



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

8 February 2010

APPLICATION FOR LICENCE FOR INTENTIONAL RELEASE OF GMOs INTO THE ENVIRONMENT: Application No. DIR 101

SUMMARY INFORMATION

Project Title:	Limited and controlled release of cotton genetically modified for insect resistance and herbicide tolerance ¹
Applicant:	Monsanto Australia Limited
Common name of the parent organism:	Cotton
Scientific name of the parent organism:	<i>Gossypium hirsutum</i> L.
Modified traits:	Insect resistance, herbicide tolerance, marker gene expression and antibiotic resistance
Identity of the genes responsible for the modified traits:	<ul style="list-style-type: none">• <i>vip3A</i> (vegetative insecticidal protein 3A) synthetic gene derived from a gene from the bacterium <i>Bacillus thuringiensis</i> (insect resistance)• <i>cry1Ac</i> (<i>crystal protein 1Ac</i>) gene from <i>B. thuringiensis</i> (insect resistance)• <i>cry2Ab</i> (<i>crystal protein 2Ab</i>) gene from <i>B. thuringiensis</i> (insect resistance)• <i>cp4 epsps</i> (<i>5-enolpyruvylshikimate-3-phosphate synthase</i>) gene from the bacterium <i>Agrobacterium</i> sp. strain CP4 (herbicide tolerance)• <i>nptII</i> (<i>neomycin phosphotransferase type II</i>) gene from the bacterium <i>Escherichia coli</i> (antibiotic resistance)• <i>aph4</i> (<i>hygromycin B phosphotransferase</i>) gene from <i>E. coli</i> (antibiotic resistance)• <i>uidA</i> (β-glucuronidase) gene from <i>E. coli</i> (reporter)• <i>aad</i> (<i>3''(9)-O-aminoglycoside adenytransferase</i>) gene from <i>E. coli</i> (antibiotic resistance)
Proposed Locations:	Up to 50 sites per year in the Queensland shires of Balonne, Banana, Brisbane City, Burdekin, Central Highlands, Dalby, Goondiwindi, Isaac, Lockyer Valley, Paroo, Roma, South Burnett, Somerset and Toowoomba; the New South Wales shires of Balranald, Bogan, Bourke, Carrathool, Central Darling, Coonamble, Gunnedah, Gwydir, Hay, Inverell, Liverpool Plains, Lachlan, Moree Plains, Narrabri, Narromine, Warrumbungle, Walgett and Warren; and the Western Australian shires of Broome and Wyndham-East Kimberley.
Proposed Release Size:	A total area of up to 1150 hectares (ha) comprised of up to 50 ha in year one, up to 100 ha in year two and up to 500 ha in each of years three and four, each site being no more than 250 ha
Proposed Release Dates:	October 2010 – October 2014

¹ The title of the licence application submitted by Monsanto is 'Field testing of Bollgard III cotton'.

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 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*² outlines the assessment process that will be followed.

The application and the proposed dealings

The Regulator has received an application from Monsanto Australia Limited (Monsanto) for a licence for dealings involving the intentional release of genetically modified (GM) cotton 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 containing the *vip3A* gene (which confers insect resistance) in various combinations with other genes conferring insect resistance and herbicide tolerance already used in commercial GM cotton varieties in Australia. This would involve breeding, field trials to agronomically characterise the GM cotton, variety development trials, demonstration plantings and seed multiplication.

Bollgard II[®] insect resistant GM cotton (containing the *cry1Ac* and *cry2Ab* genes which confer insect resistance) and Roundup Ready Flex[®] GM cotton (tolerant to the herbicide glyphosate due to the introduced gene *cp4 epsps*) are grown commercially in Australia, both separately and combined in the same variety. Varieties in which the *vip3A* gene is added to Bollgard II[®] cotton will be referred to as Bollgard III cotton.

The applicant proposes to limit the release to 50 sites per year between October 2010 and October 2014, including summer plantings in current cotton growing regions of Queensland and New South Wales, and winter plantings in prospective cotton growing areas in northern Western Australia. The maximum area of plantings would be 50 ha in the first year, 100 ha in the second year, and 500 ha per year in the third and fourth years, with a maximum site size of 250 ha. The applicant also proposes to grow the GMOs in glasshouses in Toowoomba and Brisbane for the duration of the release. 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 dissemination and persistence of the GM plants and their introduced genetic material 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 cotton crops by 3 km or with a 20 m pollen trap of non-GM or commercially released GM cotton

² 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>>.

- 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 and until sites have been free of volunteers for six months
- destroying all plant material from the trial not required for testing or future trials, except for lint which may be sold
- transporting the GMOs in accordance with the Regulator's guidelines

None of the cotton plants from the release, or their by-products, would be used for animal feed or human food. Food Standards Australia New Zealand (FSANZ) has previously approved food derived from oil and linters of GM cotton containing the four transformation events proposed for release.

The applicant proposes to sell lint from the release for use as fibre in the textile industry. Lint does not contain detectable genetic material or protein.

Confidential Commercial Information

The genomic locations of some of the inserted genes are the subject of an application for declaration of Confidential Commercial Information (CCI) under section 185 of the Act, which is currently under consideration. 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 conventional crossing of GM cotton containing the *vip3A* gene with other GM cottons which have been commercially released in Australia, known as Bollgard II[®] (insect resistant) cotton and Bollgard II/Roundup Ready Flex[®] (insect resistant and herbicide tolerant) cotton. The majority of the Australian cotton crop is genetically modified, with Bollgard II[®] making up an estimated 82% of the 2008 crop.

The genetic modifications and their effect

The applicant proposes to release GM cotton containing the *vip3A* gene conferring insect resistance (VIP3A cotton, containing transformation event COT102). The VIP3A GM cotton plants contain a synthetic copy of the *B. thuringiensis vip3A* gene in which the DNA sequence has been modified to optimise expression in plants. The VIP3A protein expressed by the GM cotton plants differs by one amino acid from the protein encoded by *B. thuringiensis*.

Monsanto proposes to release GM cotton plants in which VIP3A is combined by conventional crossing with the genetic modifications in the following commercially released GM cottons:

- insect resistant Bollgard II[®] cotton (also known as MON15985), which contains separately introduced *cry1Ac* and *cry2Ab* genes from *B. thuringiensis*.
- herbicide tolerant/insect resistant Bollgard II/Roundup Ready Flex[®] cotton, which contains two copies of the *cp4 epsps* herbicide tolerance gene from *Agrobacterium* sp., in addition to the two genetic modifications in Bollgard II[®]. Bollgard II/Roundup Ready Flex[®] cotton

was produced by conventionally crossing Roundup Ready Flex[®] cotton (also known as MON88913, containing *cp4 epsps*) with Bollgard II[®] cotton.

The combination of VIP3A and Bollgard II[®], referred to as Bollgard III cotton, is expected to provide resistance to important lepidopteran pests of cotton including *Helicoverpa armigera* and *H. punctigera*. Additional inclusion of the herbicide tolerance trait (ie Bollgard III/Roundup Ready Flex[®] cotton) would provide resistance to the herbicide glyphosate (marketed as Roundup[®]).

Regulatory sequences that control expression of the introduced genes are also present in the GM cottons. These are derived from cauliflower mosaic virus (CaMV), figwort mosaic virus (FMV), soybean, pea, *Arabidopsis thaliana* and *Agrobacterium tumefaciens* (a common soil bacterium).

The GM cottons also contain a number of marker genes: the VIP3A cotton contains the *aph4* gene which provides resistance to the antibiotic hygromycin; Bollgard II[®] cotton contains the *nptII* gene which provides resistance to antibiotics such as kanamycin, and the *uidA* gene, which encodes an enzyme that can be used as a visual marker of transformation. Bollgard II[®] also contains the *aad* gene under the control of a bacterial promoter which is not active in plants; *aad* provides resistance to aminoglycoside antibiotics.

Method of genetic modification

Two methods were used to introduce genes into the GM cottons. VIP3A, Roundup Ready Flex[®] and the first modification in Bollgard II[®] (introduction of the *cryIAC*, *nptII* and *aad* genes, known as event MON531) were produced by *Agrobacterium*-mediated transformation. The genes of interest were inserted into plasmid vectors carried by *A. tumefaciens* and introduced into the Coker 312 cotton variety. These vectors are 'disarmed' because they lack the genes that encode the tumour-inducing functions of *A. tumefaciens*. This method has been widely used in Australia and overseas for introducing new genes into plants.

Following breeding of event MON531 into a commercial cotton variety, a second genetic modification was carried out to produce Bollgard II[®] cotton. Additional genes (*cry2Ab* and *uidA*) were introduced to MON531 by particle bombardment. This technique involves coating the DNA encoding the genes onto very small particles which are 'shot' into the cotton tissue, from which cotton plants are later regenerated.

Previous releases of the same or similar GMOs

All of the genetic modifications present in the GM cottons proposed for release have previously been approved for release in Australia, but have not previously been approved as a combination. VIP3A cotton has been grown in limited and controlled releases under DIR licences 017/2002, 025/2002, 036/2003, 058/2005 and 065/2006. The other GM cottons are currently commercially approved for all Australian cotton growing regions under licence DIR 066/2006, and have been grown commercially under different licences since 2002 (Bollgard II[®] cotton, DIR 012/2002) and 2006 (Roundup Ready Flex[®] and Roundup Ready Flex/Bollgard II[®] cottons, DIR 059/2006).

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 Monsanto 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 made an assessment of whether the application should be considered as a limited and controlled release, under section 50A of the Act. As its principal purpose 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 dissemination and persistence of both the GMOs and their genetic material in the environment, **the Regulator has decided that the application qualifies as a limited and controlled release.**

This means that the Regulator is not required to consult on the assessment of this application until after a 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 101.

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, Heritage and the Arts. 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 early May 2010.** 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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