



**Australian Government**

**Department of Health**

Office of the Gene Technology Regulator

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

**Licence No.: DIR 147**

**Licence holder: Monsanto Australia Pty Ltd**

**Title: Limited and controlled release of cotton genetically modified for insect resistance and herbicide tolerance**

Issued: 23 January 2017

Varied: 10 May 2021

### **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 activities involving 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 Pesticides and Veterinary Medicines Authority, Therapeutic Goods Administration, National Industrial Chemicals Notification and Assessment Scheme and the Department of Agriculture. Dealings conducted under any licence issued by the Regulator may also be subject to regulation by one or more of these agencies. It is recommended that the licence holder consult the relevant agency (or agencies) about their regulatory requirements.

Dealings permitted by this licence may also be subject to the operation of State legislation recognising areas as designated for the purpose of preserving the identity of GM crops, non-GM crops, or both GM crops and non-GM crops, for marketing purposes.

### ***Further information on Licence DIR 147***

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 or by telephoning the Office on 1800 181 030.

Information about where the GMOs have been planted pursuant to this licence can be accessed on the [OGTR website](#).

## Section 1 *Interpretations and definitions*

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

2. In this licence:

**'Act'** means the *Gene Technology Act 2000* (Commonwealth) or the corresponding State legislation under which this licence is issued.

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

- (a) in relation to an area specified in this licence as requiring Cleaning, the Destruction of the GMOs in that area, to the reasonable satisfaction of the Regulator; or
- (b) in relation to Equipment, the removal and Destruction of the GMOs from the Equipment, to the reasonable satisfaction of the Regulator.

**'Contingency Plan'** means a written plan detailing measures to be taken in the event of the unintended presence of the GMOs outside an area that must be inspected. A Contingency Plan must include procedures to:

- (a) ensure the Regulator is notified immediately if the licence holder becomes aware of the event; and
- (b) recover and/or Destroy the GMOs; and
- (c) inspect for and Destroy any Volunteers that may exist as a result of the event.

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

**'Cultivate'** means:

- (a) till the soil in a manner which will promote 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) root cutting and mulching/slashing; or
- (c) ploughing; or
- (d) burning/incineration; or
- (e) treatment with herbicide; or

- (f) hand weeding; or
- (g) autoclaving; or
- (h) burial under at least one (1) metre of soil; or
- (i) grinding seeds; or
- (j) a method approved in writing by the Regulator.

*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 only may not be a sufficient mechanism.*

**'Equipment'** includes, but is not limited to, harvesters, seeders, gins, storage equipment, transport equipment (e.g. bags, containers, trucks), clothing and tools.

**'Exclusion Zone'** means an area extending at least 1.5 kilometres outwards from the outer edge of a Planting Area, which must be kept free of deliberately planted Cotton while the GMOs are growing in the Planting Area.

**'Flowering'** is taken to begin when any plant of the class of plants referred to in a particular condition first flowers, and is taken to end when all plants in the class of plants no longer have flowers.

**'GM'** means genetically modified.

**'GMOs'** means the genetically modified organisms that are the subject of the dealings authorised by this licence. GMOs include live plants, root stock that is able to grow into live plants, and viable seed.

**'Logbook'** means a written or electronic record containing information required to be collected and maintained by this licence and which is able to be presented to the OGTR on request.

**'Monitoring Zone'** means an area of land extending at least 100 metres in all directions from the outer edge of a Planting Area.

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

**'Personal Information'** means information or an opinion about an identified individual, or an individual who is reasonably identifiable:

- (a) whether the information is true or not; and
- (b) whether the information is recorded in a material form or not.

**'Planting Area'** means an area of land where the GMOs are intentionally planted and grown pursuant to this licence, but does not include the Pollen Trap.

**'Plant Material'** means any part of the Cotton plants grown in a Planting Area or in the Pollen Trap with respect to a Planting Area, whether viable or not. This includes, but is not limited to, 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 outwards from the outer edge of a Planting Area, where only Pollen Trap Plants are grown.

**'Pollen Trap Plant'** means non-GM Cotton, or GM Cotton approved for commercial release by the Regulator grown in a Pollen Trap.

**'Regulator'** means the Gene Technology Regulator.

**'Sign-off'** means a notice in writing from the Regulator, in respect of an area, that post-harvest obligations no longer apply in respect of that area.

**'Volunteers'** means GM or non-GM Cotton plants, which have not been intentionally grown.

**'Waterways'** means all permanent natural waterways and man-made waterways that flow into natural waterways.

*Note: Irrigation channels, holding dams or storage ponds that do not flow into natural waterways are not considered Waterways for the purpose of this licence.*

## **Section 2 General conditions and obligations**

3. 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.
4. This licence remains in force until it is suspended, cancelled or surrendered. No dealings with GMOs are authorised during any period of suspension.
5. The holder of this licence ('the licence holder') is Monsanto Australia Ltd (Monsanto).
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 or otherwise authorised by the licence holder to undertake any activity in connection with the dealings authorised by this licence.
7. The dealings authorised by this licence are to conduct experiments with the GMOs, breed, propagate, grow, import, transport, and dispose of the GMOs, to use the GMOs in the course of manufacture of a thing that is not a GMO, and the possession, supply or use of the GMOs in the course of any of these dealings.

### **Obligations of the Licence Holder**

8. The licence holder must notify the Regulator in writing if any of the contact details of the project supervisor change.

*Note: please address correspondence to [ogtr.applications@health.gov.au](mailto:ogtr.applications@health.gov.au).*

*Prior to issuing a licence, the Regulator considers suitability of the applicant to hold a licence. The following conditions address ongoing suitability of the licence holder.*

9. The licence holder must, at all times, remain an accredited organisation in accordance with the Act and must comply with its instrument of accreditation.
10. The licence holder must:
  - (a) inform the Regulator immediately in writing, of:
    - i. any relevant conviction of the licence holder occurring after the issue of this licence; and
    - ii. 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
    - iii. any event or circumstances occurring after the issue of this licence that would affect the capacity of the holder of this licence to meet the conditions in it; and
  - (b) provide any information related to the licence holder's ongoing suitability to hold a licence, if requested, within the stipulated timeframe.
11. The licence holder must be able to access all Exclusion Zones (if any) and to access and control all Planting Areas, Pollen Traps (if any), Monitoring Zones (if any) and approved facilities to the extent necessary to comply with this licence, for the duration of the life of the licence.

*The following conditions seek to ensure that persons conducting the dealings are aware of the licence conditions and appropriate processes are in place to inform people of their obligations.*

12. Prior to conducting any dealings with the GMOs, the licence holder must provide to the Regulator:

- (a) names of all organisations and persons or functions or positions of the persons who will be covered by the licence, with a description of their responsibilities; and  
*Note: Examples of functions or positions are 'site manager', 'farm labourer' etc.*
- (b) detail of how the persons covered by the licence will be informed of licence conditions; and
- (c) detail of how the licence holder will access all Exclusion Zones (if any), and access and control Planting Areas, Pollen Traps (if any), Monitoring Zones (if any) and approved facilities for the duration of the licence; and  
*Note: this may include a description of any contracts, agreements, or other enforceable arrangements.*
- (d) written methodology to reliably detect the GMOs or the presence of the genetic modifications in a recipient organism, and to distinguish between categories of GMOs approved for release; and
- (e) a Contingency Plan to respond to inadvertent presence of the GMOs outside an area that must be inspected.

13. Any changes to the information provided under the immediately preceding condition must be communicated in writing to the Regulator within 14 days of the changes occurring.

14. The licence holder must inform any person covered by this licence, to whom a particular condition of the licence applies, of the following:

- (a) the particular condition (including any variations of it); and
- (b) the cancellation or suspension of the licence; and
- (c) the surrender of the licence

15. The licence holder must not permit a person covered by this licence to conduct any dealing unless:

- (a) the person has been informed of any applicable licence conditions, including any variation of them; and
- (b) the licence holder has obtained from the person a signed and dated statement that the person:
  - i. has been informed by the licence holder of the licence conditions including any variation of them; and
  - ii. has understood and agreed to be bound by the licence conditions, or variation.

16. The licence holder must:

- (a) inform the persons covered by this licence that any Personal Information relevant to the administration and/or enforcement of the licence may be released to the Regulator; and
- (b) provide the Regulator, if requested, with copies of the signed and dated statements referred to in the immediately preceding condition.

***Provision of new information to the Regulator***

*Licence conditions are based on the risk assessment and risk management plan developed in relation to the application using information available at the time of assessment. The following condition requires that any new information that may affect the risk assessment is communicated to the Regulator.*

17. The licence holder must inform the Regulator if the licence holder becomes aware of:

- (a) additional information as to any risks to the health and safety of people, or to the environment, associated with the dealings authorised by the licence; or
- (b) any contraventions of the licence by a person covered by the licence; or
- (c) any unintended effects of the dealings authorised by the licence.

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

- (a) *the licence holder will be taken to have become aware of additional information of a kind mentioned in paragraph 17(a) if he or she was reckless as to whether such information existed; and*
- (b) *the licence holder will be taken to have become aware of contraventions, or unintended effects, of a kind mentioned in paragraph 17(b) or 17(c) if he or she was reckless as to whether such contraventions had occurred, or such unintended effects existed.*

*Note: Contraventions of the licence may occur through the action or inaction of a person. For example if it is a condition of the licence that volunteers are destroyed prior to reaching maturity and a volunteer reaches maturity, then the person responsible for controlling volunteers will have contravened that licence condition.*

18. If the licence holder is required to inform the Regulator under the immediately preceding condition, the Regulator must be informed without delay.

*Note: An example of informing without delay is contact made at the time of the incident via the OGTR free call phone number 1800 181 030, which provides emergency numbers for incidents that occur out of business hours. Notification without delay will allow the OGTR to conduct a risk assessment on the incident and attend the location if required.*

19. If the licence holder informs the Regulator under the immediately preceding condition and the Regulator requests further information, the further information must be provided in a manner, and within the time period, stipulated by the Regulator.

#### ***Obligations of persons covered by the licence***

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

21. 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.

### **Section 3 Limits and control measures**

#### ***Limits on the release***

*The following licence conditions maintain the risk assessment context within which the application was assessed, by imposing limits on where and when the GMOs may be grown, and on other activities that can be undertaken.*

22. The only plants that may be grown at a Planting Area are:

- (a) the GMOs covered by this licence as described in the Attachment A of the licence;
- (b) non-GM Cotton, and GM Cotton approved for commercial release by the Regulator; and
- (c) plants approved in writing by the Regulator.

23. Planting and growing of the GMOs may only occur within the following limits:

**Area and duration**

Maximum size of any Planting Area	Maximum number of Planting Areas	Maximum area/year	Duration
2 ha	50	50 ha	2017
10 ha	50	100 ha	2018
50 ha	50	250 ha	2019 - July 2024

**Local government areas in which Planting Areas may be located**

NSW		Qld	WA
Balranald	Hilltops	Balonne	Wyndham-East Kimberley
Berrigan	Inverell	Banana	Broome
Bland	Lachlan Shire Council	Bundaberg Regional	East Pilbara
Bogan	Leeton	Burdekin Shire	Ashburton
Bourke	Liverpool Plains	Central Highlands	Port Hedland
Brewarrina	Moree Plains	Goondiwindi Regional	
Carrathool	Murray River	Isaac Regional	<b>NT</b>
Central Darling	Murrumbidgee	Lockyer Valley Regional	Roper Gulf
Coolamon	Narrabri	Maranoa Regional	
Coonamble	Narrandera	Paroo	<b>Vic</b>
Edward River	Narromine	Rockhampton Regional	Swan Hill
Federation	Parkes	South Burnett Regional	Shepparton
Forbes	Walgett	Southern Downs Regional	Rural City of Mildura
Gilgandra	Wagga Wagga	Toowoomba Regional	
Griffith	Warren	Westerns Downs Regional	
Gunnedah	Warrumbungle	Whitsunday Regional	
Gwydir	Weddin		
Hay			

24. Plant Material must not be used, sold or otherwise disposed of for any purpose which would involve or result in its use as food for humans or feed for animals.

25. Cotton lint derived from the GMOs may be sold as a commercial product.

26. GMOs not required for further experimentation or future planting must be Destroyed as soon as practicable.

27. If experimentation or analysis with the GMOs is not conducted in accordance with Notifiable Low Risk Dealings (NLRD) requirements, experimentation or analysis with the GMOs may only be undertaken within:

- (a) a Planting Area prior to post-harvest Cleaning; or
- (b) a facility approved in writing by the Regulator.

*Note: Dealings conducted in accordance with NLRD requirements must be assessed by an IBC before commencement, must comply with the requirements of the Gene Technology Regulations 2001, and are not subject to the conditions of this licence.*

**Containment measures**

*The following licence conditions maintain the risk assessment context within which the application was assessed by restricting spread and persistence of the GMOs.*

**Pollen dispersal**

28. The Planting Area must be:



- (a) surrounded by a Pollen Trap; or
- (b) surrounded by a Monitoring Zone and an Exclusion Zone.

29. If a Pollen Trap is used in accordance with the previous condition, Pollen Trap Plants must:

- (a) have a reasonably dense and vigorous growth; and
- (b) be Flowering at the same time as the GMOs; and
- (c) form a continuous barrier at least 20 m wide around the Planting Area while the GMOs are Flowering, although one path of up to 2.5 m in width is allowed in order to access the Planting Area.

30. If a Monitoring Zone and an Exclusion Zone are used in accordance with condition 28:

- (a) while the GMOs are being grown in the Planting Area, the Monitoring Zone must be maintained in a manner appropriate to allow the identification and Destruction of Cotton plants; and
- (b) the GMOs must not be planted in a Planting Area if any Cotton crop is present in the Exclusion Zone; and
- (c) the Monitoring Zone and Exclusion Zones must be inspected by people trained to recognise Cotton, and actions taken as follows:

Area	Period of inspection	Inspection frequency	Inspect for	Action
Monitoring Zone	<b>From</b> 14 days prior to the expected commencement of Flowering of any GMOs* <b>until</b> all GMOs have been harvested or Destroyed	At least once every 35 days	Cotton	Destroy before Flowering
Exclusion Zone	<b>From</b> 14 days prior to the expected commencement of Flowering of any GMOs* <b>until</b> all GMOs have finished Flowering	At least once every 35 days	Intentionally planted Cotton	Destroy before Flowering; alternatively, Destroy the GMOs before Flowering

*\*Condition 47 requires the licence holder to provide information to the Regulator on the expected flowering period, however the inspection period should be based on the observed development of the GMOs, so that inspections commence prior to any GMOs flowering.*

*Note: Details of any inspection activity must be recorded in a Logbook as detailed in Condition 43.*

### **Dispersal of GMOs**

31. The outer edge of a Planting Area, and of a Pollen Trap, must be at least 50 m away from Waterways and be confined to areas not subject to flooding.

32. All Cotton plants grown at a Planting Area or Pollen Trap are considered the GMOs for the purposes of this licence.

*Note: All conditions applying to the GMOs also apply to all other Cotton plants grown in a Planting Area or Pollen Trap.*

33. The GMOs must be harvested separately from any other crop.

34. 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.

35. Seed cotton from the GMOs must be ginned separately from any other seed cotton.
36. Areas of land used in connection with the GMOs must be Cleaned as follows:

Areas to be Cleaned	When
(a) Planting Area (b) Pollen Trap	Within 28 days of harvest of the GMOs or within 9 months of planting the GMOs, whichever occurs first
(c) any area where GMOs may have dispersed during planting, growing or harvesting, including irrigation channels and drains (d) any area used to Clean any Equipment used in connection with the GMOs (e) any area used to Destroy GMOs (f) any area used to gin, store or experiment with GMOs	As soon as practicable and before use for any other purpose

*Note: Areas of land that have been Cleaned, or from which the GMOs have been harvested, are also subject to Inspections (Condition 42). Cleaning activities must be recorded and notified to the Regulator (Condition 47 (d)).*

37. Any Equipment used in connection with the GMOs must be Cleaned as soon as practicable and before use for any other purpose.
38. Any extreme weather event that is expected to affect or has already affected a Planting Area or Pollen Trap, while the GMOs are growing or while the areas are subject to inspection requirements, must be notified in writing to the Regulator as soon as practically and reasonably possible.

**Dispersal of the GMOs during transport or storage**

39. If transport or storage is not conducted in accordance with NLRD requirements, it must be conducted in accordance with conditions 40 and 41.
40. Transport and storage of GMOs outside the Planting Area must:
- (a) only occur to the extent necessary to conduct the dealings permitted by this licence or other valid authorisation; and
  - (b) be in accordance with the Regulator’s *Guidelines for the Transport, Storage and Disposal of GMOs* for PC2 GM plants as current at the time of transportation or storage; and
  - (c) if harvested Plant Material is transported in a cotton module or bale, the cotton module or bale must be:
    - i. completely enclosed within two layers of tarpaulin (‘double wrapped in tarpaulin’); or
    - ii. completely enclosed within a layer of tarpaulin inside a layer of shade cloth (‘double wrapped in tarpaulin and shade cloth’); or
    - iii. contained within an enclosed chain-bed truck specifically designed for the purpose of transporting cotton modules or bales; and
    - iv. labelled as detailed in the Regulator’s *Guidelines for the Transport, Storage and Disposal of GMOs* as current at the time of transportation.
  - (d) comply with all other conditions of this licence.

*Note: Condition 15 requires signed statements for persons transporting or disposing of the GMOs.*

41. Methods and procedures used to transport GMOs must be recorded, and must be provided to the Regulator, if requested.

**Persistence of the GMOs or Volunteers post Cleaning**

42. After Cleaning, areas of land must be inspected by people trained to recognise volunteers. Inspections must cover the entirety of areas to be inspected. Actions must be taken as follows:

Area	Period of inspection	Inspection frequency	Inspect for	Action
(a) Planting Area (b) Pollen Trap (c) Other areas of land that have been Cleaned and where the GMOs may be able to establish*.	From the day of Cleaning until: i. the area is replanted with the GMO; or ii. the Regulator has issued a Sign-off for the area.	At least once every 35 days	Volunteers	Destroy before Flowering

*\*This excludes, for instance, areas with hard floors used to gin, store or experiment on GMOs.*

43. Details of any inspection activity must be recorded in a Logbook and must include:

- (a) date of the inspections;
- (b) name of the person(s) conducting the inspections;
- (c) details of the experience, training or qualification that enables the person(s) to recognise Volunteers, if not already recorded in the logbook;
- (d) details of areas inspected including current land use and recent management practices applied;
- (e) details of any post-harvest rainfall events including measurements at or near the area, or any irrigation events;
- (f) details of any Volunteers observed during inspections or during land-management activities, including number, developmental stage and approximate position of the Volunteers within each area inspected<sup>§§</sup>; and
- (g) date(s) and method(s) of Destruction of any Volunteer plants, including destruction of volunteers during land-management activities.

<sup>§§</sup> *Examples of acceptable ways to record the positional information for Volunteers and Related species in the Logbook include:*

- *descriptive text*
- *marking on a diagram*
- *indicating grid references on corresponding map/sketch.*

*Note: Details of Inspection activities must be provided to the Regulator (Condition 47). The Regulator has developed a standardised proforma for recording inspection activities. This is available upon request.*

44. While post-Cleaning inspection requirements apply to an area:

- (a) the Planting Area and associated Pollen Trap must be Cultivated in the first spring or summer following the harvest of the GMOs to reduce the seed bank; and
- (b) the area must be maintained in a manner appropriate to allow identification of Volunteers; and

- (c) no plants may intentionally be grown in the area unless the plants are:
  - i. those specified in condition 22 and planted in accordance with the conditions of this licence; or
  - ii. listed as post-harvest crops permitted for GM Cotton field trial sites in the OGTR Policy on Post Harvest Crops as current at the time of planting and satisfy condition 44(b); or
  - iii. agreed to in writing by the Regulator.

*Note: The OGTR's Policy on Post Harvest Crops can be found on the [OGTR website](#).*

#### **Contingency plan**

45. If any unintentional presence of the GMOs is detected outside the areas requiring inspection, the Contingency Plan must be implemented.

#### **Section 4 Sign off**

46. The licence holder may make written application to the Regulator that planting restrictions and inspection conditions no longer apply to an area if:

- (a) all post-Cleaning inspection activities have been conducted for at least 12 months on the area and all associated areas of land; and
- (b) conditions have been conducive for germination and detection; and
- (c) no Volunteers have occurred on these areas in the most recent six month inspection period.

*Note: Associated areas refer to a Planting Area and the aggregate of all other areas of land requiring post-Cleaning inspections in respect of that Planting Area. Associated areas will be signed-off as a group rather than individually. Licence conditions require Cultivation for each Planting Area and Pollen Trap prior to a Sign-off application (Condition 44(a)).*

*Note: The Regulator will take into account the management and inspection history for all the associated areas, including post-harvest crops planted (if any), tillage, irrigation, rainfall, application of herbicide and occurrence of Volunteers, in deciding whether or not further inspections are required to manage persistence of the GMOs.*

#### **Section 5 Reporting and Documentation**

*The following licence conditions are imposed to demonstrate compliance with other conditions, facilitate monitoring of compliance by staff of the OGTR, and emphasise appropriate selection of the Planting Area.*

47. Notifications must be sent to the Regulator as follows:

<b>Notice</b>	<b>Contents</b>	<b>Timeframe</b>
(a) Intention to Plant	<ul style="list-style-type: none"> <li>i. Details of the Planting Area including size, the local government area, GPS coordinates and street address or other directions</li> <li>ii. Identity of the GMOs to be planted at the Planting Area</li> <li>iii. Date on which the GMOs will be planted</li> <li>iv. Period when the GMOs are expected to Flower</li> <li>v. Period when harvesting is expected to commence</li> <li>vi. How all areas requiring post-harvest inspections are intended to be used until sign off, including the proposed post-harvest crop(s) (if any)</li> </ul>	At least 7 days prior to each planting (to be updated immediately if the notified intended planting dates change)

Notice	Contents	Timeframe
	<p>vii. Details on how you propose to manage inspection activities, including strategies for the detection and destruction of volunteer GMOs</p> <p>viii. A history indicating how the Planting Area, Pollen Trap or Monitoring Zone has been used in the preceding two years, including details of previous GMOs and post-harvest crops planted</p> <p>ix. Whether the Planting Area will be surrounded by a Pollen Trap or by a Monitoring Zone and Exclusion Zone</p>	
(b) Planting	<p>i. Actual date(s) of planting the GMOs</p> <p>ii. Any changes to the details provided under part (a)</p>	Within 7 days of any planting
(c) Harvest	<p>i. Actual date(s) of harvesting the GMOs</p>	Within 7 days of commencement of any harvesting
(d) Cleaning	<p>i. Actual date(s) on which any areas needing Cleaning were Cleaned</p> <p>ii. Method of Cleaning</p>	Within 7 days of completion of any Cleaning
(e) Inspection activities	<p>i. Information recorded in a Logbook as per Condition 43</p>	Within 35 days of inspection

*Note: Other reports and documents that may need to be sent to the Regulator are described under Conditions 10, 12, 17 and 38.*

**DIR No: 147**

**Full Title:** Limited and controlled release of cotton genetically modified for insect resistance and herbicide tolerance

### **Organisation Details**

Postal address: Monsanto Australia Pty Ltd  
Level 1, 8 Redfern Road  
HAWTHORN EAST  
VIC 3123

Phone No: (03) 9248 6888

### **IBC Details**

IBC Name: Monsanto Australia Pty Ltd IBC

### **GMO Description**

#### **GMOs covered by this licence:**

*Gossypium hirsutum* L. genetically modified by introduction of only the genes listed below.

#### **\*Parent Organisms:**

Common Names: *Cotton*

Scientific Names: *Gossypium hirsutum* L.

#### **Modified traits:**

Categories: Insect resistance  
Herbicide tolerance  
Selectable marker - Antibiotic resistance  
Selectable marker - Reporter gene expression

**Description:** Cotton plants have been genetically modified for insect resistance and herbicide tolerance by *Agrobacterium*-mediated transformation (Table 1). The GMOs proposed for release are the insect resistant GM cotton MON 88702, and MON88702 conventionally crossed with one or more of the following:

- insect resistant MON 15985 (Bollgard® II, referred to as BGII) cotton
- insect resistant COT102 cotton
- herbicide tolerant MON 88913 (Roundup Ready Flex®, referred to as RRF) cotton
- herbicide tolerant MON 88701 cotton

The plants may also contain antibiotic resistance and reporter genes as selectable markers (Table 1). Some GM cottons proposed for release will contain short regulatory elements. These sequences are derived from plants (including thale cress, pea, petunia, pima cotton and soybean), a soil bacterium (*A. tumefaciens*) and plant viruses (Cauliflower mosaic virus, Figwort mosaic virus, Peanut chlorotic streak caulimovirus and Tobacco etch virus). The GM cottons proposed for release will contain some or all of these regulatory elements.

#### **Purpose of the dealings with the GMOs:**

Monsanto Australia Limited has applied for a licence to release genetically modified (GM) cottons into the environment on a limited scale and under controlled conditions. The purpose of the trial is to generate data for future submissions to regulatory agencies, to breed and develop varieties using elite

germplasm suitable for use under Australian conditions, and for seed increase. The GM cotton is not permitted to be used for human food or animal feed.

**Table 1. The candidate genes and selectable markers introduced into the GM cottons**

GM event	Gene	Source	Function
MON 88702	<i>mCry51Aa2</i>	<i>Bacillus thuringiensis</i>	hemipteran and thysanopteran insect resistance
BGII	<i>cry1Ac</i>	<i>B. thuringiensis</i>	lepidopteran insect resistance
	<i>nptII</i>	<i>Escherichia coli</i>	selectable marker – antibiotic resistance
	<i>aad</i>	<i>E. coli</i>	selectable marker – antibiotic resistance
	<i>cry2Ab</i>	<i>B. thuringiensis</i>	lepidopteran insect resistance
	<i>uidA</i>	<i>E. coli</i>	selectable marker – reporter
COT102	<i>vip3Aa19</i>	<i>B. thuringiensis</i>	lepidopteran insect resistance
	<i>aph4</i>	<i>E. coli</i>	selectable marker – antibiotic resistance
RRF	<i>cp4 epsps</i>	<i>Agrobacterium sp.</i> strain CP4	glyphosate herbicide tolerance
	<i>cp4 epsps</i>	<i>Agrobacterium sp.</i> strain CP4	glyphosate herbicide tolerance
MON 88701	<i>dmo</i>	<i>Stenotrophomonas maltophilia</i>	dicamba herbicide tolerance
	<i>bar</i>	<i>Streptomyces hygroscopicus</i>	glufosinate herbicide tolerance

## ATTACHMENT B

### Checklist of documents that must be sent to the Regulator:

When	What	Condition	Timeframe
Prior to conducting any dealings	Details of persons covered	<b>12(a)</b>	
	Plan to inform people covered by the licence	<b>12(b)</b>	
	Plan to ensure control and access to all the Planting Areas, Pollen Traps and approved facilities	<b>12(c)</b>	
	Detection methodology	<b>12(d)</b>	
	Contingency plan	<b>12(e)</b>	
Prior to planting	Intention to plant	<b>47(a)</b>	At least 7 days prior to any planting
During growing	Planting	<b>47(b)</b>	Within 7 days of any planting
	Harvest	<b>47(c)</b>	Within 7 days of commencement
Post-Cleaning	Cleaning	<b>47(d)</b>	Within 7 days of completion
	Inspection	<b>47(e)</b>	Within 35 days of each inspection
Any time after issue of the licence	Any changes of the project supervisor contact details	<b>8</b>	As soon as practicable
	Any relevant conviction, revocation, suspension or cancellation of any relevant permit or circumstances that may affect compliance to licence conditions	<b>10(a)</b>	Immediately, if occurs
	Any information relevant to on-going suitability	<b>10(b)</b>	If and when requested
	Any changes to details provided under conditions 12(a) - 12(e)	13	Within 14 days of the changes
	Signed statements from persons covered under the licence	16(b)	If and when requested
	Any additional information regarding health and safety of the people and the environment, contraventions of this licence or any unintended effects of the dealings authorized by the licence	17	As soon as practically and reasonably possible, after becoming aware
	Extreme weather conditions	38	As soon as practically and reasonably possible, if expected or occurs
	Methods and procedures for transport	41	If and when requested