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

17 November 2011
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APPLICATION FOR LICENCE FOR INTENTIONAL RELEASE OF GMOs INTO THE ENVIRONMENT: Application No. DIR 113

SUMMARY INFORMATION

Project Title:	Limited and controlled release of cotton genetically modified for insect resistance and herbicide tolerance[2]
Applicant:	Bayer CropScience Pty Ltd
Common name of the parent organism:	Cotton
Scientific name of the parent organism:	*Gossypium hirsutum* L.
Modified traits:	• Insect resistance • Herbicide tolerance • Antibiotic resistance selectable marker
Identity of the genes responsible for the modified traits:	• This information has been declared Confidential Commercial Information (CCI).
Proposed Locations:	Up to 6 sites per year in Narrabri, NSW, Wyndham-East Kimberly, WA, and Central Highlands, Qld[1].
Proposed Release Size:	A total area of up to 78 hectares (ha) comprised of up to 6 ha in year one and up to 36 ha in years two and three, each site being no more than 1 ha in the first year and 6 ha in years two and three[1].
Proposed Release Dates:	May 2012 – May 2015

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 and make decisions under the legislation. The Regulator is supported by the Office of

[1] The original licence application submitted by Bayer was for release in up to four sites per year in the local government areas (LGAs) of Narrabri and Wyndham-East Kimberley. The applicant later requested additional sites in an additional LGA, and an increase in area per site in the second and third years, in order to conduct efficacy trials to meet Australian Pesticides and Veterinary Medicines Authority requirements.
[2] The title of the licence application submitted by Bayer is 'Limited and controlled release of GM Herbicide resistant and insect tolerant Cotton (*Gossypium hirsutum*)'.

the Gene Technology Regulator (OGTR), an Australian Government regulatory agency located within the Health and Ageing portfolio.

The legislation sets out requirements for considering applications for licences for dealings with GMOs including matters that the Regulator must take into account before deciding whether or not to issue a licence. The Regulator's *Risk Analysis Framework*[3] outlines the assessment process that will be followed.

The application and the proposed dealings

The Regulator has received an application from Bayer CropScience Pty Ltd (Bayer) for a licence for dealings involving the intentional release of genetically modified (GM) cotton (*Gossypium hirsutum* L.) into the Australian environment on a limited scale under controlled conditions.

The purpose of the proposed trial is to develop and assess GM cotton varieties modified for insect resistance and herbicide tolerance, specifically to:

- assess the agronomic performance of the GM cottons
- assess the efficacy of the insecticidal proteins against the target pest, *Helicoverpa armigera* (cotton bollworm), under Australian conditions
- produce seed for use in further studies or releases (subject to additional approvals).

The applicant proposes to limit the release to six sites per year between May 2012 and May 2015, including summer plantings in Narrabri, NSW, and Central Highlands, Qld, and summer and winter plantings in Wyndham-East Kimberly, WA. The maximum area of plantings would be 6 ha in the first year and 36 ha in the second and third years, giving a maximum cumulative area of 78 ha. The applicant proposes to limit access to the field sites to authorised personnel.

The applicant has proposed a number of control measures to restrict the spread and persistence of the GM plants and their introduced genetic material in the environment that will be considered in the assessment of this application, including:

- locating trial sites at least 50 m away from natural waterways
- separating trial sites from other cotton crops by a 100m monitoring zone and a 3 km isolation zone or with a 20 m pollen trap of non-GM or commercially released GM cotton
- cleaning all planting and harvest equipment used at field planting sites of GM material
- harvesting and ginning cotton from the trial separately to other cotton
- cultivating field planting sites after harvest to encourage decomposition or germination of remaining seed
- post harvest monitoring and destroying any volunteer cotton at field planting sites for at least 12 months
- destroying all plant material from the trial not required for testing or future trials
- transporting the GMOs in accordance with the Regulator's guidelines
- not allowing GM plant material or products to be used for human food or animal feed.

[3] The Risk Analysis Framework and further 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 <http://www.ogtr.gov.au>.

Confidential Commercial Information

Details of the names and sequences of the genes used for herbicide tolerance, insect resistance and the antibiotic resistance selectable marker in the GM cotton have been declared Confidential Commercial Information (CCI) under section 185 of the Act. The confidential information will be made available to the prescribed experts and agencies that will be consulted on the Risk Assessment and Risk Management Plan (RARMP) for this application.

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

The proposed release involves GM cotton modified by gene insertion for insect resistance and herbicide tolerance, or conventional crosses of these GM cottons. All events have been backcrossed in to the FibreMax 966 genetic background (a commercial variety grown in the USA) and may be crossed into other elite commercial backgrounds.

The genetic modifications and their effect

The applicant proposes to release GM cotton containing insect resistance and herbicide tolerance traits. The insect resistance genes were isolated from the common soil bacterium *Bacillus thuringensis*. Some of the GM lines may also contain an antibiotic resistance selectable marker gene from commonly occurring bacteria which was used in the laboratory to select transformed GM plants during early stages of development.

Short regulatory sequences that control expression of the genes will also be present in the GM cottons, and will be derived from plants (including thale cress), bacteria (*Agrobacterium tumefaciens, Escherichia coli*) and viruses.

Method of genetic modification

The gene constructs were introduced into cotton 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.

Previous releases of the same or similar GMOs

Some of the GM cotton lines proposed for release have previously been approved for limited and controlled release in Australia.

In addition, GM cotton containing introduced genes for insect resistance and/or herbicide tolerance have been approved for commercial release in Australia under the trade names Bollgard II®, Roundup Ready®, Roundup Ready Flex®, Liberty Link® and WideStrike™.

There have been no reports of adverse effects on human health and safety or the environment resulting from any of these releases.

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 capacity to meet the conditions of a licence, relevant convictions and revocation of a licence or permit held under a law relating to the health and safety of people or the environment.

The Regulator has determined that Bayer 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 decided that the application qualifies as a limited and controlled release, under section 50A of the Act. The principal purpose of the application 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 spread and persistence of both the GMOs and their genetic material in the environment.

This means that the Regulator is not required to consult on the assessment of this application until after a consultation 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 113.

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. 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 his decision whether or not to issue a licence.

At this stage, **the RARMP is expected to be released for comment in February 2012.** 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:

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