



**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 055/2004**

**Licence holder: Monsanto Australia Ltd**

**Title: Field trials of herbicide tolerant (Roundup Ready<sup>®</sup> Flex cotton MON 88913) and herbicide tolerant/insect resistant (Roundup Ready<sup>®</sup> Flex cotton MON 88913/Bollgard II<sup>®</sup>) Cottons.**

Issued: 26 April 2005  
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**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**

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 stakeholders, including regulatory authorities, on risks to human health and safety and the environment in assessing applications for dealings involving the intentional release of GMOs into the Australian environment.

### **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. Monsanto has 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. This licence contains a condition that prohibits this use.

### **Note in relation to Herbicide and Insecticide Resistance Management**

The *Gene Technology (Consequential Amendments) Act (2000)* requires the Australian Pesticides and Veterinary Medicines Authority (APVMA) 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.

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 parent organisms (Bollgard II<sup>®</sup>) 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.

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.

### **Note about where dealings with GMOs are being undertaken pursuant to this licence**

Information about where the GMOs are being planted pursuant to this licence, including the exact site details will be made available at the beginning of winter (2005), summer (2005/2006) and winter (2006) planting seasons.

## SECTION 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) words and phrases used in this licence have the same meaning as they do in the Act and the Regulations;
- (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 has a corresponding meaning;
- (g) 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.

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

**‘Burial site’** means a site at which seed from the GMOs or the Pollen Trap plants is destroyed by burial under at least 1 metre of soil.

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

- (a) in relation to a Location or other area, the Destruction of the GMOs, Pollen Trap plants and Plant Material 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, Pollen Trap plants and Plant Material 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; or
- (f) autoclaving; or
- (g) in respect of seed only, burial under at least 1 metre of soil.

*Note (1): ‘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.*

*Note (2): Where method (g) is adopted, this licence contains additional conditions relating to burial as a method of destruction.*

**‘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.

**‘Insect-proof Glasshouse’** means a facility used for growing plants that is constructed, maintained and used in such a manner as to prevent insects entering and/or leaving the facility.

**‘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 and for purposes of this licence does not include an insect-proof glasshouse.

**‘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.

**‘Plant Material’** means viable parts of the GMOs or Pollen Trap plants, including seed, stubble and pollen, whether from the plant itself or derived from or produced by the plant.

**‘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.

**‘Population of Cotton or *Gossypium barbadense*’** means a group, or groups, of 5 or more plants per 10 square meters of land belonging to the species *Gossypium hirsutum* or *Gossypium barbadense*.

**‘Regulator’** means the Gene Technology Regulator.

**‘Sign-off’** means a notice in writing from the Regulator, in respect of a place or a Location, whichever applies, that post harvest inspection conditions no longer apply in respect of that place or Location.

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

## **SECTION 2 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.

### **Persons covered by this GMO licence**

6. 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**

7. 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.
8. 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**

9. 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**

10. 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**

11. 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.
12. 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.

### **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 3 SPECIFIC CONDITIONS

### GMOs covered by this licence

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

### Permitted dealings

2. 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.

### Locations and size of trial

3. The permitted dealings with the GMOs may be undertaken during the cotton growing seasons in Summer 2005/2006 and Winter 2006 within the Shires set out in the following table:

Table 1: Shires where permitted dealings with the GMOs may be conducted in Summer 2005/2006 and Winter 2006

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

4. Subject to condition 3, the permitted dealings with the GMOs may also be undertaken during the cotton growing season in Winter 2005 and Winter 2006 within the Burdekin shire (Queensland) to an area of up to 0.1 hectare each season.
5. The GMOs may also be grown in Insect-proof Glasshouses if grown pursuant to the special conditions contained in conditions 26 to 32.
6. For the cotton growing seasons in Summer 2005/2006 and Winter 2006, the maximum number of Locations for those growing seasons (where permitted dealings may be conducted) are set out in Table 2 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 2 at Column 3.

*Note: This condition does not apply to insect-proof glasshouses. See the definition of Location.*

Table 2: Maximum numbers of Locations and combined areas

Growing season	Maximum number of Locations	Maximum combined area of all Locations
Summer 2005/2006	86	1770 ha
Winter 2006	5	45 ha

7. In the Summer 2005/2006 growing season, the maximum size of any individual Location is 100 hectares. (No individual field trial site can be more than 100 hectares.)
8. 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.
9. The GMOs must not be planted within 50 metres of a natural waterway.

#### **Non-GM Cotton not excluded from Location**

10. Non-GM cotton may be planted and grown at a Location along with the GMO but must be treated as a GMO for purposes of this licence.

*Note: This means that all conditions which apply to the GMO apply equally to any non GM cotton planted on a Location.*

#### **Notice of planting**

11. 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.

12. 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 are being planted pursuant to this licence, including the exact site details will be made available at the beginning of winter (2005), summer (2005/2006) and winter (2006) planting seasons.*

### **Notice of Harvest and Cleaning**

13. The licence holder must provide a notice in writing to the Regulator stating when the Location was harvested and when the Location was 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 of the Location concluded.

### **Measures to manage Gene Flow**

14. Each Location north of latitude 22 degrees South must be surrounded by an Isolation Zone.

15. Each Location south of latitude 22 degrees South must be surrounded by a Pollen Trap.

### **Restrictions on the use of Isolation Zones**

16. A Location cannot be surrounded by an Isolation Zone if there is:

- (a) a naturalised Population of Cotton or of *Gossypium barbadense* within 450m of the Location; or
- (b) a Population of Cotton or *Gossypium barbadense* within 450m of the Location, other than a population of Cotton planted pursuant to this licence.

### **Other conditions about Pollen Traps**

17. Each Pollen Trap must be planted out with non-genetically modified Cotton or Bollgard II<sup>®</sup> 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.

18. 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.

19. 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 Plant Material must be handled and controlled as if it is the GMOs (ie subject to other applicable conditions elsewhere in this licence).

20. 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**

21. 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.
22. 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.
23. Any vegetative Cotton or *Gossypium barbadense* plants occurring in an Isolation Zone must be Destroyed prior to flowering.
24. 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.
25. If a Population of Cotton (other than a Population of Cotton planted pursuant to this licence) or *Gossypium barbadense* is planted within 450m of a Location with an Isolation Zone around it, either this Population 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.

#### **Special conditions that apply where GMOs are grown in an Insect-proof Glasshouse**

26. If the GMOs are grown in an Insect-proof Glasshouse ('glasshouse'):
- (a) the GMOs must be grown in pots; and
  - (b) while the GMOs are growing in the glasshouse, sticky pest strips must be maintained within the glasshouse; and
  - (c) the glasshouse must be maintained and kept insect-proof at all times; and
  - (d) the GMOs must be grown only during the period between September 2005 and November 2006 only in the Shires set out in table 1; and
  - (e) no more than 10 glasshouses may be used for growing the GMOs at any one time; and
  - (f) the licence holder must be able to control and access the glasshouse to the extent necessary to comply with this licence for the duration of the licence; and
  - (g) conditions 33 to 48, 66 and 69 apply to GMOs being grown in the glasshouses as if the glasshouses were Locations; and
  - (h) all plants growing in the glasshouse must be treated as if they were the GMOs.
27. When any of the GMOs growing in glasshouses are no longer required for purposes of dealings authorised under this licence:

- (a) soil from the pots in which the GMOs were grown, must be relocated, as soon as practicable, to a Location that is subject to post-harvest monitoring, or, sterilised using non-pressurised steam sterilisation; and
  - (b) the GMOs and the Plant Material must be:
    - (i) relocated to a Location that is subject to post-harvest monitoring, or
    - (ii) relocated to a facility described in condition 34, or
    - (iii) Destroyed.
28. When the last GMO in a glasshouse has been Destroyed or relocated, the glasshouse must be Cleaned.
29. GMOs and Plant Materials must be transported in accordance with the OGTR Guidelines for the Transport of GMOs (June 2001) issued by the Regulator.
30. Written notices must be provided to the Regulator within 14 days of the first GMO being planted in each glasshouse. The notice must include the street address and GPS coordinates of the glasshouse.
31. Written notices must be provided to the Regulator within 14 days of any soil, GMOs or Plant Material being relocated to a Location under condition 27. The notice must include the street address and GPS coordinates of the Location to which the soil, GMOs or Plant Material was relocated and the date of relocation.
32. Written notices must be provided to the Regulator within 14 days of the last GMO in a glasshouse being Destroyed or relocated. The notice must include the street address and GPS coordinates of the glasshouse.

*Note: The immediately preceding condition is the last of the Special Conditions applying to glasshouses.*

#### **Material from the GMOs may be collected**

33. Any material from the GMOs, including Plant Material, may be collected from a Location for the purpose of conducting experiments on it.
34. Any material from the GMOs, including Plant Material, 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 Plant Material is stored within the facility; or
  - (c) a laboratory at the Monsanto Research Facility in Toowoomba and signed so as to indicate that GM Plant Material is stored within the facility; or
  - (d) a locked cool room or freezer at the Monsanto Research Facility in Toowoomba and signed so as to indicate that GM Plant Material is stored within the facility;

and may be experimented on and stored in any one or more of these facilities.

35. After any experiments with the material from the GMOs are completed, the Plant Material must be Destroyed or freeze dried.

### **Harvest and post-harvest – Ginning and use of seed**

36. If the GMOs or Pollen Trap plants are harvested, they must be harvested separately from any other crop.
37. If seed Cotton harvested from the GMOs or from Pollen Trap plants is ginned, it must be ginned separately from any other crop.
38. 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;
  - (c) Destroyed by burning; or
  - (d) Destroyed by burial under at least 1 metre of soil.
39. 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 burial, or take them to a facility certified by the Regulator to physical containment level 2 (PC2).
40. Cotton lint obtained from ginning of seed Cotton harvested from the GMOs or Pollen Trap plants may be sold.

### **Harvest and post-harvest – Storage in Cotton Modules**

41. Seed cotton harvested from the GMOs or from pollen trap plants in the 2005/2006 growing season may be stored in cotton modules at a Location for up to six months from the date of harvest provided that the Regulator is notified in writing within 30 days of harvest that the cotton is to be stored in cotton modules at that Location.
42. Cotton modules used to store cotton pursuant to the previous condition must be double covered down to the ground, either in two layers of tarpaulin or in a layer of tarpaulin and a layer of shade cloth, and labelled to indicate that they contain GM cotton.
43. Cotton modules used to store cotton pursuant to the previous two conditions must be inspected monthly and any damage to the tarpaulin or shade cloth must be repaired immediately.
44. The licence holder must notify the Regulator in writing of the date and results of inspections conducted under the previous condition within 14 days of the date on which the inspection takes place.

### **Conditions relating to burial of seed**

45. If seed from the GMOs or Pollen Trap plants is buried, the licence holder must:
- (a) Within 30 days of burial, provide the Regulator by notice in writing of the precise location of the Burial site (GPS coordinates and either a street address or other directions to the Burial site) and the date on which it was buried.
  - (b) Monitor the burial site at least once every 3 months for a period of 12 months to identify:
    - (i) any significant disturbance that may effect the emergence of volunteer plants and if disturbance is identified, notify the Regulator of appropriate remedial action taken; and
    - (ii) any emergence of Volunteer plants. If Volunteer plants are identified, the Burial site must be Cleaned.

### **Cleaning – post harvest and generally**

46. Equipment, a Location or other area (including a gin) used pursuant to this licence in respect of GMOs, Pollen Trap plants or Plant Material must be Cleaned.
47. 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.
48. 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.)
49. Cleaning must occur immediately or as soon as practicable after 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 crop is ginned.)
50. 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**

51. Following Cleaning of 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;
  - (e) the area between the Location and any sinkholes into which water from the Location flows, as well as the immediate area surrounding these sinkholes; and

- (f) any areas used to Clean Equipment used in connection with the GMOs at the Location or to Destroy the GMOs, Pollen Trap plants or Plant Material.

52. Inspection must be performed by a person who is able to recognise Volunteer plants.

53. For each Location, 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 until the Regulator has issued a Sign-off.

54. 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.

55. Any Volunteer plant identified must be Destroyed prior to the plant flowering.

56. For each Location, and all places in respect of that particular Location as listed in condition 50,

- (a) if inspections have been routinely completed in that Location and all those places for a period of at least 12 months, and,

- (b) if inspection records for that Location and all those places 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 to that particular Location and the places in respect of that particular Location as listed in condition 50.

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

### **General conditions on use of Locations post-harvest**

58. 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 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; or
- (c) the plants are non-GM cotton which are planted for one growing season only, and which are treated as GMOs for purposes of this licence.

*Note: This means that all conditions which apply to the GMO apply equally to any non GM cotton planted on a Location post-harvest.*

### **Transportation of the GMOs, Pollen Trap plants and Plant Material**

- 59. Subject to the conditions immediately below in respect of transportation, the GMOs, Pollen Trap plants and Plant Material must be transported in accordance with the OGTR Guidelines for the Transport of GMOs (June 2001) issued by the Regulator.
- 60. Harvested GMOs, Pollen Trap plants and Plant Material 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.
- 61. 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.
- 62. Cotton lint derived from GMOs and Pollen Trap plants from ginning is not subject to transportation conditions.
- 63. Every container used to transport the GMOs, Pollen Trap plants and Plant Material 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.
- 64. The licence holder must have in place accounting procedures to verify whether the same quantity of GMOs, Pollen Trap plants or Plant Material sent is delivered and must document routes, methods and procedures used for transportation of GMOs, Pollen Trap plants and Plant Material.

## **Contingency Plans**

65. 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, Pollen Trap plants or Plant Material, outside an area that must be inspected.
66. 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, Pollen Trap plants or Plant Material; and
  - (c) inspect for and Destroy any Volunteer plants that may exist as a result of the event.
67. The Contingency Plan must be implemented in the event that the unintended presence of the GMOs, Pollen Trap plants and Plant Material is discovered outside an area that must be inspected.

## **Compliance Management Plan**

68. 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**

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

## **Testing methodology**

70. 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 30 days of the issuing of this licence.

## **Use of GMOs, Pollen Trap plants and Plant Material**

71. The GMOs, Pollen Trap plants and Plant Material must not be used, sold or otherwise disposed of for any purpose which would involve or result in their use as food for animals or humans.

**DIR No: 055/2004**

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

**Organisation Details**

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**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<sup>®</sup> Flex cotton MON 88913) and/or confer resistance to caterpillar pests (Roundup Ready<sup>®</sup> Flex cotton MON 88913/Bollgard II<sup>®</sup> or Bollgard II<sup>®</sup>).

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

*cp4 epsps* gene from *Agrobacterium* sp. strain CP4 (herbicide tolerance)

*cry1Ac* 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)

**Purpose of the Dealing with the GMOs:**

The aims of the proposed release are to transfer the herbicide tolerant trait into elite cotton varieties suitable for use under Australian conditions, to test the agronomic performance of the GM cottons, to produce seed for future releases (which would require separate approval), to set up demonstration sites for industry, government, researchers and the wider community and to collect data required for future applications.

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