



APPLICATION FOR LICENCE FOR INTENTIONAL RELEASE OF GMOs INTO THE ENVIRONMENT: Application No. DIR 056/2004

SUMMARY INFORMATION

Project Title: Field trial¹ of herbicide tolerant (LLCotton25) and herbicide tolerant/insect resistant (LLCotton25/Bollgard II[®]) cottons

Applicant: Bayer CropScience Pty Ltd
East Hawthorn VIC 3123

Common name of the parent organism: Cotton

Scientific name of the parent organism: *Gossypium hirsutum* L.

Modified trait(s): Herbicide tolerance, insecticidal action, antibiotic resistance, reporter gene expression

Identity of the gene(s) responsible for the modified trait(s):

- *bar* gene from the bacterium *Streptomyces hygroscopicus* (herbicide tolerance)
- *cry1Ac* and *cry2Ab* genes from the bacterium *Bacillus thuringiensis* (insecticidal)
- *nptII* gene from the bacterium *Escherichia coli* (antibiotic resistance)
- *uidA* gene from the bacterium *Escherichia coli* (reporter gene)

Proposed Location(s) Cotton growing areas of New South Wales (NSW) and southern and central Queensland (Qld)

Proposed Release Sizes and Dates:

Season	Maximum number of sites	Maximum total area (hectares)
Summer 2005/06	12	500
Summer 2006/07	12	500
Total	24	1000

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).

¹ Application DIR 056/2004 originally proposed an unrestricted commercial release. The application has been revised to request approval for a limited and controlled, large scale field trial. A commercial release licence may be sought in a future application.

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, which includes the preparation of a risk assessment and risk management plan (RARMP) for each proposed intentional release of a GMO into the environment, and the matters that the Regulator must take into account before deciding whether, or not, to issue a licence.

The application and the proposed dealings

The OGTR has received an application from Bayer CropScience Pty Ltd (Bayer) for a licence to intentionally release genetically modified (GM) herbicide tolerant cotton (LLCotton25) and herbicide tolerant/insect resistant cotton (LLCotton25/Bollgard II[®]) into the environment under limited and controlled conditions.

Application DIR 056/2004 was originally submitted as an application for commercial release of LLCotton25. The original application comprised two distinct phases: (i) a pre-commercial phase in which large scale grower evaluations, seed increases and the development of additional lines adapted for particular regional conditions would be undertaken in the current cotton growing regions of NSW and Qld, and (ii) the full commercial release. Bayer subsequently revised the application to cover only the first of the two phases (the pre-commercial release) and to add the combined herbicide tolerant/insect resistant cotton LLCotton25/Bollgard II[®].

A separate application for the commercial scale release is expected to be submitted to the OGTR, and the APVMA (for use of the herbicide to which the GM cotton is tolerant on the crop), at a later date.

Bayer proposes to conduct a large scale field trial on up to 24 sites covering a total area of up to 1000 hectares over two planting seasons. 500 hectares each would be planted in the 2005/06 and 2006/07 summer growing seasons in the cotton growing regions of New South Wales and southern and central Queensland.

LLCotton25 contains the *bar* gene which confers tolerance to the herbicide glufosinate ammonium (also called phosphinothricin), the active constituent of the herbicides Basta[®], Finale[®], Buster[®] and Liberty[®]. LLCotton25 plants can be sprayed with glufosinate ammonium to kill problem weeds without damaging the crop itself.

LLCotton25/Bollgard II[®] was produced by conventional breeding of LLCotton25 with GM Bollgard II[®] cotton. This introduced two genes that produce insecticidal proteins which provide resistance to the major caterpillar pests of cotton. Bollgard II[®] cotton is approved for commercial release south of latitude 22° South in Australia (DIR 012/2002).

The aims of the proposed release are to:

- test the agronomic performance of the GM cottons;
- transfer the herbicide tolerance and herbicide tolerance/insect resistance traits into elite cotton varieties suitable for use under Australian conditions;
- produce seed for future releases (which would be subject to future assessments and approvals);
- conduct demonstration trials for farmers; and
- conduct tests with material from the GM cottons in the laboratory.

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has regulatory responsibility for the use and safety of herbicides in Australia. Glufosinate ammonium is not currently registered for use on GM cotton. If a licence were to be issued by the Regulator for the proposed release, a research permit from the APVMA would be required before any non-registered use of glufosinate ammonium could occur. Bayer has submitted an application to the APVMA for the required permit.

None of the cotton plants from the release, nor their by-products, would be used for animal feed or human food. Bayer has submitted an application to Food Standards Australia New Zealand (FSANZ) for approval of oil and linters (a type of short fibre that does not contain any genetic material) derived from LLCotton25 for human food use. An approval from FSANZ would be required before materials from the GM cottons could be used for human consumption. However, the applicant proposes to sell lint from the release for use as fibre in the textile industry. Processed lint does not contain genetic material or protein.

Previous releases of the GMOs and other GM Cottons

Under the former voluntary system overseen by the Genetic Manipulation Advisory Committee (GMAC), CSIRO conducted two limited and controlled releases of LLCotton25 (PR-124X and PR-124X(2)). Two field trials of LLCotton25 have been approved under the current regulatory system (DIR 015/2002 and DIR 038/2003).

GM cottons very similar to LLCotton25 (i.e. containing different transformation events with either the same *bar* gene, or related *pat* gene, and different combinations of regulatory sequences) were also field trialled under GMAC (PR-82, PR82-X and PR-124). The LLCotton25 transformation event was eventually chosen for further development. Additional GM cottons containing either the *bar* herbicide tolerance gene, or the related *pat* gene, as well as introduced insecticidal and/or antibiotic resistance genes, have been (DIR 016/2002), or are currently being (DIR 036/2003, DIR 040/2003 and DIR 044/2003), trialled in Australia.

Bollgard II[®] cotton was approved for commercial release by the Regulator in 2002 (licence DIR 012/2002). The commercial release was restricted to the cotton growing regions of NSW and Qld south of latitude 22° South because of concerns about the potential weediness of the insecticidal GM cotton in the northern tropical areas. Therefore, field trials of Bollgard II[®] cotton north of latitude 22° South are being conducted under limited and controlled conditions.

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

Parent organism

The parent organism is cultivated cotton (*Gossypium hirsutum*), which is exotic to Australia and is grown as an agricultural crop in NSW, central and southern Qld and on a trial basis in WA, the NT and northern Qld.

The cotton variety Coker 312 was used to produce the initial GM plants because it can be readily cultured and regenerated in the laboratory. The herbicide tolerant GM cotton varieties proposed for release are backcross progeny of conventional crosses between LLCotton25 and a number of elite Australian cotton cultivars that are suitable for current Australian cotton production areas.

Genetic modification and its effect

LLCotton25 contains a single copy of the *bar* gene derived from the common soil bacterium *Streptomyces hygroscopicus*. The *bar* gene encodes the phosphinothricin acetyltransferase

(PAT) enzyme, which converts glufosinate ammonium, the active constituent in herbicides such as Basta[®] and Liberty[®], into an inactive form and thus renders the plant tolerant to the herbicide.

The *bar* gene confers tolerance to the herbicide glufosinate ammonium in both laboratory cultures during the initial stage of selection of GM plants and when applied to whole plants in the field. No other selectable marker was used. The GM plants show tolerance to the herbicide at all developmental stages.

LLCotton25/Bollgard II[®] was produced by conventional breeding of LLCotton25 with GM Bollgard II[®] cotton. LLCotton25/Bollgard II[®] cotton plants contain all of the genes introduced into each of the parental GM cottons.

Bollgard II[®] cotton contains two insecticidal genes, *cry1Ac* and *cry2Ab*, both derived from a common soil bacterium, *Bacillus thuringiensis* (Bt). These genes encode proteins that are toxic to lepidopteran caterpillars, including the two key *Helicoverpa* pests of cotton (*H. armigera* and *H. punctigera*).

Bollgard II[®] cotton plants also contain two bacterial antibiotic resistance genes, *nptII* (conferring resistance to kanamycin and neomycin) and *aad* (conferring resistance to streptomycin and spectinomycin), and a reporter gene, *uidA* (enabling visualisation of plant tissues in which this gene is being expressed). The *aad* gene is not expressed in the GM cotton plants because the bacterial promoter that controls its expression is not active in plants. This gene was used as a marker to select for bacteria containing the modified DNA in the laboratory prior to the production of the genetically modified plants.

Short regulatory sequences that control expression of the genes are also present in the GM cottons. These are derived from Cauliflower mosaic virus (CaMV), the common soil bacterium *Agrobacterium tumefaciens* and Glycine max (soybean). Although two of these organisms (CaMV and *A. tumefaciens*) are plant pathogens, the regulatory sequences comprise only a small part of their total genome and are not in themselves capable of causing disease.

Method of genetic modification

The *bar* gene was introduced into cotton variety Coker 312 on a plasmid vector carried by *A. tumefaciens*. The vector is ‘disarmed’ since it lacks the genes that encode the tumor-inducing functions of *A. tumefaciens*. This method has been widely used in Australia and overseas for introducing new genes into plants without causing any biosafety problems.

The herbicide tolerant GM cotton varieties proposed for release are backcross progeny of conventional crosses between the original LLCotton25 transformation event and a number of elite Australian cotton cultivars.

Bollgard II[®] cotton was produced by particle bombardment of the *cry2Ab* and *uidA* genes into GM INGARD[®] cotton (containing the *cry1Ac*, *nptII* and *aad* genes). This technique involves coating the DNA containing the genes onto very small tungsten or gold particles which are ‘shot’ into the cotton tissue, followed by selection of plants that contained single, functional copies of the genes. INGARD[®] cotton was produced using a disarmed plasmid vector (containing the *cry1Ac*, *nptII* and *aad* genes) carried by *A. tumefaciens*.

LLCotton25/Bollgard II[®] was produced by conventional crossing of LLCotton25 with Bollgard II[®] cotton.

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 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. In the interim, copies of the application are available on request from the OGTR. Please quote application number DIR 056/2004.

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 and the public in finalising the RARMP.

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. Summaries and copies of the RARMP 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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