



APPLICATION FOR LICENCE FOR COMMERCIAL RELEASE OF GMO INTO THE ENVIRONMENT: Application No. DIR 062/2005

SUMMARY INFORMATION

Project Title:	Commercial release of herbicide tolerant Liberty Link [®] Cotton for use in the Australian cropping system
Applicant:	Bayer CropScience Pty Ltd East Hawthorn VIC 3123
Common name of the parent organism:	Cotton
Scientific name of the parent organism:	<i>Gossypium hirsutum</i> L.
Modified trait(s):	Herbicide tolerance
Identity of the gene(s) responsible for the modified trait(s):	<i>bar</i> gene from the bacterium <i>Streptomyces hygroscopicus</i>
Proposed Location(s)	Current cotton growing regions in NSW and southern QLD and potential future areas that may be suitable for cotton cultivation in NSW, QLD, NT, WA, VIC and SA
Proposed Release Size:	Phased introduction over 3 years to commercial scale planting, as well as transport and stockfeed use anywhere in Australia
Proposed Time of Release	Ongoing from August 2006

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 licence¹.

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 (Liberty Link[®] Cotton) into the environment. The aim of the proposed release is to commercially release Liberty Link[®] Cotton into the Australian agricultural system, and undertake ongoing product research and development.

Bayer does not propose to use any containment measures and intends that the GM cotton plants and their products would be used in the same manner as conventional and other commercially approved GM cottons. Hence, the dealings would include use in human food (subject to approval, see below), transportation and use as stockfeed anywhere in Australia, sale of lint and exporting seed.

Liberty Link[®] Cotton (previously known as LLCotton25 or Liberty[®] cotton), developed from the LLCotton25 transformation event, contains the *bar* gene which confers tolerance to glufosinate ammonium (also called phosphinothricin), the active constituent of the herbicides Basta[®], Finale[®], Buster[®] and Liberty[®]. Liberty Link[®] Cotton plants can be sprayed with glufosinate ammonium to kill weeds without damaging the crop itself.

The applicant anticipates a phased introduction over 3 years, involving large scale grower evaluations and seed increases, and the development of additional lines adapted for particular regional conditions. The rate of uptake will be determined by market acceptance, and seed and variety availability.

Bayer expects the most substantial adoption of the GM cotton to occur initially in the existing cotton growing regions of New South Wales (NSW) and Queensland (QLD), followed by uptake in other areas where environmental conditions are suitable for cotton cultivation. Potential future cotton growing regions include additional parts of NSW and QLD, the Northern Territory (NT), northern Western Australia (WA), and in South Australia (SA) and Victoria (VIC), close to the NSW border. Small scale use for demonstrations and educational purposes is also proposed outside these areas. A map of current cotton growing shires can be accessed via the OGTR website: www.ogtr.gov.au/pdf/public/cotmaplga.pdf.

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has regulatory responsibility for the use of herbicides in Australia. Bayer currently has a research permit for small scale use of glufosinate ammonium in current cotton trials involving this GMO, and has submitted an application to the APVMA to register its use in commercial scale cultivation of the Liberty Link[®] Cotton.

Cotton seed is processed for oil that is used in a variety of food products and for cotton linters (short fibres from the seed surface that do not contain any genetic material) that are used as a cellulose base for several consumer food products. Bayer has submitted an application to Food Standards Australia New Zealand (FSANZ) for approval of oil and linters derived from Liberty Link[®] Cotton for human food use.

¹ More information on the comprehensive assessment required for licence applications to release a genetically modified organism (GMO) into the environment is 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>. Further information on the evaluation process is contained in the Regulator's *Risk Analysis Framework* (OGTR, 2005), <http://www.ogtr.gov.au/pdf/rafinal2.2.pdf>.

Previous releases of the GMO and other GM Cottons

Liberty Link[®] Cotton (previously known as Liberty[®] or LLCotton25) has been trialled under limited and controlled conditions in Australia under both the current regulatory system and the former voluntary system. Two trials {PR-124X and PR-124X(2)} were authorised by the Genetic Manipulation Advisory Committee (GMAC) and three trials (DIR 015/2002, DIR 038/2003 and DIR 056/2004) have been approved by the Regulator.

The limited and controlled releases under DIR 015/2002 and DIR 038/2003 took place in the current cotton growing regions of NSW and QLD on trial sites ranging from 0.04 to 135 hectares. Licence DIR 056/2004 authorises the field trial of both GM herbicide tolerant (LLCotton25) and herbicide tolerant/insect resistant (LLCotton25/Bollgard II[®]) cottons in NSW and QLD during the 2005-06 and 2006-07 summer growing seasons. In each season the GM cottons may be grown on up to 12 sites covering a maximum area of 500 hectares.

GM cottons very similar to Liberty Link[®] Cotton (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). 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.

Three DIR licences have previously been issued for the commercial release of GM cottons (DIRs 12/2002, 22/2002 and 23/2002). These authorise the commercial scale planting of insect resistant Ingard[®] (now phased out) and Bollgard II[®], and conventional crosses with the herbicide tolerant Roundup Ready[®], which is tolerant to the application of glyphosate. Due to uncertainty whether insecticidal genes confer a survival advantage in northern Australia, where insect feeding may be a factor in limiting the survival and spread of cotton plants, the release of these GM cottons is only permitted under limited and controlled conditions north of latitude 22°S, pending the conduct of further research. Liberty Link[®] Cotton does not contain any insecticidal genes and glufosinate ammonium is a less widely used herbicide than glyphosate.

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

Parent organism

The parent organism is cultivated cotton (*Gossypium hirsutum*), which is exotic to Australia.

The cotton variety Coker 312 was used to produce the GM plants containing the LLCotton25 transformation event because of its ease of use in the tissue culture system employed in the genetic modification process. The Liberty Link[®] Cotton varieties proposed for release are backcross progeny of conventional crosses between plants from the original GM plants containing the LLCotton25 transformation event and a number of elite Australian cotton cultivars that are suitable for current Australian cotton production areas.

Genetic modification and its effect

The GM cotton plants contain 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 into an inactive form.

The *bar* gene confers tolerance to herbicides containing 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.

Short regulatory sequences that control expression of the gene are also present in the GM cotton. These are derived from Cauliflower mosaic virus and the common soil bacterium *Agrobacterium tumefaciens*. Although both organisms are plant pathogens, the regulatory sequences comprise only a small part of their total genomes, and are not in themselves capable of causing disease.

Method of genetic modification

The *bar* gene was 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 without causing any biosafety problems.

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. **The Regulator has decided that the proposed release does not pose a significant risk to human health and safety or the environment for the following reasons:**

- there have been a number of field trials of this and similar GMOs and commercial releases of other GM cottons in Australia with no reported adverse effects on human health and safety or the environment;
- based on the initial analysis of the application, the risk of weediness, increased toxicity or allergenicity, and the impact of outcrossing to native or naturalised cottons or other plant species are no greater than for non-GM or other commercially released GM cottons; and
- this GM cotton does not contain any introduced insecticidal genes that would provide protection from predation by insects.

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. However, 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 that will then form the basis of her decision whether to issue a licence.

At this stage, the consultation version of the RARMP is expected to be issued for an extended 8 week consultation period in **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. Summaries and copies of the RARMP will be available from the OGTR, or on the OGTR website. In the interim, copies of the application are available on request from the OGTR. Please quote application number DIR 062/2005.

Issues to be considered by the Regulator

In making a decision on whether to issue a licence for the proposed release, the Regulator is required to consider applications and submissions within the context of the object of the Act, which focuses upon **protecting the health and safety of people and the environment.**

Please note that issues such as food labelling, the use and safety of herbicides, marketability and trade implications do NOT fall within the scope of the evaluations conducted under the Act as these are the responsibility of other agencies and authorities.

If you have any questions about the application or the assessment process, please contact the OGTR at:

The Office of the Gene Technology Regulator

MDP 54

PO Box 100

WODEN ACT 2606

Tel: 1800 181 030

Fax: 02 6271 4202

Email: ogtr@health.gov.au

Website www.ogtr.gov.au