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

APPLICATION FOR LICENCE FOR INTENTIONAL RELEASE OF GMOs INTO THE ENVIRONMENT: Application No. DIR 074/2007

SUMMARY INFORMATION

Project Title:	Limited and controlled release of GM insect resistant and/or herbicide tolerant *Gossypium barbadense* cotton[1]
Applicant:	Monsanto Australia Limited
Common name(s) of the parent organism:	Extra Long Staple (ELS) or Pima cotton
Scientific name of the parent organism:	*Gossypium barbadense*
Modified traits:	Insect resistance and antibiotic resistance and/or herbicide tolerance
Identity of the genes responsible for the modified traits:	• *cry1Ac* and *cry2Ab* genes from the bacterium *Bacillus thuringiensis* (insect resistance) • *cp4 epsps* gene from *Agrobacterium sp*. strain CP4 (herbicide tolerance) • *nptII* gene from the bacterial Tn5 transposon (antibiotic resistance) • *aad* gene from the bacterial Tn7 transposon (antibiotic resistance) • *uidA* gene from *Escherichia coli* (reporter gene)
Proposed Locations	Up to 13 sites in the New South Wales shires of Bourke, Carrathool, Griffith, Moree Plains, Narrabri, Walgett, Warren, Hay, Balranald, Central Darling and Lachlan; Lake Tandou (an unincorporated area) and the Queensland shires of Paroo and Balonne
Proposed Release Size:	Maximum total of 26 hectares
Proposed Release Dates:	Summer cotton growing seasons 2007/08 and 2008/09

[1] The title of the licence application submitted by Monsanto Australia Ltd is "Licence application to the OGTR for field tests covering Bollgard II® (MON 15985) and Roundup Ready Flex® (MON 88913) in Extra Long Staple Cotton (*Gossypium barbadense*) in Australia"

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 licence[2].

The application and the proposed dealings

The Regulator has received an application from Monsanto Australia Limited (Monsanto) for a licence for the intentional release of genetically modified (GM) Extra Long Staple (ELS) cotton (*Gossypium barbadense* L.), also known as Pima cotton, into the environment on a limited scale and under controlled conditions.

Monsanto proposes to trial GM *G. barbadense* cotton on up to 13 sites (of no more than 2 hectares each) on a maximum total area of 26 hectares, over 2 summer growing seasons (2007/08 and 2008/09). The proposed sites are located in the New South Wales (NSW) shires of Bourke, Carrathool, Griffith, Moree Plains, Narrabri, Walgett, Warren, Hay, Balranald, Central Darling and Lachlan; Lake Tandou (an unincorporated area) and the Queensland shires of Paroo and Balonne.

The GM *G. barbadense* cotton contains two introduced genes for insect resistance (*cry1Ac* and *cry2Ab*) and/or two copies of the herbicide tolerance gene, *cp4 epsps*. GM *G. hirsutum* containing the same introduced genes for insect resistance and herbicide tolerance have been approved for commercial release in Australia under the trade names Bollgard II® and Roundup Ready Flex®, respectively.

The aims of the proposed field trial are to conduct research to:

- breed, select and assess the agronomic performance, yield and fibre quality of the GM *G. barbadense* cotton
- collect data for future applications to the OGTR and other regulators
- produce seed for use in further studies or releases (subject to additional approvals).

Monsanto has proposed a number of containment measures for the conduct of the field trial that will be considered in the assessment of this application, including:

- locating the proposed trial sites 50 m away from natural waterways
- restricting access to field trial sites to authorised personnel
- after harvest, destroying all viable GM plant material (excluding seed required for analysis and possible future releases)
- transporting GM cotton seed and plant materials in accordance with OGTR transportation guidelines
- after harvest, monitoring each site for at least 12 months and destroying any volunteer GM cotton plants.

Cotton seed oil from Bollgard II® cotton and Roundup Ready Flex® cotton varieties (*Gossypium spp.*) has previously been approved by Food Standards Australia New Zealand (FSANZ) for use in human food. However, none of the GM material from the proposed trial will be used for human food or animal feed. The applicant has requested approval to sell lint ginned from the GM cotton seeds. Lint does not contain the introduced genes or their expressed proteins.

[2] More information on the assessment of licence applications and copies of the *Risk Analysis Framework* are 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> and <http://www.ogtr.gov.au/pdf/public/ raffinal2.2.pdf> respectively.

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has regulatory responsibility for the use of agricultural chemicals, including herbicides and insecticidal products, in Australia. Although Roundup Ready® Herbicide is currently registered for use on Roundup Ready Flex® *G. hirsutum*, and the APVMA has registered the use of the insecticidal proteins as produced by the insecticidal genes (*cry1Ac* and *cry2Ab*) in GM Bollgard II® *G hirsutum* as insecticidal products in Australia, research permits from the APVMA may be necessary to conduct the proposed field trial with GM *G. barbadense*.

Parent organism

The parent organism is Extra Long Staple (ELS) or Pima cotton (*Gossypium barbadense* L.), which is exotic to Australia and is grown as an agricultural crop primarily in western NSW near Bourke (Bourke LGA), Lake Tandou (an unincorporated area) and Hillston (Carrathool LGA). *G. barbadense* currently constitutes less than 1% of the total cotton crop in Australia in an average year.

While *G. barbadense* and the more commonly grown *G. hirsutum* are morphologically similar they are genetically distinct, requiring at least eight backcrossing generations to restore either parental genotype after hybridisation. *G. barbadense* produces higher quality cotton fibre than *G. hirsutum* but it has a lower yield, a longer growing season, and may be more susceptible to temperature stress.

The insect resistant and herbicide tolerant GM *G. barbadense* cotton proposed for release will be derived from selected conventional crosses of several breeding lines with Bollgard II® *G. hirsutum* and Roundup Ready Flex® *G. hirsutum* containing Monsanto's transformation events MON 15985 and MON 88913, respectively.

Genetic modification and its effect

The Bollgard II® (MON 15985) *G. barbadense* contains two insect resistance genes, *cry1Ac* and *cry2Ab*, derived from a common soil bacterium *Bacillus thuringiensis*. These genes encode proteins that are selectively toxic to the major lepidopteran caterpillar pests of cotton (*Helicoverpa armigera* and *H. punctigera*).

The Roundup Ready Flex® (MON 88913) *G. barbadense* contains two copies of the herbicide tolerance gene, *cp4 epsps*, which is derived from another common soil bacterium, *Agrobacterium tumefaciens*. The *cp4 epsps* gene produces a protein that provides tolerance to glyphosate, the active constituent in Roundup Ready® Herbicide. Expression of two copies of the same herbicide tolerance gene in Roundup Ready Flex® *G. hirsutum* cotton confers tolerance to glyphosate throughout the growing season.

The Roundup Ready Flex®/Bollgard II® *G. barbadense* will be generated through conventional crossing of Bollgard II® *G. barbadense* with Roundup Ready Flex® *G. barbadense.* The introduction of the MON 15985 and the MON 88913 events will confer both the insect resistance and herbicide tolerance traits.

Some of the GM *G. barbadense* cotton also contains antibiotic resistance marker genes (*nptII* and *aad*) and a reporter gene (*uidA*) which helped identify and select modified bacteria, plant tissue or plants during the development of the GMOs in the laboratory.

The GM *G. barbadense* cotton also contains short regulatory sequences derived from the plants *Glycine max* (soybean), *Pisum sativum* (pea) and *Arabidopsis thaliana* and from the plant pathogens Cauliflower mosaic virus, Figwort mosaic virus and *Agrobacterium tumefaciens*. Although the last three of these organisms are plant pathogens, these regulatory sequences are not capable of causing disease.

Method of genetic modification

Bollgard II® *G. hirsutum* was generated by particle bombardment of the *cry2Ab* and *uidA* genes into INGARD® *G. hirsutum* (containing the *cry1Ac*, *nptII* and *aad* genes). This technique involved coating the genes onto very small particles which were 'shot' into cotton plant tissue, followed by regeneration and selection of plants that contained single, functional copies of the genes until the plant containing transformation event MON 15985 was chosen as the parent plant from which further breeding would occur.

Roundup Ready Flex® *G. hirsutum* was produced by the introduction of two copies of the *cp4 epsps* gene and associated regulatory sequences into cotton plant tissue via a bacterial vector, *Agrobacterium tumefaciens*. (The vector was 'disarmed' since it lacked the genes that encode the tumour-inducing functions of *A. tumefaciens*.) This was followed by regeneration and selection of plants that contained only one pair of *cp4 epsps* genes, until the plant containing transformation event MON 88913 was chosen as the parent plant from which further breeding would occur.

Previous releases of the same or similar GMOs

GM *G. barbadense* cotton has not been released previously in Australia. However, GM *G. hirsutum* cotton containing the same transformation events has been extensively trialled under the current regulatory system. Bollgard II®, Roundup Ready Flex® and Roundup Ready Flex®/Bollgard II® *G. hirsutum* cotton were approved for commercial release throughout Australia by the Regulator under DIRs 012/2002, 059/2005 and 066/2006. There have been no reports of adverse effects on human health and safety or the environment resulting from these releases.

In the USA, Roundup Ready Flex® *G. barbadense* derived from conventional breeding with Roundup Ready Flex® *G. hirsutum* has been commercially released. No additional approval was required for the GM *G. barbadense* 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 similarity between the GM *G. barbadense* cotton proposed for release and commercially approved GM *G. hirsutum* cotton, the control measures that have been proposed, and the limited scale and 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 for consultation. In the interim, copies of the application are available on request from the OGTR. Please quote application number DIR 074/2007.

In preparing the RARMP, the Regulator will seek input from a wide range of key stakeholders and expert groups including State and Territory Governments, Australian Government agencies, the Minister for the Environment and Water Resources, the Gene Technology Technical Advisory Committee and relevant local councils. The Regulator will consult again with these prescribed experts, agencies and authorities, as well as the public, in finalising the RARMP, which then forms 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 a six week consultation period in **mid August 2007.** 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 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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