

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 Australian Government agencies, the Minister for the Environment and Heritage, the Gene Technology Technical Advisory Committee and appropriate local councils, as required by section 50 of the Act. In accordance with section 52 of the Act, the Regulator will again consult with these prescribed agencies and authorities as well as the public in finalising the RARMP.

At this stage, the consultation version of the RARMP is expected to be issued for an extended 6 week consultation period in **May 2004.** The public will be invited to provide submissions 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 abut the application or the assessment process, please contact the OGTR at:

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