



Australian Government

Department of Health and Ageing

Office of the Gene Technology Regulator

Licence for dealings involving an intentional release of a GMO into the environment

Licence No.: DIR 081/2007

Licence holder: Monsanto Australia Limited

Title: Limited and controlled release of cotton genetically modified for altered water use efficiency

Issued: 16 September 2008

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 nationally consistent regulatory system controlling the development and use of genetically modified organisms (GMOs).

This licence is issued by the Gene Technology Regulator in accordance with the *Gene Technology Act 2000* and, as applicable, Corresponding State Law.

The Gene Technology Regulator is required to consult with, and take into account advice from a range of key stakeholders, including other 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.

The licence authorises the licence holder and persons covered by the licence to conduct specified dealings with the genetically modified organism(s) listed in Attachment B of this licence.

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.

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

Information about where the GMOs have been planted pursuant to this licence can be found in a separate document entitled 'DIR 081/2007 Site Details'. This document can be viewed by accessing the document on the OGTR website at

<http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/dir081-2007>

Proposed licence conditions for DIR081/2007

Section 1 Interpretations and Definitions

1. 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.
2. In this licence:
 - (a) unless defined otherwise in this licence, 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) or the corresponding State legislation under which this licence is issued.

'Annual Report' means a written report provided to the Regulator within ninety (90) days of each anniversary of issue of this licence containing all the information required by this licence to be provided in the Annual Report.

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

- (a) in relation to a Place specified in this licence as requiring Cleaning, the Destruction of the GMOs and Plant Material in that Place, to the reasonable satisfaction of the Regulator; or
- (b) in relation to the Location specified as Brisbane or Toowoomba glasshouses in this licence as requiring Cleaning, the Destruction of the GMOs, Plant Material, plant pots and soil used for cultivating the GMO in that Place, to the reasonable satisfaction of the Regulator; or
- (c) in relation to Equipment, the removal and Destruction of the GMOs and Plant Material from the Equipment, to the reasonable satisfaction of the Regulator.

'Cotton' means plants of the species *Gossypium hirsutum* L. and *G. barbadense* L.

'Cultivate' means the following:

- (a) till the soil in a manner suitable for the germination of Cotton seed; and
- (b) provide adequate soil moisture to promote the germination of Cotton seed.

‘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) burial under at least one (1) metre of soil.

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 organisms that are the subject of the dealings authorised by this licence.

‘Harvest’ means the gathering of crops at maturity.

‘Location’ means an area of land or glasshouse where the GMOs or other plants are planted and grown pursuant to this licence, but does not include the Pollen Trap.

‘Monitoring Zone’ means an area of land extending at least one hundred (100) metres in all directions from the outside edge of a Location.

‘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.

‘Personal Information’ means information or an opinion (including information 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.

‘Place’ means an area required to be cleaned and/or inspected under this licence in respect of each Location.

‘Plant Material’ means the whole, or any part of the GMO plants or non-GM Cotton plants grown at the Location or in the Pollen Trap with respect to that Location, whether viable or not, including, but not limited to, seed, lint, 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 twenty (20) metres in all directions from the outside edge of a Location.

‘Pollen Trap Plant’ means non-GM or commercially approved GM Cotton.

‘Sign-off’ means a notice in writing from the Regulator, in respect of a Site, that post-Harvest inspection conditions no longer apply in respect of that Site.

‘Site’ for each Location means the aggregate of all Places in respect of that Location.

‘Volunteer Plants’ means progeny of the GMOs or non-GM Cotton plants grown at the Location or of the Pollen Trap Plants, or regrowth of previous GMOs or non-GM Cotton plants.

Section 2 General conditions

Duration of Licence

3. 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

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

Project Supervisor

5. The Project Supervisor in respect of this licence is a person named in Attachment A of the licence.

6. The licence holder must immediately notify the Regulator in writing if any of the contact details of the Project Supervisor change.

No dealings with the GMOs except as authorised by this licence

7. Persons covered by this licence must not Deal with the GMOs except as expressly permitted by this licence.

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 or otherwise authorised by the licence holder to undertake any activity in connection with the Dealings authorised by 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. Prior to a person covered by this licence conducting any Dealings, the licence holder must obtain signed statements from those persons that the licence holder has informed those people of the conditions of this licence that apply to them and that they have understood the conditions and agree to be bound by them. The licence holder must provide the Regulator, on the Regulator's written request, with copies of these signed statements from persons covered by this licence.

11. The immediately preceding condition does not apply to conditions imposed by way of variation to the licence. Where a variation to a licence imposes a new

condition, the licence holder must notify persons to whom the condition applies within the time period, and in the manner, stipulated by the Regulator at the time the licence is varied.

12. The licence holder must notify the project supervisor and all persons covered by a licence 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.

Applicant to notify of circumstances that might affect suitability

13. 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; and
- (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; and
- (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

14. 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

15. It is a condition of this licence that the licence holder informs 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 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, if he or she was reckless as to whether such contraventions had occurred, or such unintended effects existed.*

16. 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

17. If a person is authorised by this licence to Deal with the 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.

18. The licence holder must be able to access and control all Sites to the extent necessary to comply with this licence, for the duration of the life of the licence.

Remaining an Accredited organisation

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

Notices

20. The licence holder must provide all notices to the Regulator required to be given by this licence and each notice must be provided in the manner required by Section 7 of this licence.

Section 3 Growing the GMOs

GMOs covered by this licence

21. The GMOs covered by this licence are described in Attachment B of the licence.

Permitted dealings

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

Non-GM Plants

23. Non-GM Cotton may be planted and grown at the Locations, but if planted, Plant Material from non-GM plants grown at the Locations must be handled and controlled as if it were Plant Material from the GMOs (ie subject to other conditions elsewhere in this licence).

Limits - locations, growing season and size of trial

24. The permitted dealings with the GMOs may be undertaken between September 2008 and June 2010 inclusive, within the New South Wales local government areas (LGAs) of Balranald, Bourke, Central Darling, Carathool, Coonamble, Gunnedah, Hay, Lachlan, Moree Plains, Narrabri, Narromine, Walgett, Warren and Lake Tandou (an unincorporated area); the Queensland LGAs of Paroo, Balonne, Dalby Regional, Goondiwindi Regional, Toowoomba Regional, Somerset Regional, Brisbane City and Lockyer Valley Regional; and the Western Australia LGA of Wyndham-East Kimberley.

25. No more than 20 Locations may be used in one season.

26. Each Location may have a maximum area of 2 ha per season and the maximum combined area of the 20 Locations must not exceed 40 hectares per season.

27. If a Location is a glasshouse it must be located at the Monsanto Biotechnology Research Centre, 3 Rocla Court, Toowoomba, Qld (LGA of Toowoomba Regional) or

at the Department of Primary Industries Quarantine Facility, 160 Curtin Ave, West Eagle Farm, Qld (LGA of Brisbane City).

28. Prior to the first planting at a Location, the licence holder must provide a notice in writing to the Regulator of the details of the Location including the size, and a street address and GPS coordinates for the Location and Pollen Trap (if any).

29. This licence allows dealings with the GMOs at Location(s) which are currently subject to the conditions of licence DIR 064/2006 even if Sign-off has not occurred with respect to that Location. To the extent that any condition under DIR 064/2006 is inconsistent with the conditions applying under this licence with respect to Dealings conducted,

- (a) at a Location of DIR 064/2006, and/or
- (b) the Site in respect of that Location,

the conditions of this licence prevail.

Notice of intention to plant and of planting

30. The licence holder must, in the manner required by condition 81, give advance notice to the Regulator of an intention to plant the GMOs.

31. The licence holder must, in the manner required by condition 82, give notice to the Regulator of the actual date of planting the GMOs.

Controls – planting and growing

32. An insect control program must be implemented which is capable of minimising dispersal of pollen by insect vectors from GMOs grown at a glasshouse. Details of the insect control program and its implementation must be made available to the Regulator upon request.

33. Each Location (with the exception of a glasshouse) must be:

- (c) surrounded by a Monitoring Zone and located at least 3 km from the outer edge of the Location to the outer edge of the nearest intentionally planted Cotton crop, or;
- (d) surrounded by a Pollen Trap.

34. Subject to condition 33, if any intentionally planted Cotton crop not grown pursuant to this licence occurs within 3 km of a Location with a Monitoring Zone, while the GMOs are being grown at the Location, either the Cotton crop or the GMOs in the Location must be Destroyed prior to flowering. If GMOs are Destroyed pursuant to this condition, the GMOs are taken to have been Harvested for the purposes of this licence and all conditions applying to post-Harvest apply equally to post-Destruction.

Conditions relating to Monitoring Zones

35. If used, the Monitoring Zone must be inspected and any Cotton plants found in the Monitoring Zone Destroyed prior to flowering while the GMOs are being grown at the Location.

36. If used, the Monitoring Zone 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 the Location within it.

Conditions related to Pollen Traps

37. Each Pollen Trap must contain only Pollen Trap Plants grown in such a way as to reasonably promote a dense and vigorous growth and in such a way as to ensure that the Pollen Trap Plants flower at the same time and for the same period of time as the GMOs.

38. Each Pollen Trap must be planted and maintained in a way that ensures that for the duration of flowering of the GMOs there is a continuous barrier of plants at least twenty (20) metres deep in all directions around the Location, although allowance may be made for a path of approximately 2.5 m in width in order to access the Location.

39. The edge of every Pollen Trap that is farthest from the GMOs (the 'outer edge of the Pollen Trap') must not be within fifty (50) metres of a Natural Waterway.

40. Pollen Trap Plants and Plant Material from Pollen Trap Plants must be handled and controlled as if they were the GMOs (ie subject to other applicable conditions elsewhere in this licence).

Section 4 Use of Plant Material

Experiment and storage

41. Experiments and/or analysis of Plant Material is only permitted if:

- (a) the experiment and/or analysis is a notifiable low risk dealing; and
- (b) the experiment and/or analysis does not involve the feeding of the Plant Material to humans or animals.

Note: A dealing will only be a notifiable low risk dealing if:

- (a) *an Institutional Biosafety Committee has been asked to assess whether the proposed Dealing is a notifiable low risk dealing; and*
- (b) *the Committee has assessed the proposed dealing to be a notifiable low risk dealing; and*
- (c) *the person who proposes to undertake the proposed dealing and the project supervisor for the proposed dealing have been notified that the Committee;*
 - i) has assessed the proposed dealing to be a notifiable low risk dealing;*
 - and*
 - ii) considers that the personnel to be involved in the proposed dealing have appropriate training and experience.*

42. Experiments and/or analysis of Plant Material must take place

- (a) at the Location or an area used to Clean Equipment in respect of that Location; or
- (b) in a facility certified by the Regulator to PC2; or
- (c) in a facility approved in writing by the Regulator and signed so as to indicate that GM Plant Material is stored within the facility

and Plant Material must be Destroyed as soon as practicable.

Note: Transport of Plant Material must comply with conditions 51 to 53.

Note: The above conditions do not permit experiments involving any genetically modified organisms other than that covered by this licence to be performed in these facilities.

Plant Material not to be used in food

43. 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 or for processing.

Section 5 Transport, Cleaning and Disposal

44. If GMOs are Destroyed, they are taken to have been Harvested for the purposes of this licence and all conditions applying to post-Harvest apply equally to post-Destruction.

Notice of Harvest and cleaning following Harvest

45. The licence holder must, in the manner required by condition 83, provide the Regulator with a notice of intention to Harvest the GMOs at each Location.

46. The licence holder must, in the manner required by condition 84, provide the actual date or dates of Harvesting of the GMOs at each Location.

Harvest and post-Harvest procedures

47. If the GMOs or non-GM plants grown at each Location or Pollen Trap Plants are Harvested, they must be Harvested separately from any other crop.

48. Following harvest, seed cotton harvested from the GMOs and non-GM plants grown at the Location and Pollen Trap Plants must only be:

- (a) stored separately from any other seed cotton in a sealed container, within a locked facility (PC2 or approved in writing by the Regulator) that is signed so as to indicate that GM seed cotton is stored within the facility; and/or
- (b) ginned; and/or
- (c) experimented with in accordance with conditions 41 and 42; and/or
- (d) Destroyed.

49. If seed Cotton Harvested from the GMOs or non-GM plants grown at the Location or Pollen Trap Plants is ginned, it must be ginned separately from any other crop.

50. Following ginning, seed from the GMOs and non-GM plants grown at the Location and Pollen Trap Plants must only be:

- (e) stored in a sealed container, within a locked facility (PC2 or approved in writing by the Regulator) that is signed so as to indicate that GM Cotton seed is stored within the facility; and/or
- (f) exported; and/or
- (g) replanted subject to the conditions of this licence or other relevant authorisation under the Act; and/or
- (h) experimented with in accordance with conditions 41 and 42; and/or
- (i) Destroyed.

Note: Transport of Plant Material must comply with conditions 51 to 53.

Transportation of Plant Material

51. Subject to conditions 51 and 52, any Plant Material transported must be transported in accordance with the guidelines for the transportation of GM Plant Material found in the OGTR *Guidelines for the Transport of GMOs* as current at the time of transportation, and routes, methods and procedures used for this transportation in accordance with this licence must be documented and provided to the Regulator on request.

52. Harvested Plant Material must be transported in a cotton module that is:

- (a) completely enclosed within two layers of tarpaulin ('double wrapped in tarpaulin'); or
- (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.

53. In addition to the requirements of the above conditions, every container used to transport 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.

54. To the extent that conditions 52 and 53 are inconsistent with condition 51, conditions 52 and 53 will prevail.

Cleaning of Equipment and Places

55. Cleaning of Equipment must occur immediately or as soon as practicable after use and before it is used for any other purpose (eg if GM seed is ginned, the gin must be Cleaned immediately following its use and before any other Cotton crop is ginned).

56. In the case of Equipment used at the Site, the Equipment must be cleaned before it is removed from the Site (eg if a mechanical harvester is used at a Site it must be Cleaned before it is moved to another Site)

57. The following Places must be Cleaned in accordance with these licence conditions:

- (a) each Location and the Pollen Trap (if any) in respect of each Location;
- (b) any areas used to gin Plant Material;
- (c) any areas used to Clean Equipment used in connection with Plant Material at each Location and the Pollen Trap in respect of each Location or to Destroy Plant Material.

58. Each Place in respect of each Location must be Cleaned either within fourteen (14) days of Harvest of the GMOs or within nine (9) months of planting of the GMOs, whichever occurs first.

59. The licence holder must, in a manner required by condition 85, give notice to the Regulator of the date on which Cleaning of the Place concluded.

Section 6 Inspection, Use of Site and Sign-off

60. Inspections must be performed by a person who is able to recognise Volunteer Plants.

Post-Harvest (or post-Destruction) Inspections at a Location

61. Following Cleaning of a Location or other areas, the following Places must be inspected for the existence of Volunteer Plants:

- (a) the Location (except for glasshouses);
- (b) the Pollen Trap in respect of the Location;
- (c) irrigation channels and drains through which water flows to and from the Location and the Pollen Trap;
- (d) any areas used to Clean Equipment used in connection with Plant Material or to Destroy Plant Material.

62. Any Volunteer plant must be Destroyed prior to the plant flowering.

63. For each Location, all the Places required to be inspected must be inspected at least once every two (2) months, commencing on the last day of Cleaning of the Location and continuing until the Regulator has issued a Sign-off for the relevant Site.

64. The licence holder must, in the manner required by paragraph 87, provide the Regulator with the findings of the inspections.

65. Inspection conditions do not apply with respect to a Place within a Site if the licence holder has received a Sign-off for that Site.

General conditions on use of Location post - Harvest

66. If the GMOs are grown at a Location, no plants may be planted at the Location, or the Pollen Trap in respect of the Location, until inspection obligations are completed unless:

- (a) the plants are included in the OGTR policy on post-Harvest crops at the time of planting (refer to table that specifies the post-Harvest crops permitted for GM Cotton field trials at <http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/policies-1>); or
- (b) the plants are the GMOs or non-GM Cotton planted in accordance with the conditions of this licence as they apply to GMOs and non-GM Cotton plants; or
- (c) the plants are plants agreed to in writing by the Regulator;

Note: In respect of condition 66, inspection conditions would continue to apply until Sign-off of the Site in respect to that Location.

Cotton seed bank reduction (not applicable glasshouses)

67. In the first spring or summer season following the Harvest of the GMOs, the licence holder must Cultivate each Location and Pollen Trap with respect to that Location so as to promote the germination of Volunteer Plants.

68. If, in Cultivating the Location and Pollen Trap with respect to that Location, the soil does not contain sufficient moisture through accumulated rainfall or irrigation to

cause the germination of Volunteer Plants, the licence holder must ensure that the Location and Pollen Trap with respect to that Location is irrigated sufficiently to cause the germination of Volunteer Plants.

Note: Any Volunteer Plants must be Destroyed in a manner indicated elsewhere in this licence (eg Destruction methods include uprooting by ploughing).

Sign off

69. For Sites in which the associated Location is a glasshouse,

- (a) if the Location has been Cleaned, and
- (b) there are no other Places in respect of the Location requiring inspections,

the licence holder may make written application to the Regulator that these inspection conditions no longer apply to the Site and that the Site receive 'Sign-off'.

70. For all other Sites,

- (c) if inspections have been routinely completed for a period of at least twelve (12) months, and,
- (d) if inspection records for that Site show that no Volunteers have been observed in the most recent six (6) month inspection period,

the licence holder may make written application to the Regulator that these inspection conditions no longer apply to the Site and that the Site receive 'Sign-off'.

Section 7 Reporting and Documentation Requirements

Compliance Management Plan

71. 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 and must include,

- (a) A list of the names of all organisations or natural persons who will be persons covered by this licence. Where a name of a person is not known at the time of submitting the Compliance Management Plan the function or position of the person to be covered must be provided.

Note: Examples of functions or positions are 'Site manager', 'Farm labourer' etc.

- (b) An explanation of how the licence holder has informed, or proposes to inform, each person intended to be covered by the licence of the conditions of this licence including conditions related to the collection of Personal Information by the licence holder from the person intended to be covered by the licence.
- (c) A description of the responsibilities of the licence holder and of each person covered by the licence in relation to the requirements of this licence.
- (d) A description of how any contracts, agreements, or other enforceable arrangements between the licence holder and persons covered by the licence will allow the licence holder to access and control a Site to the extent necessary to comply with this licence, for the duration of the life of the licence.

- (e) A description of the licence holder's plans for post-Harvest use of a Site during the life of this licence.

72. Where any of the details of the compliance management plan change, the Regulator must be notified of the changes within fourteen (14) days of the change occurring.

Contingency Plan for unintended presence of Plant Material

73. Within thirty (30) days of the date of issue 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 or Plant Material outside an area that must be inspected.

74. 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 or Plant Material found outside of the Site; and
- (c) inspect for and Destroy any Volunteer Plants that may exist as a result of the event.

75. The Contingency Plan must be implemented in the event that the unintended presence of the GMOs or Plant Material is discovered outside an area that must be inspected.

76. If for any reason the licence holder cannot implement the Contingency Plan when required to do so, the Licence holder must notify the Regulator as soon as is reasonably practicable.

Contingency Plan for Pollen Trap (not applicable to Brisbane and Toowoomba glasshouses)

77. Within thirty (30) days of the date of issue of this licence, a written Contingency Plan must be submitted to the Regulator detailing measures to be taken in the event that:

- (a) the Pollen Trap Plants are not likely to flower at the same time as the GMOs planted at the Location; and
- (b) there is a flowering, intentionally planted, Cotton crop outside the Site but within three (3) kilometre of the Site.

78. The Contingency Plan must contain details of procedures to prevent the dissemination of pollen from the Site.

79. The Contingency Plan must be implemented if,

- (a) the Pollen Trap Plants are not likely to flower at the same time as the GMOs planted at the Location; and
- (b) there is a flowering, intentionally planted, Cotton crop outside the Site but within three (3) kilometre of the Site.

80. If for any reason the licence holder cannot implement the Contingency Plan when required to do so, the Licence holder must notify the Regulator as soon as is reasonably practicable.

Notice of intention to plant and of planting

81. For all Locations, at least seven (7) days prior to the date on which planting of the GMOs is intended to commence, the licence holder must provide a notice in writing to the Regulator which contains:

- (a) the date(s) on which planting of the GMOs and Pollen Trap Plants (if any) are intended to commence;
- (b) details of each Location where the GMOs will be planted, including the size of each Location, the local government area (including a map of the Location and its surroundings), a street address and GPS coordinates for each Location;
- (c) the period during which the licence holder considers the GMOs and Pollen Trap Plants are likely to flower;
- (d) the period during which the licence holder considers the GMOs and other plants authorised by this licence are likely to be Harvested (or Destroyed in lieu of Harvest);
- (e) if GMOs have previously been planted at a Location or within the Pollen Trap with respect to that Location, a history indicating how the Location and the Pollen Trap with respect to that Location has been used in the preceding two years, including details of previous GMOs and post-Harvest crops planted at the Location and the Pollen Trap with respect to that Location; and a description of how the Location and the Pollen Trap with respect to that Location are intended to be used during the first two years following the Harvest of the GMOs.

82. For all Locations, within seven (7) days of planting of the GMOs, the licence holder must provide a notice in writing to the Regulator which contains:

- (a) the actual date(s) on which planting of the GMOs and Pollen Trap Plants (if any) occurred;
- (b) details of each Location where the GMOs were planted, including the size of each Location, the local government area (including a map of the Location and its surroundings), a street address and GPS coordinates for each Location;
- (c) the period during which the licence holder considers the GMOs and Pollen Trap Plants are likely to flower;
- (d) the period during which the licence holder considers the GMOs and other plants authorised by this licence are likely to be Harvested (or Destroyed in lieu of Harvest); and
- (e) a description of how the Location and Pollen Trap with respect to the Location are intended to be used during the first two (2) years following the final Harvest of the GMOs.

Notice of Harvest and Cleaning following Harvest

83. The licence holder must provide the Regulator with a notice of intention to Harvest the GMOs at the Location. This notice must be provided at least seven (7) days, and not more than twenty one (21) days, in advance of the intended date of Harvest set out in the notice. Any change of intention prior to the intended Harvest

date must be notified to the Regulator as soon as is reasonably and practically possible.

84. The licence holder must provide the actual date or dates of Harvest of the GMOs at the Location within seven (7) days of completion of Harvest of the GMOs at the Location.

85. The licence holder must provide a notice in writing to the Regulator when a Place is Cleaned following Harvest. The notice must be provided to the Regulator within fourteen (14) days of the date on which Cleaning of the Place concluded.

86. 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.

Results of inspection activities

87. The results of inspection activities must be recorded in a logbook or paper file. The findings of the inspections as recorded in the logbook or paper file must be forwarded to the Regulator within fourteen (14) days of inspection taking place and must also 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 current land use (eg type of crop being grown) and of recent land management practices (eg irrigation, cultivation or spraying) applied in the areas inspected;
- (c) the date(s) of inspection;
- (d) 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 and Related Species;
- (e) the means of inspection used;
- (f) the number of Volunteer Plants or native cotton species observed, if any;
- (g) details of the development stages reached by the Volunteer Plants or Related Species, if any;
- (h) details of methods used to Destroy Volunteer Plants, if any;
- (i) if Volunteer Plants were found, the actual date(s) of Destruction, which must be confirmed within fourteen (14) days of Destruction.

88. The licence holder must keep records of the type of GM Cotton lines grown at the Site as part of the trial, and the area planted to each type.

Annual Report

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

Testing methodology

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 (for details see Attachment B of the licence) in a recipient organism. The instrument must be provided within 30 days of the issuing of this licence.

ATTACHMENT A

DIR No: 081/2007

***Full Title:** Limited and controlled release of cotton genetically modified for altered water use efficiency

Organisation Details

Postal address: Monsanto Australia Ltd
Level 12, 600 St Kilda Road
Melbourne VIC 3004

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 Limited

Postal Address: Monsanto Australia Ltd
Level 12, 600 St Kilda Road
Melbourne VIC 3004

IBC Details

IBC Name: Monsanto Australia Ltd IBC

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

GMO Description

Purpose of the Dealings with the GMOs:

The aim of the proposed release is to conduct early stage research to evaluate the efficacy of up to 504 GM cotton lines modified to enhance water use efficiency as compared to non-GM cotton lines; to assess their agronomic performance under field conditions; to test yield and fibre quality of the GM cotton lines under optimum watering and water stress treatments. Seed will also be collected for further studies and possible future releases (subject to additional assessments and approvals).

The GMOs covered by this licence are as follows:

Cotton modified for enhanced water use efficiency

***Parent Organism(s):**

Common Name: Cotton

Scientific Name: *Gossypium hirsutum* L.

***Modified trait:**

Category: Water use efficiency

Description: Cotton plants have been genetically modified for enhanced water use efficiency

***Genes responsible for conferring the modified trait:**

[This is Confidential Commercial Information]