



## Australian Government

Department of Health and Ageing  
Office of the Gene Technology Regulator

19 October 2012

### Summary of Licence Application DIR 118

#### Application for licence for intentional release of GMOs into the environment

<b>Project Title:</b>	Commercial release of herbicide tolerant (Roundup Ready Flex <sup>®</sup> MON 88913) pima cotton in Australia <sup>1</sup>
<b>Applicant:</b>	Monsanto Australia Ltd (Monsanto)
<b>Common name of the parent organism:</b>	Cotton (pima cotton)
<b>Scientific name of the parent organism:</b>	<i>Gossypium barbadense</i>
<b>Modified trait(s):</b>	Herbicide tolerance
<b>Identity of the gene(s) responsible for the modified trait(s):</b>	Glyphosate herbicide tolerance conferred by the <i>cp4 epsps</i> gene obtained from the bacterium <i>Agrobacterium sp.</i> strain CP4
<b>Proposed Location(s):</b>	All cotton growing areas of Australia
<b>Proposed Release Size:</b>	N/A
<b>Proposed Release Dates:</b>	Ongoing from date of approval

#### 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 by managing those risks through 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*<sup>2</sup> outlines the assessment process that will be followed.

#### The application and the proposed dealings

The Regulator has received an application from Monsanto seeking approval for the commercial release of genetically modified (GM) cotton (*Gossypium barbadense*) into the Australian environment. The cotton species *G. barbadense*, also known as pima cotton, has been modified to

<sup>1</sup> The title of the licence application submitted by Monsanto is "Licence application to the OGTR for general release of herbicide tolerant (Roundup Ready Flex<sup>®</sup> MON88913) *Gossypium barbadense* in Australia."

<sup>2</sup> 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>>.

be tolerant to the herbicide glyphosate. The genetic modification in the GM pima cotton proposed for release is the same as that already approved for commercial release in another species of cotton, *G. hirsutum*, this latter GM cotton being known as Roundup Ready Flex<sup>®</sup> cotton. To distinguish these two GM cottons, the new GM cotton is referred to as Roundup Ready Flex<sup>®</sup> pima cotton.

Roundup Ready Flex<sup>®</sup> pima cotton has been produced by the conventional breeding of Roundup Ready Flex<sup>®</sup> *G. hirsutum* with unmodified *G. barbadense*.

Monsanto is seeking approval for unrestricted commercial release of Roundup Ready Flex<sup>®</sup> pima in all cotton growing areas of Australia. It is envisaged that the locations of sowing will be dependent on the technical fit of the product to the field conditions, as well as the availability of seed. However, as *G. barbadense* is most suited to western NSW, it is likely that the GM plants will be grown in this region. In the future, expansion could occur into areas in southern Queensland.

Food Standards Australia New Zealand (FSANZ) has assessed and approved food from the GM parent (Roundup Ready Flex<sup>®</sup> *G. hirsutum*). This approval includes any food derived from offspring produced through conventional breeding, and therefore covers Roundup Ready Flex<sup>®</sup> pima cotton. The Australian Pesticides and Veterinary Medicines Authority (APVMA) has registered Roundup Ready<sup>®</sup> Herbicide by Monsanto for use on Roundup Ready Flex<sup>®</sup> cotton. This registration also applies to Roundup Ready Flex<sup>®</sup> pima cotton.

### **Parent organism**

The parent organism, *G. barbadense*, is commonly known as pima cotton, Extra Long Staple (ELS) or Egyptian cotton. Pima cotton produces a superior fibre to the more commonly grown *G. hirsutum* cotton but constitutes only 1% of the cotton grown in Australia. *G. barbadense* is mainly grown in western NSW, where the associated weather pattern (in particular the dry autumn) is optimum for the production of high fibre quality. Commercial cotton species are not native to Australia, but originated in the Americas, *G. barbadense* likely coming from South America.

### **The genetic modification and its effect**

The GM Roundup Ready Flex<sup>®</sup> pima cotton contains two copies of the *cp4 epsps* gene derived from the soil bacterium *Agrobacterium tumefaciens*, these genes conferring tolerance to the herbicide glyphosate. The *epsps* gene encodes 5-enol-pyruvylshikimate-3-phosphate synthase, EPSPS, which catalyses the conversion of phosphoenol pyruvate (PEP) and shikimate 3-phosphate (SHKP) to 5-enol-pyruvylshikimate-3-phosphate (EPSP). This reaction, part of the shikimic acid pathway, is essential for the biosynthesis of the aromatic amino acids phenylalanine, tyrosine, and tryptophan. The enzyme is found in plants and microorganisms, but is absent from mammals, birds, reptiles and fish. Plant EPSPS enzymes are inhibited by glyphosate, which resembles PEP, and binds preferentially to the active site. However, the *cp4 epsps* enzyme has a greater affinity for PEP than glyphosate, making GM plants carrying this gene tolerant to the herbicide. The GM plants of this application do not contain any antibiotic resistance marker(s).

Expression of the introduced *cp4 epsps* genes in the GM cotton is controlled by regulatory sequences derived from plant pathogens (cauliflower mosaic virus and figwort mosaic virus) and from the plants *Pisum sativum* (pea) and *Arabidopsis thaliana* (thale cress).

### **Method of genetic modification**

The *cp4 epsps* genes were initially introduced into *G. hirsutum* by *Agrobacterium tumefaciens* mediated transformation. This method has been widely used in Australia and overseas for introducing new genes into plants. Conventional breeding was used to transfer the genetic modification from Roundup Ready Flex<sup>®</sup> *G. hirsutum* to non-GM *G. barbadense*. Plants deriving

from an initial cross between Roundup Ready Flex<sup>®</sup> *G. hirsutum* to non-GM *G. barbadense* were back-crossed with non-GM *G. barbadense* to introgress the *cp4 epsps* genes into the genome of *G. barbadense*.

### **Previous releases of the same or similar GMOs**

The Regulator has previously issued licence DIR 074/2007 to Monsanto for a field trial of Roundup Ready Flex<sup>®</sup> pima cotton. Licences were also issued to Monsanto for the same genetic modification in *G. hirsutum*. Roundup Ready Flex<sup>®</sup> *G. hirsutum* was approved for field trials under licences DIRs 035/2003 and 055/2004, and for commercial release under licences DIR 059/2005 (south of latitude 22° south) and DIR 066/2006 (throughout Australia). Other herbicide tolerant and/or insect resistant GM cottons have been approved for commercial release under the trade names Bollgard<sup>®</sup>, Roundup Ready<sup>®</sup>, Liberty Link<sup>®</sup>, and Widestrike<sup>™</sup>.

### **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 any revocation of a licence or permit held under 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**

Since this application is for commercial purposes, it cannot be considered a limited and controlled release application under section 50A of the Act.

This means that the Regulator is required to seek advice from prescribed experts, agencies and authorities on matters relevant to the preparation of a Risk Assessment and Risk Management Plan (RARMP), in accordance with section 50 of the Act. This first round of consultation must include the Gene Technology Technical Advisory Committee, State and Territory Governments, Australian Government agencies, any local council that the Regulator considers appropriate and the Environment Minister. While the Regulator is not required to seek public comment at this stage, copies of the application are available on request from the OGTR.

In a second round of consultation, the Regulator will seek comment on the consultation RARMP from the public as well as prescribed experts, agencies and authorities. 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 at the end of April 2013**. 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:

**The Office of the Gene Technology Regulator, MDP 54 GPO Box 9848 Canberra ACT 2601**

**Telephone: 1800 181 030 Facsimile: 02 6271 4202 E-mail: [ogtr@health.gov.au](mailto:ogtr@health.gov.au)**

**[OGTR Website](#)**