



**Australian Government**

**Department of Health and Ageing  
Office of the Gene Technology Regulator**

# **Licence for Dealings Involving an Intentional Release of GMOs into the Environment**

**Licence No.: DIR 048/2003**

**Licence holder: Hexima Ltd**

**Title: A field trial to assess transgenic insecticidal cotton  
expressing natural plant genes**

**Issued: 30 July 2004  
Varied: 25 October 2004  
Varied: 21 August 2006  
Surrendered: 15 June 2011**

**More information about this licence is contained in the Risk Assessment and Risk Management Plan prepared in connection with this licence. This document can be obtained from the Office of the Gene Technology Regulator website at <http://www.ogtr.gov.au>, or by telephoning the Office on 1800 181 030.**

## ***Gene Technology Regulation in Australia***

The *Gene Technology Act 2000* (Cth) and corresponding state and territory legislation form a substantial part of a range of integrated regulatory measures relevant to controlling genetically modified organisms (GMOs) and their use.

The Gene Technology Regulator is required to consult with, and take into account advice from, a range of regulatory authorities on risks to human health and safety and the environment in assessing applications for dealings involving the intentional release of GMOs into the Australian environment.

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

Food Standards Australia New Zealand (FSANZ) is responsible for human food safety assessment. FSANZ approval would need to be obtained before any parts of the GM cottons such as oil and linters derived from GM cottonseed could be used as human food. This licence contains a condition that prohibits this use.

### ***Note in relation to herbicide and insecticide resistance management***

The *Gene Technology (Consequential Amendments) Act 2000* (Cth) requires the Australian Pesticides and Veterinary Medicines Authority (APVMA) to consult the Gene Technology Regulator for the purposes of making certain decisions including imposition of conditions regarding registration or issuing a permit for a chemical product that is or contains a genetically modified product.

The GMOs referred to in this licence fall under the *Agricultural and Veterinary Chemicals Code Act 1994* (Cth) definition of agricultural chemical products, due to their production of insecticidal substance, and are therefore subject to regulation by the APVMA. The APVMA assesses the hazard of development of insecticide resistance as part of its evaluation process and would impose conditions to manage any identified risks. Therefore, the conditions of this licence do not relate to management of insecticide resistance, and do not displace any conditions set by the APVMA.

## SECTION 1 INTERPRETATION AND DEFINITIONS

This licence does not authorise dealings with GMOs that are otherwise prohibited as a result of the operation of State legislation declaring areas to be GM, GM free, or both, for marketing purposes.

In this licence:

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

In this licence:

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

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

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

**‘cotton’** means plants of the species *Gossypium hirsutum* L. and *G. barbadense*;

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

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

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

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

**'GM'** means genetically modified.

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

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

**'Plant Material'** means viable parts of the GMOs or Pollen Trap Plants grown at the location, including seed, stubble and pollen, whether from the plant itself or derived from or produced by the plant.

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

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

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

**'Pollen Trap plant'** means cotton from a Pollen Trap planted in accordance with condition 10 of section 3 of this licence.

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

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

## **SECTION 2 GENERAL CONDITIONS**

### **Duration of Licence**

1. This licence remains in force until it is suspended, cancelled or surrendered. No dealings with GMOs are authorised during any period of suspension.

### **Holder of Licence**

2. The holder of this licence ('the licence holder') is Hexima Ltd.

### **Project Supervisor**

3. The Project Supervisor in respect of this licence is identified at Attachment A.
4. The licence holder must immediately notify the Regulator in writing if any of the contact details of the Project Supervisor change.

### **No dealings with GMOs except as authorised by this licence**

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

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

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

### **Permitted dealings**

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

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

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

### **Informing people of their obligations**

9. The licence holder must inform any person covered by this licence, to whom a particular condition of this licence applies, of the following:
  - (a) the particular condition (including any variations of it);
  - (b) the cancellation or suspension of the licence;
  - (c) the surrender of the licence.

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

#### **Licence holder to notify of circumstances that might affect suitability**

11. The licence holder must immediately, by notice in writing, inform the Regulator of:
  - (a) any relevant conviction of the licence holder occurring after the commencement of this licence;
  - (b) any revocation or suspension of a licence or permit held by the licence holder under a law of the Australian Government, a State or a foreign country, being a law relating to the health and safety of people or the environment;
  - (c) any event or circumstances occurring after the commencement of this licence that would affect the capacity of the holder of his licence to meet the conditions in it.

#### **Additional information to be given to the Regulator**

12. It is a condition of a licence that the licence holder inform the Regulator if the licence holder:
  - (a) becomes aware of additional information as to any risks to the health and safety of people, or to the environment, associated with the dealings authorised by the licence; or
  - (b) becomes aware of any contraventions of the licence by a person covered by the licence; or
  - (c) becomes aware of any unintended effects of the dealings authorised by the licence.

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

13. If a person is authorised by this licence to deal with GMOs and a particular condition of this licence applies to the dealing by that person, the person must allow the Regulator, or a person authorised by the Regulator, to enter premises where the dealing is being undertaken, for the purposes of auditing or monitoring the dealing.

#### **Remaining an Accredited organisation**

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

## SECTION 3 SPECIFIC CONDITIONS

### Locations and size of trial

1. The permitted dealings with the GMOs may be undertaken during the Summer cotton growing seasons in 2004/2005, 2005/2006 and 2006/2007 in the Shires and sizes and quantities as indicated below in Table 1:

Table 1: Shires in which the GMOs may be grown and maximum Location sizes

| Shires                          | State | Maximum number of Locations per growing season | Maximum combined area of all Locations per growing season |
|---------------------------------|-------|--|---|
| Wambo, Pittsworth and Jondaryan | QLD   | 2  | 0.5 ha  |

2. A Location must not be within 3 kilometres of a nature reserve, national park or state forest.
3. The licence holder must be able to access and control a Location to the extent necessary to comply with this licence, for the duration of the life of the licence.

### Notification of planting of the GMOs

4. The licence holder must provide a notice in writing to the Regulator each time the GMOs are planted at a Location.
5. The notice must set out:
  - (a) The date on which planting of the GMOs commenced;
  - (b) Details of the Location where the GMOs are planted, including a street address and GPS coordinates for the Location;
  - (c) The period during which the licence holder considers the GMOs are likely to flower; and
  - (d) The period during which the licence holder considers the GMOs are likely to be harvested (or Destroyed at a Location in lieu of harvest).
6. The notice must be provided to the Regulator within 14 days of the date on which planting of the GMOs commenced.

### Notice of harvest or Destruction of the GMOs

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

## **Pollen Traps**

9. A Pollen Trap must surround every Location.
10. Each Pollen Trap must be planted out with non-genetically modified plants of the species *Gossypium hirsutum* L., grown in such a way as to reasonably promote a dense and vigorous growth and flowering of the non-genetically modified *Gossypium hirsutum* L. at the same time as the GMOs. Pollen Trap plants must be grown in the Pollen Trap while ever the GMOs are being grown at the Location within it.
11. The edge of every Pollen Trap that is farthest from the GMOs (the ‘outer edge of the Pollen Trap’) must not be within 50 metres of a Natural Waterway.
12. Pollen Trap plants must be handled and controlled as if they are the GMOs (ie subject to other applicable conditions elsewhere in this licence), and Plant Material must be handled and controlled as if it is the GMO (ie subject to other applicable conditions elsewhere in this licence).
13. A Pollen Trap must be able to be accessed and controlled by the licence holder to an extent that is commensurate with the licence holder’s rights to access and control the Location within it.

## **Harvest and post-harvest procedures**

14. If the GMOs or Pollen Trap plants are harvested, they must be harvested by hand separately from any other cotton.
15. Any GM cotton seed obtained from harvesting may only be transported to the extent necessary to transfer it to a facility certified by the Regulator to physical containment level PC2.

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

16. Equipment, a Location or other area used pursuant to this licence in respect of GMOs, or destroy the GMOs, Pollen Trap Plants or Plant Material must be Cleaned.
17. For each Location, either within 14 days of harvest of the GMOs or by 31 May 2007, whichever occurs first, the Location must be Cleaned.
18. If Equipment is Cleaned, the area in which the Equipment is Cleaned must also be Cleaned. (For the sake of clarity, it is not necessary for Equipment to be Cleaned only at a Location.)
19. Cleaning must occur immediately or as soon as practicable after the use and before it is used for any other purpose.
20. 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.

### **Post harvest inspections must be conducted**

21. Following Cleaning of the GMOs, Pollen Trap plants and Plant Material at a Location or other area, the following places must be inspected for the existence of Volunteer plants:
  - (a) the Location;
  - (b) the Pollen Trap in respect of the Location;
  - (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 the GMOs at the Location or to Destroy the GMOs, Pollen Trap plants or Plant Material.
22. Inspection must be performed by a person who is able to recognise Volunteer plants.
23. The results of inspection activities must be recorded in a logbook. The logbook must be available on request for examination or photocopying by the OGTR. The findings of the inspections as recorded in the logbook must be included in the licence holder's annual report to the Regulator. The logbook must contain at least the following:
  - (a) details of the areas inspected;
  - (b) details of the date of inspection;
  - (c) the names of the person or persons who undertook the monitoring and details of the experience, training or qualification that enabled them to recognise Volunteer plants;
  - (d) the number of Volunteer plants observed, if any;
  - (e) details of the development stages reached by the Volunteer plants, if any; and
  - (f) details of methods used to Destroy Volunteer plants, if any.
24. Any Volunteer plant identified must be Destroyed prior to the plant flowering.
25. All the places required to be inspected must be inspected at least once every 2 months, commencing on the last day of Cleaning of the Location.
26. If:
  - (a) inspections have been routinely completed in a place for a period of at least 1 year; and
  - (b) inspection records for that place show that no Volunteers have been observed in the most recent 6 month inspection period;
  - (c) the licence holder may make written application to the Regulator that these inspection conditions no longer apply in respect of that place.
27. These inspection conditions do not apply in respect of a place if the licence holder has been issued with a notice from the Regulator that these inspection conditions do not apply in respect of that place. (These notices are called 'sign-offs'.)

### **General conditions on use of Locations while GMOs are growing and post-harvest**

28. Subject to condition 32 below, if the GMOs are grown at a Location, that Location cannot be used to grow the GMOs again.

29. Subject to condition 32 below, if the GMOs are grown at a Location, no Cotton may be grown at the Location or its Pollen Trap.
30. Subject to conditions 31 and 32 below, if the GMOs are grown at a Location, no other plants may be planted at the Location or its Pollen Trap.
31. Subject to condition 32 below, after the GMOs have been grown at a Location, only the following plants may be grown at a Location and its Pollen Trap:
  - (a) grasses (grass pastures); or
  - (b) plants agreed to in writing by the Regulator; and
32. Conditions 29, 30 and 31 above, do not apply in respect of a place if inspection obligations under this licence have been completed and the licence holder has received a sign-off in respect of that place.
33. NB: For the purposes of the above condition, it is the policy of the Regulator to agree in writing to plants being grown in circumstances where a licence holder can satisfy the Regulator that monitoring and Destruction of Volunteer plants prior to setting seed will not be adversely affected by the plants being grown.

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

34. Subject to condition 34, below, in respect of transportation, the GMOs, Pollen Trap plants and Plant Material must be transported in accordance with the OGTR Guidelines for the Transport of GMOs (June 2001) issued by the Regulator.
35. Every container used to transport the GMOs, Pollen Trap plants and Plant Material must be labelled:
  - (a) to indicate that it contains genetically modified cotton; and
  - (b) with telephone contact numbers for the licence holder and instructions to contact the licence holder in the event that the container is broken or misdirected.

*Note: Cotton lint derived from GMOs and Pollen Trap plants from ginning is not Plant Material and is not subject to transportation guidelines.*

#### **Contingency Plans**

36. Within 30 days of the date of the commencement of this licence, a written Contingency Plan must be submitted to the Regulator detailing measures to be taken in the event of the unintended presence of the GMOs, Plant Material or Pollen Trap plants or outside an area that must be inspected.
37. The Contingency Plan must include details of procedures to:
  - (a) ensure the Regulator is notified immediately if the licence holder becomes aware of the event;
  - (b) destroy any of the GMOs, Pollen Trap plants or Plant Material; and
  - (c) inspect and Destroy any Volunteer plants that may exist as a result of the event.
38. The Contingency Plan must be implemented in the event that the unintended presence of the GMOs, Pollen Trap plants and Plant Material is discovered outside an area that must be inspected.

## **Compliance Management Plan**

39. Prior to growing the GMOs, a written Compliance Management Plan must be provided to the Regulator. The Compliance Management Plan must describe in detail how the licence holder intends to ensure compliance with these conditions and document that compliance.

## **Reporting**

40. The licence holder must provide the Regulator with a written report within 90 days of each anniversary of this licence, in accordance with any Guidelines issued by the Regulator in relation to annual reporting. This report must include information on any adverse impacts on human health and safety or the environment, caused as a result of the GMOs, Pollen Trap plants or Plant Material Research requirements
41. The licence holder must, in consultation with the OGTR, develop an agreed research program to collect information regarding:
  - (a) the levels of expression of the serine protease inhibitors and the plant parts in which they are expressed under Australian field conditions; and
  - (b) the potential toxicity of the GMOs to representative non-target organisms.

## **Testing methodology**

42. The licence holder must provide a written instrument to the Regulator describing an experimental method that is capable of reliably detecting the presence of the GMOs and the presence of the genetic modifications described in this licence (at Attachment B) in a recipient organism. The instrument must be provided within 12 months of the issuing of this licence.

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

43. The GMOs, Pollen Trap plants and Plant Material must not be used for stockfeed and must not enter the human food supply.

**DIR No: 048/2003**

**\*Full Title:** Field trial to assess transgenic insecticidal cotton expressing natural plant genes

**Organisation Details**

**Postal address:** Hexima Limited  
200 Queen Street  
MELBOURNE VIC 3000

**Phone No:** (03) 8629 2929

**Fax No:** (03) 8629 2990

**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:** Hexima Ltd

**Postal Address:** School of Botany  
The University of Melbourne VIC 3010

**IBC Details**

**IBC Name:** Hexima Limited IBC

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

**Note: Confidential commercial information (CCI) has been removed from this attachment.**

ATTACHMENT B

### **GMOs Description**

- \* **Parent Organism Common Name:** Cotton
- \* **Parent Organism Scientific Name:** *Gossypium hirsutum* L.

### **Modified Traits**

- \***Category:** Insecticidal and antibiotic resistance
- \***Description:** Cotton Plants have been genetically modified by the insertion of a number of genes encoding a serine protease inhibitor, which confers insecticidal properties on the plant, and an antibiotic resistance gene.

### **\*Genes responsible for conferring the modified traits**

- *NaPI* {**Confidential Commercial Information**} gene from the plant *Nicotiana glauca* (serine protease inhibitor: insecticidal).
- {**Confidential Commercial Information**} (serine protease inhibitor: insecticidal).
- *PotI* gene from the plant *Solanum tuberosum* (serine protease inhibitor: insecticidal).
- *nptII* gene from *Escherichia coli* (antibiotic resistance: selectable marker).

### **Details**

The GMOs covered by this licence are as follows:

{**Confidential Commercial Information**}

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

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

The aims of the proposed release are to test the efficacy of the GM cottons against lepidopteran pests of cotton and to evaluate their respective agronomic performance.

**Notes in relation to places where GMOs are grown pursuant to this licence**

By written notice dated 14 October 2004, the licence holder identified the following places as Locations where the GMOs will be grown pursuant to this licence:

Site 1 (Gebar)

Area 0.0576 ha (GMO area) (24 x 24 m)  
Local government Area Wambo  
Street address/Directions: Gebar  
1818 Marnhull-Macalister Road  
Jandowae, Queensland 4410

GPS coordinates:

|                      |           |            |
|----------------------|-----------|------------|
| South Western Corner | 26.52.660 | 151.05.267 |
| North Western Corner | 26.52.647 | 151.05.270 |
| North Eastern Corner | 26.52.663 | 151.05.285 |
| South Eastern Corner | 26.52.663 | 151.05.282 |

Site 2 (Balmoral)

Area 0.0624 ha (GMO area) (24 x 28 m)  
Local Government Shire Pittsworth  
Street address/Directions: Balmoral  
387 Balmoral Road  
Pittsworth, Queensland 4356

GPS coordinates:

|                      |           |            |
|----------------------|-----------|------------|
| South Western Corner | 27.49.695 | 151.31.407 |
| North Western Corner | 27.49.672 | 151.31.412 |
| North Eastern Corner | 27.49.666 | 151.31.424 |
| South Eastern Corner | 27.49.689 | 151.31.419 |