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

31 October 2008

APPLICATION FOR LICENCE FOR INTENTIONAL RELEASE OF GMOs INTO THE ENVIRONMENT: Application No. DIR 091

SUMMARY INFORMATION

Project Title:	Commercial release of cotton genetically modified for insect resistance (Widestrike™ Insect Protection cotton[1])
Applicant:	Dow AgroSciences Australia Ltd
Common name of the parent organism:	Cotton
Scientific name of the parent organism:	*Gossypium hirsutum* L.
Modified trait(s):	• Insect resistance • Herbicide tolerance
Identity of the gene(s) responsible for the modified trait(s):	• *cry1Ac* (synthetic gene; insect resistance) • *cry1F*[2] (synthetic gene; insect resistance) • *pat* (herbicide tolerance, selectable marker)
Proposed Location(s):	Cotton growing areas of Australia south of latitude 22º South
Proposed Release Size:	N/A The release will occur in all cotton growing regions of Australia south of latitude 22º South.
Proposed Release Dates:	Ongoing from date of approval

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,

[1] The title of the licence application submitted by Dow AgroSciences is 'Application for licence to commercially release WidestrikeTM Insect Protection'.
[2] The *cry1F* gene was referred to as *cry1Fa* in the applications for licences DIR 040/2003 and DIR 044/2003 and the corresponding RARMPs and other OGTR material.

to issue a licence. The Regulator's *Risk Analysis Framework*[3] outlines the assessment process that will be followed.

Confidential Commercial Information

Some details, including some specific Dow AgroSciences documents, which contain details of the gene constructs, gene sequence information and molecular characterisation of the inserted genetic materials, have previously been declared Confidential Commercial Information (CCI) under section 185 of the Act, in connection with licence application DIR 040/2003. An additional application for CCI for some information supplied with licence application DIR 091 is currently under consideration. The confidential information will be available to the prescribed experts and agencies that will be consulted on the preparation RARMP for this application.

The application and the proposed dealings

The Acting Regulator has received an application from Dow AgroSciences for a licence for dealings involving the intentional release of genetically modified (GM) cotton (*Gossypium hirsutum* L.) into the Australian environment.

The GM cotton proposed for release contains two insecticidal genes that are derived from a common soil bacterium. The introduced genes provide resistance to a range of lepidopteran insect species that are considered pests on cultivated cotton.

The proposed release would involve the commercial release of GM insect resistant cotton known as Widestrike™ Insect Protection cotton. The applicant proposes that the GM cotton will be grown in all cotton growing areas of Australia south of latitude 22º South, and that plant material from the GM cotton would be used in the same manner as plant material from non-GM cotton and commercially approved GM cotton.

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 and on a trial basis in northern Qld, north western WA and the NT.

The GM cotton plants proposed for release were produced using the cultivar GC510. This cultivar was used as a starting point for research as it can be easily genetically modified in the laboratory; it is not grown commercially in Australia. The modified plants were later crossed to the elite cotton cultivar PSC355.

The genetic modifications and their effect

The GM cotton contains the genes *cry1Ac* and *cry1F* derived from the common soil bacterium *Bacillus thuringiensis* (Bt). These genes confer resistance to a range of major lepidopteran caterpillar pests of cotton. The two *cry* genes are synthetic genes. The synthetic *cry1Ac* is composed of part of the *cry1Ac*, *cry1Ca3* and *cry1Ab1* genes from Bt and the synthetic *cry1F* is composed of parts of the *cry1Fa*, *cry1Ca3* and *cry1Ab1* genes. These genes encode the synthetic proteins Cry1Ac and Cry1F which belong to the class of proteins called Bt toxins.

In addition to the synthetic *cry1Ac* and *cry1F* genes, the GM cotton contains a selectable marker gene (*pat*) from the common soil bacterium S*treptomyces viridochromogenes*. The *pat* gene confers tolerance to the herbicide glufosinate ammonium. During development of the GM cotton, this marker gene enabled identification and selection of plant tissues in which this herbicide tolerant gene was also present. The applicant does not intend use glufosinate ammonium as an herbicide in the field and therefore does not intend to seek approval from the Australian Pesticide and Veterinary Medicines Authority (APVMA) for the use of this herbicide on the GM cotton in the field.

[3] More information on the assessment of licence applications is available from the Office of the Gene Technology Regulator (OGTR). Free call 1800 181 030

Short regulatory sequences that control expression of the genes are also present in the GM cotton. These are derived from a plant, *Zea mays* (corn), and from a common soil bacterium, *Agrobacterium tumefaciens*. Although *A. tumefaciens* 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.

Method of genetic modification

The *cry1Ac* and *cry1F* genes were introduced separately into cotton plant tissue (American cotton cultivar GC510) to generate transformation events 281-24-236 and 3006-210-23, respectively. Each insecticidal gene was introduced in combination with a selectable marker gene, the *pat* gene, providing a means of selection of plant cells expressing the desired modifications. The gene constructs were originally introduced on a plasmid vector carried by *A. 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.

Each event was crossed with the same elite commercial cotton cultivar (PSC355, an American cotton cultivar) and then backcrossed to the PSC355 cultivar three times to obtain the characteristics of the elite cotton cultivar. After backcrossing, the two cotton events expressing the insecticidal genes were combined by conventional breeding to generate the GM cotton proposed for release (Widestrike™ Insect Protection cotton). This GM cotton contains both the *cry1Ac* and *cry1F* genes and two copies of the *pat* gene.

Previous releases in Australia of the same or similar GMOs

The GM cotton proposed for release in this application has been previously approved for field trials in Australia under licences DIR 040/2003 and DIR 044/2003 issued to Dow AgroSciences. There have been no reports of adverse effects on human health and safety or the environment resulting from these releases.

The oil and cotton linters derived from this GM cotton have been approved by FSANZ for use in human food[4].

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 Acting Regulator has determined that Dow AgroSciences 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

Since this application is for commercial purposes, it cannot be considered as a limited and controlled release application under section 50A of the Act.

This means that the Acting Regulator is required to seek advice from prescribed experts, agencies and authorities on matters relevant to the Risk Assessment and Risk Management Plan (RARMP) that must be prepared, in accordance with section 51 of the Act. This first round of consultation must include the Gene Technology Technical Advisory Committee, State and Territory Governments, Australian Government agencies, any local council that the Regulator considers appropriate and the Minister for the Environment, Heritage and the Arts. While the Regulator is

[4] Insect-protected, glufosinate ammonium-tolerant cotton line MXB-13, Dow Agro Sciences, FSANZ Application A518.

not required to seek public comment at this stage, copies of the application are available on request from the OGTR.

In a second round of consultation, the Acting Regulator will then seek comment on the consultation RARMP from the public as well as prescribed experts, agencies and authorities. The RARMP will 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 consultation version of the RARMP is expected to be released for comment in **April 2009.** 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, MDP 54 GPO Box 9848 Canberra ACT 2601

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

OGTR website