



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 035/2003

Licence holder: Monsanto Australia Ltd

Title: Field trials of herbicide tolerant (Roundup Ready® Flex cotton MON 88913) and herbicide tolerant/insect resistant (Roundup Ready® Flex cotton MON 88913/Bollgard II®) Cotton

Issued: 15 October 2003
Varied: 13 February 2004
Varied: 28 May 2004
Varied: 15 October 2004
Varied: 17 March 2005
Varied: 03 June 2005
Varied: 14 September 2005
Varied: 17 October 2005

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.

Note in relation to approval of genetically modified foods for human consumption

Food Standards Australia New Zealand (FSANZ, formerly the Australia New Zealand Food Authority), is responsible for human food safety assessment. Currently, Monsanto has not applied to FSANZ for evaluation of material from the GM cottons for use in human food. FSANZ approval would need to be obtained before any parts of the GM cottons such as oil and linters derived from GM cotton seed could be used as human food.

Note in relation to Herbicide Tolerance and Insecticide Resistance Management

The *Gene Technology (Consequential Amendments) Act (2000)* requires the Australian Pesticides and Veterinary Medicines Authority (APVMA, formerly the National Registration Authority for Agricultural and Veterinary Chemicals, NRA) to consult the Gene Technology Regulator for the purposes of making certain decisions regarding registration or issuing a permit for a chemical product that is or contains a genetically modified product.

The GMOs referred to in this licence have been modified to be tolerant to a herbicide. The APVMA has responsibility for setting registration conditions for the use of herbicides in Australia, including implementation of herbicide resistance management programs. Conditions of this licence do not relate to use of herbicides, and do not replace any conditions set by the APVMA. The licence holder must comply with any conditions imposed by the APVMA in relation to the use of herbicides in connection with these GMOs.

One of the genetically modified organisms referred to in this licence also falls into *the Agricultural and Veterinary Chemicals Code (1994)* definition of an agricultural chemical product, due to its production of an insecticidal substance, and therefore is subject to regulation by the APVMA.

The APVMA has imposed conditions in connection with the insecticidal activity of one of the genetically modified organisms (Bollgard® II), including specifying maximum areas for release, for the purpose of managing the development of insecticide resistance in the target pest species. Conditions of this licence do not relate to management of insecticide resistance, and do not replace any conditions set by the APVMA. The licence holder must comply with any conditions imposed by the APVMA in relation to dealings with this GMO.

Note about where the GMOs have been planted pursuant to this licence

Information about where the GMOs have been planted pursuant to this licence can be found here: [Site Details](#)

SECTION 1 GENERAL CONDITIONS

Duration of Licence

1. This licence remains in force until it is suspended, cancelled or surrendered. No dealings with 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.

No dealings with GMOs except as authorised by this licence

5. Persons covered by this licence must not deal with the GMOs except as expressly permitted by this licence.

GMOs covered by this licence

6. The GMOs covered by this licence are described at Attachment B.

Permitted dealings

7. The permitted dealings with the GMOs are to plant, grow and conduct experiments with the GMOs, and the possession, supply, use, transport and disposal of the GMOs for the purpose of any of the permitted dealings with the GMOs, or in the course of any of these dealings.

Persons covered by this GMO licence

8. The persons covered by this licence are the licence holder and employees, agents or contractors of the licence holder and other persons who are, or have been, engaged to undertake any activity in connection with GMOs grown in a Location pursuant to this Licence.

Informing people of their obligations

9. 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.

10. The licence holder must provide the Regulator, on the Regulator's written request, signed statements from persons covered by this licence that the licence holder has informed those people of the conditions of this licence that apply to them.

Applicant to notify of circumstances that might affect suitability

11. 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.

Additional information to be given to the Regulator

12. 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.

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

13. If a person is 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

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

SECTION 2 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:

Words and phrases used in this licence have the same meaning as they do in the Act and the Regulations;

Words importing a gender include any other gender;

Words in the singular include the plural and words in the plural include the singular;

Words importing persons include a partnership and a body whether corporate or otherwise; 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;

Where any word or phrase is given a defined meaning, any other part of speech or other grammatical form in respect of that word has a corresponding meaning;

Specific conditions prevail over standard conditions to the extent of any inconsistency.

In this licence:

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

‘Clean’ (or **‘Cleaned’**), as the case requires, means:

- a) in relation to a Location or other area, the Destruction of the GMOs, Material from the GMOs, Pollen Trap plants and Material from Pollen Trap plants in that Location or area, to the reasonable satisfaction of the Regulator; or
- b) in relation to Equipment, the removal and Destruction of the GMOs, Material from the GMOs, Pollen Trap plants and Material from Pollen Trap plants from the Equipment, to the reasonable satisfaction of the Regulator.

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

‘Destroy’, (or **‘Destroyed’** or **‘Destruction’**) means, as the case requires, killed by one or more of the following methods:

- (a) stalk pulling; or
- (b) uprooting by ploughing; or
- (c) burning; or
- (d) treatment with herbicide; or
- (e) hand weeding.

Note: 'As the case requires' has the effect that, depending on the circumstances, one or more of these techniques may not be appropriate. For example, in the case of killing the remains of harvest of the GMOs, treatment of post harvest remains by herbicide would not be a sufficient mechanism.

'Equipment' includes harvesters, seeders, storage equipment, transport equipment (eg bags, containers, trucks), clothing and tools.

'GM' means genetically modified.

'GMOs' means the genetically modified organism or organisms authorised for release by this licence.

'Isolation Zone' means the area of land extending outwards 50 metres in all directions from the outer edge of a Location.

'Location' means an area of land where the GMOs are planted and grown.

'Material from Pollen Trap plants' means seed, stubble, pollen or any GM material (including parts of a plant) that is derived from or produced by cotton from a Pollen Trap.

'Material from the GMOs' means genetically modified material, including parts of GMOs that are derived from or produced by the GMOs.

'Natural Waterways' means waterways other than irrigation channels, holding dams or storage ponds used to collect water runoff from irrigated areas.

'OGTR' means the Office of the Gene Technology Regulator.

'Pollen Trap' means an area of land, extending at least 20 metres in all directions from the outside edge of a Location.

'Pollen Trap plant' means cotton from a Pollen Trap.

'Regulator' means the Gene Technology Regulator.

'Research Zone' means an area of land, extending at least 400 metres in all directions from the outside edge of a Location.

'Sign-off' means a notice in writing from the Regulator, in respect of a place, that post harvest inspection conditions no longer apply in respect of that place.

'Volunteer plants' means progeny of the GMOs or Pollen Trap plants, or regrowth of previous GM or non-GM cotton plants.

SECTION 3 SPECIFIC CONDITIONS

Locations and size of trial

1. The permitted dealings with the GMOs may be undertaken during the Summer 2003/2004 cotton growing season in the Shires and valleys and sizes and quantities as indicated in below in Table 1:

Table 1: Shires in which the GMOs may be grown in Summer 2003/2004

Shire	Valley	State	Maximum area of Locations including GMOs and non-GM cotton, excluding Pollen Trap (ha)
Narrabri Shire	Upper Namoi	NSW	0.4
Narrabri Shire	Lower Namoi	NSW	2.2
Narromine Shire	Macquarie	NSW	0.7
Moree Plains Shire	Gwydir	NSW	0.5
Jondaryan Shire	Darling Downs	QLD	0.6

2. The permitted dealings with the GMOs may be undertaken during the cotton growing seasons in Winter 2004, Summer 2004/2005 and Winter 2005 within the Shires set out in following table:

Table 2: Shires where permitted dealings with GMOs may be conducted in Winter 2004, Summer 2004/2005 and Winter 2005

NSW	QLD	NT	WA
Balranald	Aramac	Katherine	Broome
Bingara	Balonne		Wyndham – East Kimberley
Bland	Banana		
Bogan	Cambooya		
Bourke	Chinchilla		
Brewarrina	Clifton		
Broken Hill	Dalby		
Carrathool	Emerald		
Central Darling	Fitzroy		
Coonamble	Flinders		
Deniliquin	Gatton		
Dubbo	Goondiwindi		
Forbes	Inglewood		
Griffith	Jondaryan		
Gunnedah	Kingaroy		
Hay	Milmeran		
Jerilderie	Monto		
Lachlan	Murilla		
Moree Plains	Murweh		
Murrumbidgee	Peak Downs		
Narrabri	Pittsworth		
Narromine	Richmond		
Parry	Rosalie		
Quirindi	Toowoomba		
Tamworth	Waggamba		
Walgett	Wambo		
Warren	Warroo		
Yallaroi	Wondai		

3. For the cotton growing seasons in Winter 2004, Summer 2004/2005 and Winter 2005, the maximum number of Locations for those growing seasons (where permitted dealings may be conducted) are set out in Table 3 at Column 2. The maximum combined area of all Locations where permitted dealings may occur in those growing seasons is limited to the size set out in Table 3 at Column 3:

Table 3: Maximum numbers of Locations and combined areas

Growing season	Maximum number of Locations	Maximum combined area of all Locations
Winter 2004	4	30 ha
Summer 2004/5	32	885.8 ha
Winter 2005	4	30 ha

4. In the Summer 2004/2005 growing season, the maximum size of any individual Location is 50 hectares. (No individual field trial site can be more than 50 hectares.)
5. The licence holder must be able to access and control a Location to the extent necessary to comply with this licence, for the duration of the life of the licence.

Non GM Cotton not excluded from Location

6. Non-GM cotton may be planted at a Location but must be treated as a GMO for purposes of this licence (see condition 11).

Notice of planting

7. The licence holder must provide a notice in writing to the Regulator which contains:
 - (a) the date on which planting of the GMOs is intended to commence;
 - (b) the date on which planting of any non-GMOs is intended to commence;
 - (c) details of the Location where the GMOs will be planted, including a street address and GPS coordinates for the Location;
 - (d) the period during which the licence holder considers the GMOs are likely to flower;
 - (e) the period during which the licence holder considers the GMOs are likely to be harvested (or Destroyed in lieu of harvest); and
 - (f) if GMOs have previously been planted at a site, a history indicating how the site has been used in the preceding two years, including details of previous GMOs and post-harvest crops planted at the Location.

The notice must be provided to the Regulator at least 7 days prior to the date on which planting of the GMOs is intended to commence.

Note : Information about where the GMOs have been planted pursuant to this licence can be found here: [Site Details](#)

Notice of Cleaning

8. The licence holder must provide a notice in writing to the Regulator when a Location is Cleaned (following harvest or Destruction of GMOs at a Location in lieu of harvest). The notice must be provided to the Regulator within 14 days of the date on which Cleaning the Location concluded.

Measures to manage Gene Flow

9. Locations north of latitude 22 degrees South must be surrounded by an Isolation Zone.
10. Locations south of latitude 22 degrees South must be surrounded by a Pollen Trap.
11. Any non-GM cotton planted at a Location while the GMO is growing at the Location must be handled and controlled as though it were the GMO (ie subject to other applicable conditions elsewhere in this licence).

Restrictions on the use of Isolation Zones - not near to naturalised cotton populations or other crops of cotton

12. A Location cannot be surrounded by an Isolation Zone if there is:
 - (a) a naturalised population of cotton or *Gossypium barbadense* within 450m of the Location; or
 - (b) a crop of cotton within 450m of the Location, other than a crop of Cotton or *Gossypium barbadense* planted pursuant to this licence.

Other conditions about Pollen Traps

13. Each Pollen Trap must be planted out with non-genetically modified cotton or Bollgard® II cotton. These plants must be grown in such a way as to reasonably promote a dense and vigorous growth and flowering of the plants at the same time as the GMOs.
14. The edge of every Pollen Trap that is farthest from the GMOs (the ‘outer edge of the Pollen Trap’) must not be within 50 metres of a Natural Waterway.
15. Pollen Trap plants must be handled and controlled as if they are the GMOs (ie subject to other applicable conditions elsewhere in this licence), and Material from Pollen Trap plants must be handled and controlled as if it is Material from the GMOs (ie subject to other applicable conditions elsewhere in this licence).
16. A Pollen Trap must be able to be accessed and controlled by the licence holder to an extent that is commensurate with the licence holder’s rights to access and control the Location within it.

Other conditions about Isolation Zones

17. No cotton or *Gossypium barbadense* of any kind may be grown in an Isolation Zone while the GMOs are being grown at the Location within it.

18. No flowering cotton or *Gossypium barbadense* plants may be present in an Isolation Zone while the GMOs are being grown at the Location within it.
19. Any vegetative cotton or *Gossypium barbadense* plants occurring in an Isolation Zone must be Destroyed prior to flowering.
20. An Isolation Zone must be able to be accessed and controlled by a licence holder to an extent that is commensurate with the licence holder's rights to access the Location within it.
21. If a crop of cotton (other than a crop of Cotton planted pursuant to this licence) or *Gossypium barbadense* is planted within 450m of a Location with an Isolation Zone around it, either the crop of cotton or the GMOs in the Location must be Destroyed prior to flowering. If GMOs in a Location are Destroyed pursuant to this condition, they are taken to have been harvested for the purposes of this licence.

Research Zones

22. Each Location of 1 hectare or more in size that is planted to the GMOs in the Winter 2004, Summer 2004/2005 and Winter 2005 growing seasons must be surrounded by a Research Zone unless the licence holder has a notice in writing from the Regulator that a Research Zone in connection with the Location is not required.
23. Each Research Zone must be able to be accessed and controlled by the licence holder to the extent necessary to enable the licence holder to meet its obligations under this licence to conduct research in the Research Zone.

Material from the GMOs may be collected

24. Any Material from the GMO and Material from Pollen Trap plants may be collected from a Location within the Frank Wise Institute (Kununurra) for the purpose of conducting experiments on it.
25. Subject to conditions 26 any Material from the GMO and Material from Pollen Trap plants that is collected may be transported off the Location to:
 - a) a facility certified by the Regulator to physical containment level 2 (PC2); or
 - b) a facility approved in writing by the Regulator and signed so as to indicate that GM material is stored within the facility,and may be experimented on and stored in any one or more of these facilities.
26. Any Material from the GMO and Material from Pollen Trap plants that is collected from Locations at the Frank Wise Institute (Kununurra) may be transported off the Location to the following facilities within the same farm unit:

- a) building 6 and building 21, Room 1 (laboratories); or
- b) building 7 (office); or
- c) buildings 12, 18, 19 and 20 (sheds),

and may be experimented on and stored in any one or more of these facilities. Each facility must be signed so as to indicate that GM material is stored within the facility.

27. After any experiments with the material from the GMOs are completed, the Material from the GMO and Material from Pollen Trap plants must be Destroyed.

Harvest and post-harvest procedures

28. If the GMOs or Pollen Trap plants are harvested, they must be harvested separately from any other Cotton.
29. If seed cotton harvested from the GMOs or from Pollen Trap plants is ginned, it must be ginned separately from any other Cotton.
30. The GMOs, Material from the GMOs, Pollen Trap plants and Material from Pollen Trap plants, must not be used for stockfeed and must not enter the human food supply.
31. Following ginning, seed from the GMOs and Pollen Trap plants must be:
- (a) stored in a sealed container, within a locked facility that is signed so as to indicate that GM cotton seed is stored within the facility;
 - (b) exported; or
 - (c) Destroyed by burning.
32. Any GM cotton seed obtained from ginning may only be transported to the extent necessary to store them, export them, Destroy them by burning or take them to a facility certified by the Regulator to physical containment level PC2.
33. Cotton lint obtained from ginning of seed cotton harvested from the GMOs or Pollen Trap plants may be sold.

Cleaning – post harvest and generally

34. Equipment, a Location or other area used pursuant to this licence in respect of GMOs, Material from the GMOs, Pollen Trap plants or Material from Pollen Trap plants, must be Cleaned.
35. For each Location, either within 14 days of harvest of the GMOs or within 9 months of planting of the GMOs, whichever occurs first, the Location must be Cleaned.
36. If Equipment is Cleaned, the area in which the Equipment is Cleaned must also be Cleaned. (For the sake of clarity, it is not necessary for Equipment to be Cleaned only at a Location.)
37. Cleaning must occur immediately or as soon as practicable after the use and before it is used for any other purpose. (For example, if GM seed is ginned, the gin must be Cleaned immediately following its use and before any other Cotton is ginned.)

38. On the request of the Regulator, the Regulator must be provided with written documentation of the procedures in place to ensure continuing compliance with the Cleaning conditions in this licence.

Inspection

39. Following Cleaning of the GMOs, Material from the GMOs, Pollen Trap plants and Material from Pollen Trap plants (if any), at a Location or other area, the following places must be inspected for the existence of Volunteer plants:
- (a) the Location;
 - (b) the Pollen Trap in respect of the Location (if any);
 - (c) the Isolation Zone in respect of the Location (if any);
 - (d) irrigation channels and drains through which water flows to and from the Location and the Pollen Trap; and
 - (e) any areas used to Clean Equipment used in connection with the GMOs at the Location or to Destroy the GMOs, Material from the GMOs, Pollen Trap plants or Material from Pollen Trap plants.
40. Inspection must be performed by a person who is able to recognise Volunteer plants.
41. All the places required to be inspected must be inspected at least once every 2 months, commencing on the last day of Cleaning of the Location and continuing either until the Regulator has issued a sign-off or until the GMOs are once again grown at the Location in a new growing season, pursuant to this Licence.
42. The results of inspection activities must be recorded in a logbook or paper file. The logbook or paper file must be available on request for examination or photocopying by the OGTR. The findings of the inspections as recorded in the logbook or paper file must be included in the licence holder's annual report to the Regulator. The logbook or paper file must contain at least the following:
- (a) details of the areas inspected;
 - (b) details of the date of inspection;
 - (c) the names of the person or persons who undertook the monitoring and details of the experience, training or qualification that enabled them to recognise Volunteer plants;
 - (d) the number of Volunteer plants observed, if any;
 - (e) details of the development stages reached by the Volunteer plants, if any; and
 - (f) details of methods used to Destroy Volunteer plants, if any.
43. Any Volunteer plant identified must be Destroyed prior to the plant flowering.
44. If:
- (a) inspections have been routinely completed in a place for a period of at least 12 months; and
 - (b) inspection records for that place show that no Volunteers have been observed in the most recent 6 month inspection period;

the licence holder may make written application to the Regulator that these inspection conditions no longer apply in respect of that place.

45. These inspection conditions do not apply in respect of a place if the licence holder has received a sign-off.

Use of a Location planted with a GMO authorised under Licence DIR 055/2004 and general conditions on use of Locations post-harvest

46. A Location may be planted with GMOs licenced under DIR 055/2004 following Cleaning of that Location provided that notice of an intention to plant those GMOs is provided to the Regulator at least 7 days before planting occurs.

47. The notice in writing to the Regulator under the immediately preceding condition must contain:

- (a) the date on which planting of the GMOs is intended to commence;
- (b) the date on which planting of any non-GMOs is intended to commence;
- (c) details of the Location where the GMOs will be planted, including a street address and GPS coordinates for the Location;
- (d) the period during which the licence holder considers the GMOs are likely to flower;
- (e) the period during which the licence holder considers the GMOs are likely to be harvested (or Destroyed in lieu of harvest); and
- (f) a history indicating how the site has been used in the preceding two years, including details of previous GMOs and post-harvest crops planted at the Location.

48. If notice of an intention to plant GMOs, as licensed under DIR 055/2004, is provided to the Regulator at least 7 days before planting occurs then the conditions of this licence cease to apply to that Location when the Location is planted.

49. If a Location is planted with a GMO licenced under DIR 055/2004 following Cleaning of that Location the conditions of licence DIR 055/2004 apply to that GMO and that Location.

Note: This means that the conditions applying to a Location planted with a GMO authorised under DIR 055/2004 would apply to the GMO and the Location rather than the conditions of this licence.

50. Subject to conditions 42 to 45 no other Cotton plant of any kind may be grown at the Location, Pollen Trap or Isolation Zone in respect of the Location, after harvest of the GMOs or Pollen Trap plants, except in accordance with this licence, until inspection obligations are completed.

51. If the GMOs are grown at a Location, no plants may be planted at the Location, Pollen Trap or Isolation Zone in respect of the Location, except in accordance with this licence, until inspection obligations are completed unless:

- (a) the plants are grasses (grass pastures), cereals (cereal crops); or
- (b) the plants are plants agreed to in writing by the Regulator; and
- (c) the Regulator is satisfied that monitoring and Destruction of Volunteer plants prior to setting seed will not be adversely affected by the planting.

Transportation of the GMOs, Material from GMOs, Pollen Trap plants and Material from Pollen Trap plants

52. Subject to the conditions immediately below in respect of transportation, the GMOs, Material from the GMOs, Pollen Trap plants and Material from Pollen Trap plants must be transported in accordance with the OGTR Guidelines for the Transport of GMOs (June 2001) issued by the Regulator.
53. Harvested GMOs, Pollen Trap plants, Material from the GMOs or Material from Pollen Trap plants may be transported to a ginning facility in a cotton module that is:
- (a) completely enclosed within 2 layers of tarpaulin ('double wrapped in tarpaulin');
 - (b) completely enclosed within a layer of tarpaulin inside a layer of shade cloth ('double wrapped in tarpaulin and shade cloth'); or
 - (c) contained within an enclosed chain-bed truck specifically designed for the purpose of transporting cotton modules.
54. Fuzzy Cottonseed from the GMOs or Pollen Trap plants may be transported between Kununurra and Narrabri within calico bags that are tied shut and then placed inside closed wooden boxes. Wooden boxes used to transport the fuzzy Cottonseed may have ventilation holes, up to 25mm in diameter, if the ventilation holes are securely covered with fly-proof wire mesh.
55. Cotton lint derived from GMOs and Pollen Trap plants from ginning is not subject to transportation conditions.
56. Every container used to transport the GMOs, Material from the GMOs, Pollen Trap plants and Material from Pollen Trap plants must be labelled:
- (a) to indicate that it contains genetically modified Cotton; and
 - (b) with telephone contact numbers for the licence holder and instructions to contact the licence holder in the event that the container is broken or misdirected.
57. The licence holder must have in place accounting procedures to verify whether the same quantity of GMOs, Material from the GMOs, Pollen Trap Plant or Material from Pollen Trap plants sent is delivered and must document routes, methods and procedures used for transportation of GMOs, Material from the GMOs, Pollen Trap plants and Material from Pollen Trap plants.

Contingency Plans

58. Within 30 days of the date of the commencement of this licence, a written Contingency Plan must be submitted to the Regulator detailing measures to be taken in the event of the unintended presence of the GMOs, Material from the GMOs, Pollen Trap plants or Material from Pollen Trap plants, outside an area that must be inspected.
59. The Contingency Plan must include details of procedures to:

- (a) ensure the Regulator is notified immediately if the licence holder becomes aware of the event;
 - (b) destroy any of the GMOs, Material from the GMOs, Pollen Trap plants or Material from Pollen Trap plants; and
 - (c) inspect and Destroy any Volunteer plants that may exist as a result of the event.
60. The Contingency Plan must be implemented in the event that the unintended presence of the GMOs, Material from the GMOs, Pollen Trap plants and Material from Pollen Trap plants is discovered outside an area that must be inspected.

Compliance Management Plan

61. 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 these conditions and document that compliance.

Reporting

62. The licence holder must provide the Regulator with a written report within 90 days of each anniversary of this licence, in accordance with any Guidelines issued by the Regulator in relation to annual reporting. This report must include information on any adverse impacts on human health and safety or the environment, caused as a result of the GMOs, Material from the GMOs, Pollen Trap plants or Material from Pollen Trap plants.

Research requirements

63. The licence holder must, in consultation with the OGTR, develop an agreed research program to collect information regarding:
- (a) genetic segregation and molecular characterisation of the introduced genetic material;
 - (b) the levels of expression of proteins by the introduced genes;
 - (c) the stability and persistence of introduced proteins in the soil under Australian conditions;
 - (d) the expression of the glyphosate tolerant phenotype during development of the GM plants;
 - (e) the agronomic characteristics indicative of potential weediness of the GM cottons under Australian conditions;
 - (f) validation of previous research on the efficacy of the Pollen Trap; and
 - (g) validation of previous research on gene transfer from GM Cotton to other Cotton using the Research Zone.
64. In accordance with any Guidelines issued by the Regulator in relation to annual reporting, the licence holder must provide the Regulator with a written report of the progress and results of the research program. This report must accompany the annual report to be sent to the Regulator.

Testing methodology

65. 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 12 months of the issuing of this licence.

Use of GMOs, Material from the GMOs, Pollen Trap plants and Material from Pollen Trap plants

66. The licence holder must ensure that the GMOs, Material from the GMOs, Pollen Trap plants or Material from Pollen Trap plants are not consumed by humans or used in the manufacture of animal feed or therapeutics.

DIR No: 035/2003

***Full Title:** Field trials of herbicide tolerant (Roundup Ready® Flex cotton MON 88913) and herbicide tolerant/insect resistant (Roundup Ready® Flex cotton MON 88913/Bollgard II®) Cotton

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: Monsanto Australia Ltd

Postal Address: PO Box 6051
St Kilda Road Central, 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

***Parent Organism(s) Common Name:** Cotton

***Parent Organism(s) 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/or confer resistance to caterpillar pests (Roundup Ready[®] Flex cotton MON 88913/Bollgard[®] II or Bollgard[®] II).

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

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 *Escherichia coli* (reporter gene)

Purpose of the Dealing with the GMOs:

The aim of the proposed release is to evaluate the agronomic performance of genetically modified cottons and to collect further data for future large scale or commercial releases.

*** INFORMATION THAT MUST BE INCLUDED IN THE RECORD OF GM PRODUCTS AND GMOs DEALINGS.**