



Australian Government

Department of Health and Aged Care
Office of the Gene Technology Regulator

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

Licence No.: DIR 203

Licence Holder: Monsanto Australia Pty Ltd

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

Issued: 13 May 2024

Office of the Gene Technology Regulator

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.

This licence is issued by the Gene Technology Regulator (the Regulator) in accordance with the *Gene Technology Act 2000* and, as applicable, corresponding State law.

In assessing applications for dealings involving the intentional release of genetically modified organisms into the Australian environment, the 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 genetically modified organisms into the Australian environment.

Other agencies that also regulate genetically modified organisms or GM products include Food Standards Australia New Zealand, Australian Pesticides and Veterinary Medicines Authority, Therapeutic Goods Administration, Australian Industrial Chemicals Introduction Scheme and the Department of Agriculture, Fisheries and Forestry. 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 A** of this licence.

Further information on licence DIR 203

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 \(OGTR\) 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 in this licence have the same meaning as they do in the Act and the Regulations;
- (b) words importing a gender include every other gender;
- (c) words in the singular number include the plural and words in the plural number include the singular;
- (d) expressions used to denote persons generally (such as “person”, “party”, “someone”, “anyone”, “no one”, “one”, “another” and “whoever”), include a body politic or corporate as well as an individual;
- (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 a word or phrase is given a particular meaning, other grammatical forms of that word or phrase have corresponding meanings;
- (g) specific conditions prevail over general conditions to the extent of any inconsistency.

2. In this licence:

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

‘Clean’ means, as the case requires:

- (a) in relation to Equipment or a facility, remove and/or Destroy the GMOs; or
- (b) in relation to an area of land specified in this licence as requiring Cleaning:
 - i. Destroy cotton plants, if present, to the reasonable satisfaction of the Regulator, and
 - ii. remove cotton seeds from the soil surface to the reasonable satisfaction of the Regulator.

Note: The intent of removing seeds from the soil surface is to minimise seed dispersal. One method of removing seeds from the soil surface is Tillage, which moves seeds to under the soil.

‘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 to the reasonable satisfaction of the Regulator; and
- (c) inspect for and Destroy any Volunteers that may exist as a result of the event to the reasonable satisfaction of the Regulator.

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

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

- (a) uprooting;

- (b) root cutting and shredding/mulching;
- (c) Tillage;
- (d) treatment with herbicide;
- (e) burning/incineration;
- (f) autoclaving;
- (g) crushing or grinding of seed;
- (h) burial, but only in accordance with condition 33;
- (i) 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, treatment with herbicide would not successfully kill GM seeds.

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

'Extreme Weather' includes, but is not limited to, fires, flooding, cyclones or torrential rain, that could disperse GMOs or affect the licence holder's ability to comply with licence conditions.

'Flowering' is taken to begin when any plant of the class of plants referred to in a particular condition first has an open flower, 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.

'Isolation Zone' means an area extending at least 1.4 kilometres outwards from the outer edge of a Monitoring Zone, as shown in Figure 1A.

'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 Regulator on request.

'Monitoring Zone' means an area of land extending outwards at least 100 metres from the outer edge of a Planting Area, as shown in Figure 1A.

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

'Planting Area' means an area of land where the GMOs and non-GM cotton and GM cotton approved for commercial release by the Regulator are intentionally planted and grown pursuant to this licence, but does not include the Pollen Trap.

'Plant Material' means any part of the GM or non-GM cotton plants grown at a Planting Area or Pollen Trap, whether viable or not, or any product of these plants.

'Pollen Trap' means an area of land extending outwards at least 20 metres from the outer edge of a Planting Area, where only Pollen Trap Plants are grown, as shown in Figure 1B.

'Pollen Trap Plants' means non-GM cotton or GM cotton approved for commercial release by the Regulator grown in a Pollen Trap.

‘Regulations’ means the Gene Technology Regulations 2001 (Commonwealth) or the corresponding State law under which this licence is issued.

‘Regulator’ means the Gene Technology Regulator.

‘Sign off’ means a notice in writing from the Regulator, in respect of an area, that post-Cleaning obligations no longer apply to that area.

‘Tillage’ means the use of any technique to disturb the soil.

‘Volunteers’ means GM or non-GM cotton plants, which have not been intentionally grown.

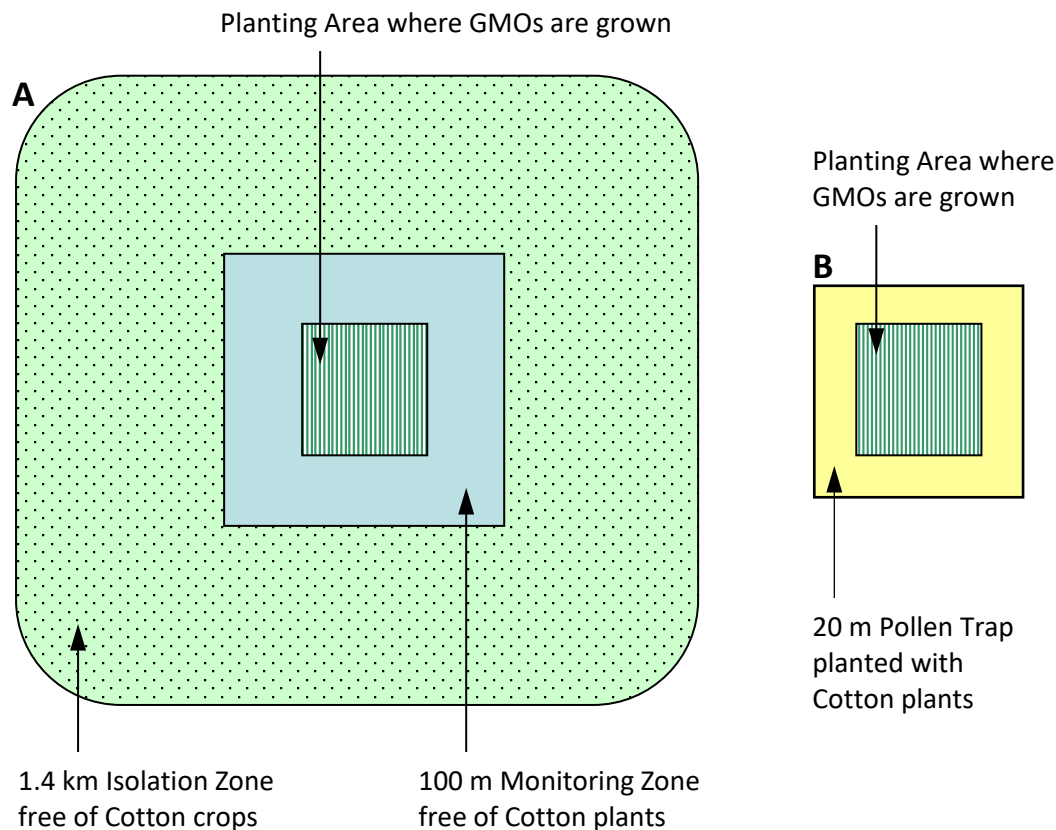


Figure 1. Diagrams (not to scale) showing the relationships between Planting Area, Monitoring Zone, Isolation Zone and Pollen Trap. A: case where a Monitoring Zone and Isolation Zone are used to restrict pollen flow; B: case where a Pollen Trap is used to restrict pollen flow

Section 2 General conditions and obligations

3. This licence does not authorise dealings with the GMOs that are otherwise prohibited as a result of the operation of State legislation recognising an area 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.
4. This licence remains in force until it is suspended, cancelled or surrendered. No dealings with the GMOs are authorised during any period of suspension.

Note: Although this licence has no expiry date, the period when GMOs may be grown is restricted in accordance with Condition 18.

5. The licence holder is Monsanto Australia Pty Ltd.

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. GMOs with which dealings are authorised by this licence are those listed at Attachment A.
8. The dealings authorised by the licence are to:
 - (a) conduct experiments with the GMOs;
 - (b) breed the GMOs;
 - (c) propagate the GMOs;
 - (d) use the GMOs in the course of manufacture of a thing that is not the GMOs;
 - (e) grow or culture the GMOs;
 - (f) import the GMOs;
 - (g) transport the GMOs;
 - (h) dispose of the GMOs;

and the possession, supply or use of the GMOs in the course of any of these dealings.

9. This licence does not apply to dealings with the GMOs conducted as a Notifiable Low Risk Dealing (NLRD) or pursuant to another authorisation under the Act.

Note: Dealings conducted as an NLRD must be assessed by an Institutional Biosafety Committee (IBC) before commencement and must comply with the requirements of the Regulations.

General obligations of the licence holder

10. The licence holder must, at all times, remain an accredited organisation in accordance with the Act and must comply with its instrument of accreditation.
11. The licence holder must be able to access all Isolation Zones and to access and control all Planting Areas, Pollen Traps, Monitoring Zones, and approved facilities to the extent necessary to comply with this licence.

Note: Arrangements to access and control these areas must be notified to the Regulator as part of each planting notification (Condition 42(a)).

12. 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;
 - (b) the cancellation or suspension of the licence;
 - (c) the surrender of the licence.
13. The licence holder must not permit a person covered by this licence to conduct any dealing with the GMOs 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.
14. The licence holder must inform the persons covered by this licence that any Personal Information relevant to the administration and/or enforcement of the licence may be disclosed to the Regulator.

General obligations of persons covered by the licence

15. If a person is authorised by this licence to deal with the GMOs and a particular condition of the licence applies to the dealing by the 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.

Note: Under the Act, the definition of premises includes a building, area of land or vehicle.

Section 3 Limits and control measures

3.1 Limits on the release

The following licence conditions impose limits on where and when the GMOs may be grown.

16. The only plants that may be intentionally grown at a Planting Area are:
- (a) the GMOs covered by this licence; and
 - (b) non-GM cotton; and
 - (c) plants approved in writing by the Regulator.
17. Non-GM cotton plants and GM cotton plants approved for commercial release by the Regulator grown in a Planting Area must be handled as if they were the GMOs.
18. Planting and growing of the GMOs may only occur within the following limits:

Area and duration

Year	Maximum sites	Maximum area (ha) per site	Maximum combined area (ha)
2024	10	3	10
2025	25	10	50
2026	25	10	50
2027	25	10	50
2028	25	25	100
2029	25	25	100

Local Government Areas in which Planting Areas may be located

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

3.2 Control measures

The following licence conditions restrict the spread or persistence of the GMOs and their genetic material in the environment.

GMOs must not enter food or feed

19. 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.

Note: Cotton lint derived from the GMOs is not considered a food or feed product for the purposes of this licence and may be sold as a commercial product.

Conditions to restrict pollen flow

20. The Planting Area must be:

- (a) surrounded by a Pollen Trap (as shown in Figure 1B); or
- (b) surrounded by a Monitoring Zone and an Isolation Zone (as shown in Figure 1A).

21. If a Pollen Trap is used in accordance with condition 20, 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 metres wide around the Planting Area while the GMOs are Flowering, although one path of up to 3 metres in width is allowed in order to access the Planting Area; and
- (d) be handled as if they were the GMOs.

22. If a Monitoring Zone and an Isolation Zone are used in accordance with condition 20:
- (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 Isolation Zone; and
 - (c) the Monitoring Zone and Isolation Zones must be inspected by people trained to recognise Cotton, and actions must be taken as follows:

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

**Condition 42(a) 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 (Condition 43) and reported to the Regulator (Condition 42).

Conditions to restrict seed dispersal

23. Equipment used in connection with the GMOs must be Cleaned as soon as practicable after use with the GMOs and before use for any other purpose.
24. Planting Areas and Pollen Traps must be at least 50 metres away from any permanent natural watercourses or man-made drainage features that flow into natural watercourses.

Note: This includes irrigation channels or storm water drains that flow into a natural watercourse.

25. Planting Areas and Pollen Traps must not be located in flood prone areas.

Conditions relating to harvesting

26. All GMOs planted within a Planting Area must be harvested or Destroyed within nine months after the first planting of any GMO within that Planting Area.
27. If all GMOs in a Planting Area have been Destroyed, then for the purposes of this licence:

- (a) the GMOs are taken to have been harvested; and
- (b) the Planting Area is taken to have been Cleaned.

Note: Cleaning activities must be reported to the Regulator (Condition 42). Areas of land that have been Cleaned are subject to inspections (Condition 31).

28. The GMOs must be harvested and ginned separately from any other crop.
29. Harvested GM seed not required for experimentation or future planting must be Destroyed as soon as practicable.

Conditions to restrict persistence of GMOs on trial sites

30. Areas of land used in connection with the GMOs must be Cleaned as follows:

Areas of land to be Cleaned	When
Planting Area and Pollen Trap	Within 28 days after harvest of the GMOs
Any area, outside a Planting Area or Pollen Trap, used to Clean any Equipment used in connection with the GMOs	As soon as practicable
Any area, outside a Planting Area or Pollen Trap, where GMOs have dispersed, e.g. during planting, growing, harvesting or Destruction	As soon as practicable

Note: Cleaning activities must be reported to the Regulator (Condition 42). Areas of land that have been Cleaned are subject to inspections (Condition 31).

31. After Cleaning, areas of land must be inspected by people trained to recognise Cotton. 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
Planting Area, Pollen Trap and other areas of land that were Cleaned in accordance with Condition 30.	From the day of Cleaning until: i. the area is planted as a new Planting Area in accordance with condition 16; or ii. the Regulator has issued a Sign off for the area.	At least once every 35 days	Volunteers	Destroy before Flowering

Note: Details of any inspection activity must be recorded in a Logbook (Condition 43) and reported to the Regulator (Condition 42).

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

- (a) in the first spring or summer following the harvest of the GMOs, the Planting Area and associated Pollen Trap must be Tilled immediately before or after a watering event as described in **Attachment B**; 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:
 - i. the area is planted as a new Planting Area in accordance with condition 16; or
 - ii. the plants are 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; or

- iii. the plants are agreed to in writing by the Regulator.

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

Destruction by burial

33. If Destruction of GMOs occurs by burial:

- (a) the GMOs must be buried in a pit and covered by a layer of soil at least one metre in depth, the top of which is no higher than the surrounding soil surface; and
- (b) seeds must be wet when buried to encourage decomposition; and
- (c) the licence holder must take measures to ensure that the burial site is not disturbed for a period of at least 12 months from the date of burial.

Note: If GMOs are dispersed on the soil surface during the process of burial, the burial site becomes an area of land that requires Cleaning under Condition 30, and is subject to post-Cleaning requirements.

Note: The date and location of burial, and measures used to ensure that the burial site is not disturbed, must be reported to the Regulator (Condition 42(f)).

Processing or experimentation with the GMOs

34. Treatment or processing of GM seed or experimentation or analysis with the GMOs may only be undertaken within:

- (a) a Planting Area before Cleaning; or
- (b) a Pollen Trap before Cleaning; or
- (c) a facility approved in writing by the Regulator.

Note: This condition does not apply to dealings conducted as an NLRD (see Condition 9).

35. Within a facility approved in writing by the Regulator in accordance with Condition 34, any area that is used for treatment, processing, experimentation or analysis of the GMOs must be Cleaned as soon as practicable and before use for any other purpose.

Transport or storage of the GMOs

36. Transport or storage of the GMOs must:

- (a) only occur to the extent necessary to conduct the dealings permitted by this licence or other valid authorisation under the Act, or to the extent necessary to enable export of the GMOs; 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 or Condition 37; and
- (c) comply with all other conditions of this licence.

Note: Activities with the GMOs within a Planting Area prior to Cleaning are not regarded as transport or storage.

Note: Condition 13 requires signed statements for persons transporting the GMOs.

Note: This condition does not apply to dealings conducted as an NLRD (see Condition 9).

37. Harvested GMOs may be transported in a cotton module or bale, if the cotton module or bale is labelled as detailed in the Regulator's *Guidelines for the Transport, Storage and Disposal of GMOs* as current at the time of transportation and:

- (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 or bales.

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

Note: The Contingency Plan must be implemented if the GMOs are detected outside areas under inspection (Condition 39).

Contingency plan

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

Section 4 Sign off

40. The licence holder may make written application to the Regulator that planting restrictions and inspection conditions no longer apply to the Planting Area and other areas requiring Cleaning if:

- (a) post-Cleaning inspection activities have been conducted for at least 12 months on the area; and
- (b) conditions have been conducive for germination and detection of Volunteers; and
- (c) no Volunteers have been detected in the area during the six months prior to the Sign off request.

Note: A Planting Area and Pollen Trap require a Tillage and a watering event prior to a Sign off application (Condition 32).

Note: The Regulator will take into account the management and inspection history for the Planting Area and other areas requiring Cleaning, 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 and facilitate monitoring of compliance by staff of the OGTR.

41. General notifications must be sent to the Regulator as follows:

Note: please send all correspondence related to the licence to OGTR.M&C@health.gov.au.

Notice	Content of notice	Timeframe
a. Changes to contact details	Changes to any of the contact details of the project supervisor that were notified in the licence application or subsequently	As soon as practicable

b. Ongoing suitability to hold a licence	<p>i. any relevant conviction of the licence holder; or</p> <p>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; or</p> <p>iii. any event or circumstances that would affect the capacity of the licence holder to meet the conditions of the licence; and</p>	As soon as practicable after any of these events occur
	<p>iv. any information related to the licence holder's ongoing suitability to hold a licence, that is requested by the Regulator</p>	Within the timeframe stipulated by the Regulator
c. People covered by the licence	<p>i. 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</p> <p><i>Note: Examples of functions or positions are 'project supervisor', 'site manager', 'farm labourer' etc.</i></p> <p>ii. detail of how the persons covered by the licence will be informed of licence conditions</p>	At least 14 days prior to conducting any dealings with the GMOs (to be updated within 14 days if the notified details change)
d. Testing methodology	A written methodology to reliably detect the genetic modifications described in this licence. The detection method/s must be capable of identifying each GM cotton line planted under this licence	At least 14 days prior to conducting any dealings with the GMOs (to be updated within 14 days if the notified details change)
e. Contingency plan	A Contingency Plan to respond to inadvertent presence of the GMOs outside an area that must be inspected	At least 14 days prior to conducting any dealings with the GMOs (to be updated within 14 days if the notified details change)
f. Training records	Copies of the signed and dated statements referred to in condition 13 if requested by the Regulator	Within the timeframe stipulated by the Regulator
g. Additional information required by the Act	<p>i. 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</p> <p>ii. any contraventions of the licence by a person covered by the licence; or</p> <p>iii. any unintended effects of the dealings authorised by the licence</p> <p><i>Note: The Act requires, for the purposes of the condition 41.g, that:</i></p> <ul style="list-style-type: none"> • <i>the licence holder will be taken to have become aware of additional information of a kind mentioned in Condition 41.g if he or she was reckless as to whether such information existed; and</i> • <i>the licence holder will be taken to have become aware of contraventions, or unintended effects, of a kind mentioned in Condition 41.g, if he or</i> 	<p>Without delay after becoming aware of any new information</p> <p><i>Note: An example of notification without delay is contact made within a day of a contravention of the licence via the OGTR free call phone number 1800 181 030. Notification without delay will allow the OGTR to conduct a risk assessment on the incident and attend the location, if required</i></p>

	<p><i>she was reckless as to whether such contraventions had occurred, or such unintended effects existed</i></p> <p><i>Note: Contraventions of the licence may occur through the action or inaction of a person.</i></p>	
h. Further details regarding additional information	Any further details requested by the Regulator in relation to information provided under condition 41.g.	Within the timeframe stipulated by the Regulator

42. Notifications relating to each trial site must be sent to the Regulator as follows:

Note: please send all correspondence related to the licence to OGTR.M&C@health.gov.au.

Notice	Content of notice	Timeframe
(a) Intention to plant	<ul style="list-style-type: none"> i. Details of the Planting Area including size, the local government area, GPS coordinates, a street address, a diagrammatical representation of the trial site (e.g. Google Maps) and any other descriptions ii. Whether a Pollen Trap will be used iii. Detail of how the licence holder will access and control the Planting Area and the associated <i>Pollen Trap, Monitoring Zone, Inspection Zone and Isolation Zone</i>, in accordance with condition 11. <i>Note: this should include a description of any contracts, agreements, or other enforceable arrangements.</i> iv. Identity of the GMOs to be planted at the Planting Area (e.g. lines or construct details) v. Date on which the GMOs will be planted vi. Period when the GMOs are expected to Flower vii. Period when harvesting is expected to commence viii. How all areas requiring post-Cleaning inspections are intended to be used until Sign off, including proposed post-harvest crops (if any) ix. Details of how inspection activities will be managed, including strategies for the detection and Destruction of Volunteers x. History of how the trial site has been used for the previous two years 	At least 7 days prior to each planting (to be updated as soon as practicable if the notified details change)
(b) Planting	<ul style="list-style-type: none"> i. Actual date(s) of planting the GMOs ii. Any changes to the details provided under part (a) of this condition 	Within 7 days of any planting
(c) Extreme Weather	<p>Any Extreme Weather event that is expected to affect or has already affected an area where the GMOs are or may be present.</p> <p><i>Note: The Contingency Plan must be implemented if the GMOs are detected outside areas requiring Cleaning (Condition 39).</i></p>	As soon as practicable

Notice	Content of notice	Timeframe
(d) Harvest	Actual date(s) of harvesting the GMOs	Within 7 days of commencement of any harvesting
(e) Cleaning	i. Date(s) on which required Cleaning was performed on any areas of land ii. Method(s) of Cleaning	Within 7 days of completion of Cleaning
(f) Destruction by burial	Date of burial, location of burial including GPS co-ordinates, and details of measures used to ensure that the burial site will not be disturbed for the period required by Condition 33	Within 7 days of burial of any GMOs
(g) Inspection activities	Information recorded in a Logbook as per the inspection requirements (Conditions 22, 31 and 43).	Within 35 days of inspection

Note: Additional records must be provided to the Regulator, if requested, in accordance with condition 38.

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

- (a) date of the inspections; and
- (b) name of the person(s) conducting the inspections; and
- (c) details of the experience, training or qualification that enables the person(s) to recognise cotton if not already recorded in the Logbook; and
- (d) details of areas inspected including current land use (including any post-harvest crops) and recent management practices applied; and

Note: management practices include Tillage events, spraying or maintenance measures used to facilitate inspections.

- (e) details of the developmental stage of the GMOs while they are being grown; and
- (f) details of any post-Cleaning rainfall events including measurements at or near the area, or any irrigation events; and
- (g) details of any cotton plants observed during required inspections or during land-management activities, including number, developmental stage and approximate position of the cotton plants within each area required to be inspected[†]; and
- (h) date(s) and method(s) of Destruction of or preventing Flowering of any Cotton plants found during inspections, including destruction of Cotton plants during land-management activities.

[†] *Examples of acceptable ways to record the positional information for Cotton plants/Volunteers in the Logbook include:*

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

Note: Details of inspection activities must be provided to the Regulator (Condition 42). The Regulator has developed a standardised proforma for recording inspection activities. This can be made available on request.

DIR No: 203

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

Organisation Details

Postal address: Monsanto Australia Pty Ltd
 Level 4, 109 Burwood Rd
 HAWTHORN, VIC, 3122

Phone No: 03 9248 6888

IBC Details

IBC Name: Monsanto Australia Pty Ltd IBC

GMO Description

GMOs covered by this licence

Cotton plants genetically modified by introduction of only the genes and genetic elements listed below.

Parent Organism

Common Name: Cotton
 Scientific Name: *Gossypium hirsutum* L.

Modified traits

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

Description Cotton plants have been genetically modified by the introduction of genes involved in herbicide tolerance and insect resistance. The plants may also contain antibiotic resistance and reporter genes as selectable markers. The event names, introduced genes and selectable markers are listed in Table 1. The GM cottons proposed for release will also contain short regulatory elements (Table 2).
 The GMOs may be used individually or in stacked combinations.

Table 1. Introduced genes in the GM cottons

GM event	Gene	Source	Function
MON 96012	CCI*	CCI*	Glyphosate, glufosinate, CCI* (HPPD inhibiting), dicamba and PPO-inhibiting herbicide tolerance
MON 89151	CCI*	CCI*	lepidopteran insect resistance
MON 15947	<i>cry2Ab2</i>	<i>Bacillus thuringiensis</i>	lepidopteran insect resistance

GM event	Gene	Source	Function
	<i>uidA</i>	<i>Escherichia coli</i>	selectable marker – reporter
MON 88702	<i>mCry51Aa2</i>	<i>B. thuringiensis</i>	hemipteran and thysanopteran insect resistance
MON 15985	<i>cry1Ac</i>	<i>B. thuringiensis</i>	lepidopteran insect resistance
	<i>nptII</i>	<i>E. coli</i>	selectable marker – antibiotic resistance
	<i>aad</i>	<i>E. coli</i>	selectable marker – antibiotic resistance
	<i>cry2Ab2</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
MON 88913	<i>cp4 epsps</i>	<i>Agrobacterium sp. strain CP4</i>	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

*This information has been declared Confidential Commercial Information (CCI) under s185 of the Act

Table 2. Introduced regulatory sequences in the GM cottons

GM event	Element function	Genetic element	Source organism
MON 96012	CCI*	CCI*	CCI*
MON 89151	CCI*	CCI*	CCI*
MON 15947	Promoter	e35S	<i>Cauliflower mosaic virus</i>
	5' UTR leader sequence	HSP70	<i>Petunia</i>
	3' UTR termination sequence	NOS 3'	<i>Arabidopsis thaliana</i>
MON 88702	Enhancer	FMV	<i>Figwort mosaic virus</i>
	Promoter and 5' UTR leader sequence	Hsp81-2	<i>A. thaliana</i>
	3' UTR termination sequence	35S	<i>CMV</i>
MON 15985, COT102, MON 88913, and MON 88701	See DIR 124 and DIR 145 Risk Assessment and Risk Management Plans for details		

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Untranslated (UTR).

ATTACHMENT B

A watering event is irrigation or natural rainfall that provides sufficient soil moisture to promote germination of cotton seeds on a trial site.

Examples of acceptable watering events are:

- At least 26 millimetres of rainfall over one day; or
- At least 28 millimetres of rainfall over two days; or
- At least 30 millimetres of rainfall over three days; or
- At least 32 millimetres of rainfall over four days; or

Irrigation that provides equivalent levels of soil moisture to one of the examples of rainfall above.

Rainfall measurements must be taken on the site or within 3 km of the site.

An irrigation or natural rainfall that matches one of the examples listed above, and occurs during the time period specified for a watering event in Condition 30 of the licence, is considered a valid watering event. The licence holder should keep records of the date/s and amount of water applied during the watering event, and provide this information when requesting Sign off of the relevant site.

If an irrigation or natural rainfall does not match one of the examples listed above, the licence holder may submit a request to the Regulator for it to be considered a watering event. The request should provide:

- evidence of amount of water applied, such as rainfall measurements on the site or within 3 km of the site, and
- evidence that resultant soil moisture is suitable for germination, such as photos of germinating plants on the site.

It is recommended that any requests that an irrigation or natural rainfall be considered a watering event be submitted at the time of the event, to minimise potential delays to Sign off of the site.