



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 059/2005

Licence holder: Monsanto Australia Ltd

Title: Commercial Release of herbicide tolerant (Roundup Ready Flex[®] MON 88913) and herbicide tolerant/insect resistant (Roundup Ready Flex[®] MON 88913/Bollgard II[®]) cotton south of latitude 22° South in Australia

Issued: 16 February 2006

More information about this licence is contained in the Risk Assessment and Risk Management Plan prepared in connection with this 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 FSANZ, APVMA, TGA, NICNAS, NHMRC and AQIS. 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.

PART 1

Interpretations and Definitions

This licence does not authorise dealings with GMOs that are otherwise prohibited as a result of the operation of State legislation declaring areas to be GM, GM free, or both, for marketing purposes.

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 *Gene Technology Act 2000* (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:

‘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 to be provided in the Annual Report.

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

‘Covered Vehicles’ means vehicles that use tight fitting covers to prevent spillage or escape of the load during transporting (for example a trailer with sides moulded or sealed to the base fitted with a roll-over tarp).

‘Deal with’ in relation to a GMO means any one or more of the following as permitted by this licence,

- (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.

‘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.

‘Restricted Zone’ means north of latitude 22° South anywhere in Australia.

‘Technology Users Agreement’ means an agreement by which the licence holder licenses, authorises or otherwise permits the use of the GMO.

‘Volunteer plant’ means progeny of the GMO.

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 Limited.

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**.

Dealings authorised by this licence SOUTH of the Restricted Zone

6. Subject to condition 7, any person, including the licence holder, may conduct any Dealing south of the Restricted Zone.
7. 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 *Gene Technology Act 2000*, 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.

Dealings authorised by this licence IN the Restricted Zone

8. Any person, including the licence holder, may, subject to the conditions of this licence,
 - (a) transport GM whole cotton seed into the Restricted Zone and/or
 - (b) use GM whole cotton seed for stock feed.

Note: This licence does not authorise any other dealing in the Restricted Zone. Dealing with the GMO in the Restricted Zone may however be permitted by another licence issued by the Regulator.

Transport and use of GM whole cotton seed in the Restricted Zone

9. If cotton seed from the GMOs is used as stock feed in the Restricted Zone, feeding must take place inside stock yards, feedlots or dairies.
10. GM whole cotton seed derived from the GMOs must not be transported to the Restricted Zone other than in accordance with the conditions of this licence.

Note: This condition does not apply to the transport of GM whole cotton seed derived from the GMOs into the Restricted Zone if it is permitted by another licence.

11. Transporters of GM whole cotton seed to destinations within the Restricted Zone must:
 - (a) only transport the GM whole cotton seed in Covered Vehicles or in unbreakable sealed containers within a vehicle;
 - (b) sign Covered Vehicles, or unbreakable containers and transporting vehicle, to indicate that they contain GM whole cotton seed, and with instructions to contact the licence holder in the event that the GM whole cotton seed is spilt or misdirected, including telephone contact numbers.
12. The licence holder must prepare and distribute to cotton gins from which GM whole cotton seed will be transported into the Restricted Zone sufficient copies of the sign required by Condition 11. This sign must accompany each shipment of cotton seed into the Restricted Zone.
13. Cotton gins from which GM whole cotton seed is transported into the Restricted Zone must provide transporters with a sign to accompany every shipment of whole cotton seed into the Restricted Zone, and must maintain a record of this action.
14. The licence holder must, in consultation with the OGTR, develop a communication strategy, including documentation for distribution, to convey the importance of appropriate control of cotton volunteers to all recipients of GM whole cotton seed. A copy of the documentation must be provided in the Compliance Management Plan.
15. The licence holder must take all reasonable steps to distribute the documentation specified in condition 14 to:
 - (a) the cotton gins from which GM whole cotton seed is sourced for transport into the Restricted Zone;
 - (b) the transporters of GM whole cotton seed into the Restricted Zone; and
 - (c) all recipients of GM whole cotton seed within the Restricted Zone, including retailers and the end users of the GM whole cotton seed.
16. A copy of the documents required by conditions 14 must be provided in the Compliance Management Plan.

Terms of Technology Users Agreement

17. The licence holder must not enter into a Technology Users Agreement or any other agreement which would permit the GMOs to be grown or in any other way dealt with in the Restricted Zone other than in a manner permitted by the licence. A copy of the standard Technology Users Agreement must be included in the Compliance Management Report.

Note: This condition does not prevent the licence holder from entering into a Technology Users Agreement permitting the GMOs to be dealt with in the Restricted Zone if the dealing is permitted pursuant to another licence.

Informing people of their obligations

18. 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.
19. Where the licence holder or an agent of the licence holder enters into a Technology Users Agreement or any other agreement to licence, authorise, or in any other way permit a person to use the GMOs, the licence holder, after having regard to the intended use of the GMO by the person, must,
- (a) notify the user of the GMO of the conditions which will apply to the user, and
 - (b) explain those conditions, and
 - (c) notify the user that breach of the conditions is an offence under the Gene Technology Act 2000
20. The licence holder must provide written notification to cotton gins from which GM whole cotton seed will be transported into the Restricted Zone which contains the following,
- (a) notice of the conditions which will apply to transporters of whole cotton seed into the Restricted Zone, and
 - (b) an explanation of those conditions, and
 - (c) a notice that breach of those conditions is an offence under the Gene Technology Act 2000 ('the Act'), and
 - (d) a request that the cotton gins convey the information contained in (a), (b) and (c) to transporters of GM whole cotton seed into the Restricted Zone.

21. Cotton gins from which GM whole cotton seed is transported into the Restricted Zone must comply with a request of the licence holder made under condition 20(d).
22. The licence holder must provide the Regulator, on the Regulator's written request, evidence that the licence holder has informed people of the conditions of this licence that apply to them.

Applicant to notify of circumstances that might affect suitability

23. 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 his licence to meet the conditions in it.

Licence holder must provide information on matters related to suitability

24. 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.

Additional information to be given to the Regulator

25. The licence holder must inform the Regulator if the licence holder becomes aware of:
 - (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; or
 - (b) any contraventions of the licence by a person covered by the licence; or
 - (c) any unintended effects of the dealings authorised by the licence.
26. The licence holder must provide the information required by paragraphs (a) (b) and (c) of the immediately preceding condition to the Regulator as soon as practically and reasonably possible and must also include the information in the Annual Report.

Remaining an accredited organisation

27. The licence holder must, at all times, remain an accredited organisation in accordance with the *Gene Technology Act 2000* and comply with any conditions of accreditation set out in the licence holder's instrument of accreditation.

Compliance management plan

28. Prior to planting 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 these conditions and to document that compliance.

Note: The Compliance Management Plan must include copies of documents required to be provided under conditions 11, 14 and 20.

Annual Report

29. The licence holder must provide an Annual Report to the Regulator.

Testing Methodology

30. 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 any transferred genetically modified material that might be present in a recipient organism. The instrument must be provided within 30 days of the issue date of the licence.

ATTACHMENT A

DIR No: 059/2005

***Full Title:** Commercial Release of herbicide tolerant (Roundup Ready Flex[®] MON 88913) and herbicide tolerant/insect resistant (Roundup Ready Flex[®] MON 88913/Bollgard II[®]) Cotton south of latitude 22° South in Australia

Organisation Details

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

Phone No: (03) 9522 7158

Fax No: (03) 9521 2725

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: Monsanto Australia Ltd

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

IBC Details

IBC Name: Monsanto Australia Limited

* 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 areas south of latitude 22 degrees South and for products of the GMOs to enter general commerce.

The GMOs covered by this licence are as follows:

Roundup Ready Flex[®] MON 88913 cotton and
Roundup Ready Flex[®] MON 88913/Bollgard II[®] cotton

***Parent Organism(s):**

Common Name: Cotton

Scientific Name: *Gossypium hirsutum* L.

Modified Trait(s):

*Category: Herbicide tolerance; Herbicide tolerance/Insect resistance

*Description: Cotton plants have been genetically modified to enhance tolerance to the herbicide glyphosate (Roundup Ready Flex[®] cotton MON 88913) and to be resistant to the major caterpillar pests of cotton (Roundup Ready Flex[®] cotton MON 88913/Bollgard II[®]).

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

two copies of the *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)

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