



Australian Government

Department of Health and Ageing

Office of the Gene Technology Regulator

Licence for dealings involving an intentional release of GMOs into the environment

Licence No.: DIR 066/2006

Licence holder: Monsanto Australia Ltd

Title: Commercial release of GM herbicide tolerant and/or insect resistant cotton lines

Issued: 26 October 2006

Varied: 22 December 2006

Varied: 6 December 2007

Varied: 15 April 2009

More information about the decision to issue this licence is contained in the Risk Assessment and Risk Management Plan prepared in connection with the assessment of the application for the licence. This document can be obtained from the Office of the Gene Technology Regulator website at <http://www.ogtr.gov.au>, or by telephoning the Office on 1800 181 030.

Gene Technology Regulation in Australia

Australia's gene technology regulatory system operates as part of an integrated legislative framework. The *Gene Technology Act 2000* (Cth) and corresponding state and territory legislation form a substantial part of a range of integrated regulatory measures relevant to controlling genetically modified organisms (GMOs) and their use.

The Gene Technology Regulator is required to consult with, and take into account advice from a range of key stakeholders, including regulatory authorities, on risks to human health and safety and to the environment in assessing applications for dealings involving the intentional release of GMOs into the Australian environment.

Other agencies that also regulate GMOs or GM products include Food Standards Australia New Zealand, Australian Pesticide and Veterinary Medicine Authority, Therapeutic Goods Administration, National Industrial Chemicals Notification and Assessment Scheme, National Health and Medical Research Council and Australian Quarantine and Inspection Service. Dealings conducted under any licence issued by the Regulator may also be subject to regulation by one or more of these agencies. It is recommended that the licence holder consult the relevant agency (or agencies) about their regulatory requirements.

Dealings permitted by this licence may also be subject to the operation of State legislation declaring areas to be GM, GM free, or both, for marketing purposes.

Section 1 Interpretations and Definitions

In this licence:

- (a) unless defined otherwise in this licence, words and phrases used in this licence have the same meanings as they do in the Act and the Gene Technology Regulations 2001;
- (b) words importing a gender include any other gender;
- (c) words in the singular include the plural and words in the plural include the singular;
- (d) words importing persons include a partnership and a body whether corporate or otherwise;
- (e) references to any statute or other legislation (whether primary or subordinate) are a reference to a statute or other legislation of the Commonwealth of Australia as amended or replaced from time to time and equivalent provisions, if any, in corresponding State law, unless the contrary intention appears;
- (f) where any word or phrase is given a defined meaning, any other part of speech or other grammatical form in respect of that word or phrase has a corresponding meaning.

In this licence:

‘Act’ means the Gene Technology Act 2000 (Cth) and equivalent provisions in corresponding State law.

‘Annual Report’ means a written report provided to the Regulator within 90 days of each anniversary of the date of issue of this licence containing all the information required by this licence.

‘Cotton’ means plants of the species *Gossypium hirsutum* L.

‘Deal with’ in relation to a GMO means one or more of the following:

- (a) conduct experiments with the GMOs;
- (b) make, develop, produce or manufacture the GMOs;
- (c) breed the GMOs;
- (d) propagate the GMOs;
- (e) use the GMOs in the course of manufacture of a thing that is not the GMOs;
- (f) grow, raise or culture the GMOs;
- (g) import the GMOs;

and includes the possession, supply, use, transport or disposal of the GMO for the purposes of, or in the course of, a dealing mentioned in any of paragraphs (a) to (g).

‘GM’ means genetically modified.

‘GMOs’ means the genetically modified organisms listed in Attachment B and authorised for release by this licence.

‘OGTR’ means the Office of the Gene Technology Regulator.

‘Personal information’ means information or an opinion (including forming part of a database), whether true or not, and whether recorded in a material form or not, about an individual whose identity is apparent, or can reasonably be ascertained, from the information or opinion.

‘Location’ means an area of land where the GMOs are planted and grown for the purposes of a licence.

‘Regulator’ means the Gene Technology Regulator.

Section 2 Licence Conditions

Duration of licence

1. This licence remains in force until it is suspended, cancelled or surrendered. No dealings with the GMOs are authorised during any period of suspension.

Holder of licence

2. The holder of this licence ('the licence holder') is Monsanto Australia Ltd.

Project Supervisor

3. The Project Supervisor in respect of this licence is identified at Attachment A.
4. The licence holder must immediately notify the Regulator in writing if any of the contact details of the Project Supervisor change.

GMOs covered by this licence

5. The GMOs covered by this licence ('the GMOs') are identified and described at Attachment B.

Location

6. This licence permits dealings with the GMOs to be conducted in all areas of Australia.
7. The extent that the conditions of any prior licence authorising dealings with the GMO are inconsistent with the conditions of this licence, the conditions of this licence will prevail.

Persons covered by this GMO licence

8. Subject to condition 9, any person, including the licence holder, may conduct any Dealing with the GMOs.
9. Where the GMOs authorised by this licence are planted or in any other way Dealt with as part of a subsequent licence, or subsequent licence variation, authorising a dealing under the Act, then, for purposes of the subsequent licence, or subsequent licence variation,
 - (a) only the persons covered by the subsequent licence or licence variation are permitted to grow or otherwise deal with the GMOs, and,
 - (b) the conditions of the subsequent licence or the licence containing the licence variation, and not the conditions of this licence, will apply to the dealing with the GMOs.

Example: If a subsequent licence contemplates the planting of these GMOs in a Location containing another GMO authorised by that later licence, the conditions of the subsequent licence and not the conditions of this licence will apply to the GMOs for purposes of the dealings conducted under that licence.

Informing people of their obligations

10. The licence holder must inform any person covered by this licence, to whom a particular condition of this licence applies, of the following:
 - (a) the particular condition (including any variations of it);

- (b) the cancellation or suspension of the licence;
 - (c) the surrender of the licence.
11. The licence holder must notify the project supervisor and all persons covered by a licence to whom a condition of this licence applies that Personal Information collected by the licence holder which is relevant to the administration and/or enforcement of the licence may be released to the Regulator.

Licence holder to notify of circumstances that might affect suitability

12. The licence holder must immediately, by notice in writing, inform the Regulator of:
- (a) any relevant conviction of the licence holder occurring after the commencement of this licence;
 - (b) any revocation or suspension of a licence or permit held by the licence holder under a law of the Australian Government, a State or a foreign country, being a law relating to the health and safety of people or the environment;
 - (c) any event or circumstances occurring after the commencement of this licence that would affect the capacity of the holder of this licence to meet the conditions in it.

Licence holder must provide information on matters related to suitability

13. The licence holder must provide information related to the licence holder's ongoing suitability to hold a licence when requested to do so in writing by the Regulator and must provide the information within a time period stipulated by the Regulator.

People dealing with GMOs must allow auditing and monitoring of the dealing

14. If a person authorised by this licence to deal with GMOs and a particular condition of this licence applies to the dealing by that person, the person must allow the Regulator, or a person authorised by the Regulator, to enter premises where the dealing is being undertaken, for the purposes of auditing or monitoring the dealing.

Remaining an accredited organisation

15. The licence holder must, at all times, remain an accredited organisation in accordance with the Act and comply with its instrument of accreditation.

Additional information to be given to the Regulator

16. It is a condition of a licence that the licence holder inform the Regulator if the licence holder:
- (a) becomes aware of additional information as to any risks to the health and safety of people, or to the environment, associated with the dealings authorised by the licence; or
 - (b) becomes aware of any contraventions of the licence by a person covered by the licence; or
 - (c) becomes aware of any unintended effects of the dealings authorised by the licence.

Note: The Act requires, for the purposes of the above condition that:

- (a) the licence holder will be taken to have become aware of additional information of a kind mentioned in condition 16 if he or she was reckless as to whether such information existed; and*
 - (b) the licence holder will be taken to have become aware of contraventions, or unintended effects, of a kind mentioned in condition 16 if he or she was reckless as to whether such contraventions had occurred, or such unintended effects existed.*
17. The licence holder must provide the information required by paragraphs (a), (b) and (c) of condition 16 to the Regulator as soon as practically and reasonably possible and must also include the information in the Annual Report.
18. If at any time the Regulator requests the licence holder to collect and provide information about any matter to do with the progress of the dealings authorised by this licence, including but not confined to,
- (a) additional information as to any risks to the health and safety of people, or to the environment, associated with the dealings authorised by the licence, whether or not the licence holder has provided information to the Regulator under condition 16(a); and
 - (b) any contraventions of the licence by a person covered by the licence, whether or not the licence holder has provided information to the Regulator under condition 16(b); and
 - (c) any unintended effects of the dealings authorised by the licence, whether or not the licence holder has provided information to the Regulator under condition 16(c); and
 - (d) information about the actual or anticipated regional location and size of the release, for a nominated period, and
 - (e) research, including by way of survey, to verify predictions of the risk assessment, or for any purpose related to risks to the health and safety of people, or to the environment, and
 - (f) scientific literature and reports in respect of the GMO(s) authorised by this licence, for a nominated period, and
 - (g) details of any refusals of applications for licences or permits (however described) to deal with the GMO(s) made pursuant to the regulatory laws of a foreign country,
- and the request is reasonable, having regard to consistency with the Act and relevance to its purpose, then the licence holder must collect the information and provide it to the Regulator at a time and in the manner requested by the Regulator.
19. If the Regulator invites the licence holder to make a submission on the reasonability of a request by the Regulator to collect and provide information relevant the progress of the GMO, the licence holder may make such a submission to the Regulator within thirty (30) days of receipt of the invitation.

Compliance management plan

20. Prior to growing the GMOs, a written Compliance Management Plan must be provided to the Regulator. The Compliance Management Plan must describe in detail how the licence holder intends to ensure compliance with each of these conditions and document that compliance.

Annual Report

21. The licence holder must provide an Annual Report to the Regulator.
22. An annual report must include the following:
 - (a) Information about any adverse impacts, unintended effects, or new information relating to risks, to human health and safety or the environment caused by the GMOs or material from the GMOs;
 - (b) Information about the volumes of the GMOs grown for commercial purposes, including seed increase operations, in each State and Territory for each growing season in the period;
 - (c) Information about the volumes of the GMOs grown for non-commercial (eg research) purposes in each State and Territory for each growing season in the period.

Testing Methodology

23. The licence holder must provide a written instrument to the Regulator describing an experimental method that is capable of reliably detecting the presence of the GMOs and the presence of the genetic modifications described in this licence (at Attachment B) in a recipient organism. The instrument must be provided within thirty (30) days of the issuing of this licence.

Attachment A

DIR No: 066/2006

***Full Title:** Commercial release of GM herbicide tolerant and/or insect resistant cotton lines

Organisation Details

Postal address: Monsanto Australia Ltd
PO Box 6051
St Kilda Road Central, MELBOURNE VIC 8008

Phone No: (03) 9522 7122

Fax No: (03) 9522 6122

Project Supervisor Details

Surname: *[Personal Information Redacted]*

First Name: *[Personal Information Redacted]*

Title: *[Personal Information Redacted]*

Phone No: *[Personal Information Redacted]*

Fax: *[Personal Information Redacted]*

Email Address: *[Personal Information Redacted]*

Position: *[Personal Information Redacted]*

Organisation: *[Personal Information Redacted]*

Postal Address: PO Box 6051
St Kilda Road Central, MELBOURNE VIC 8008

IBC Details

IBC Name: Monsanto Australia Ltd

* Information that must be included in the Record of GM Products and GMOs Dealings.

GMOs Description

Purpose of the Dealing with the GMOs:

The aim of the proposed release is to allow commercial production of the GMOs in all areas of Australia, and for products of the GMOs to enter general commerce.

The GMOs covered by this licence are as follows:

- Bollgard II[®] MON15985 cotton[§]
- Roundup Ready[®] MON1445 cotton
- Roundup Ready Flex[®] MON 88913 cotton
- Roundup Ready[®] MON1445/Bollgard II[®] MON15985 cotton[§]
- Roundup Ready Flex[®] MON 88913/Bollgard II[®] MON15985 cotton[§]

***Parent Organism(s):**

Common Name: Cotton

Scientific Name: *Gossypium hirsutum* L.

***Modified Trait(s):**

Category: Herbicide tolerance; Insect resistance;
Herbicide tolerance/Insect resistance;
Antibiotic resistance

Description: Cotton plants have been genetically modified to enhance tolerance to the herbicide glyphosate and/or to be resistant to the major caterpillar pests of cotton. Three GMOs have a single introduced trait, either insect resistance (Bollgard II[®] MON15985) or herbicide tolerance (Roundup Ready[®] and Roundup Ready Flex[®]). Two GMOs have both traits and were produced by conventional crossing of the single trait lines (Roundup Ready[®] MON1445/Bollgard II[®] MON15985 cotton and Roundup Ready Flex[®] MON 88913/Bollgard II[®] MON15985 cotton).

***Gene Responsible for Conferring the Modified Trait(s):**

one or two copies of *cp4 epsps* gene from *Agrobacterium* sp. strain CP4 (herbicide tolerance)

cryIAc and *cry2Ab* genes from the bacterium *Bacillus thuringiensis* (insect resistance)

nptII gene from the bacterial Tn5 transposon (antibiotic resistance)

uidA gene from the bacterium *Escherichia coli* (reporter gene)

[§] Includes GM Cotton containing only the *cryIAc* or *cry2Ab* gene

* Information that must be included in the Record of GM Products and GMOs Dealings.