

CONDITIONS OF LICENCE – DIR 023/2002

Note in relation to Herbicide and Insecticide Resistance Management

One of the genetically modified organisms referred to in this licence falls into *the Agricultural and Veterinary Chemicals Code (1994)* definition of an agricultural chemical product, due to its production of an insecticidal substance, and therefore is subject to regulation by the APVMA (the Australian Pesticides and Veterinary Medicines Authority, formerly the National Registration Authority for Agricultural and Veterinary Chemicals).

The APVMA has imposed conditions in connection with the insecticidal activity of this genetically modified organism, including specifying maximum areas for release, for the purpose of managing the development of insecticide resistance in the target pest species. Conditions of this licence do not relate to management of insecticide resistance, and do not replace any conditions set by the APVMA. The licence holder must comply with any conditions imposed by the APVMA in relation to dealings with this GMO.

The genetically modified organisms referred to in this licence have been modified to be tolerant to a herbicide. The APVMA has responsibility for setting registration conditions for the use of herbicides in Australia, including implementation of herbicide resistance management programs. Conditions of this licence do not relate to use of herbicide, and do not replace any conditions set by the APVMA. The licence holder must comply with any conditions imposed by the APVMA in relation to the use of herbicides in connection with these GMOs.

PART 1

This instrument, including its attachments, is a licence authorising dealings involving the intentional release of GMOs into the environment. It is issued by the Gene Technology Regulator (the Regulator) pursuant to the *Gene Technology Act 2000* (Cth).

Holder of licence

1. The holder of this licence ('the licence holder') is Monsanto Australia Limited.

Persons covered by licence

2. The persons covered by this licence are the licence holder and other persons who undertake any dealing in connection with the GMOs authorised by Clause 5 of Part 1 of this licence.

(Explanatory Note: Each person covered by this licence is a 'person covered by a GMO licence' for the purposes of the Gene Technology Act 2000 (Cth)).

Description of GMOs covered

3. The GMOs covered by this licence ('the GMOs') are Roundup Ready[®] cotton and Roundup Ready[®]/INGARD[®] cotton, which are genetically modified.

Dealings authorised by licence

4. This licence authorises the licence holder and persons covered by the licence to conduct dealings with the GMOs subject to the limitations on dealing with the GMOs that are contained elsewhere in the conditions in this licence.

Period covered by licence

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

(Note: Although the applicant has stated an intention to phase-out dealings with Roundup Ready[®]/INGARD[®] cotton over the next 2 growing seasons, while phasing-in Roundup Ready[®]/Bollgard II[®] cotton (under licence number DIR 012/2002), the proposed licence conditions for Roundup Ready[®]/INGARD[®] cotton do not include a specific termination clause. Once the phase-out is complete, the applicant can apply to the Regulator to vary the licence.)

PART 2

Interpretation and Definitions

Words and phrases used in this licence have the same meanings as they do in the *Gene Technology Act 2000* (the Act) and the *Gene Technology Regulations 2001*.

Words importing a gender include any other gender.

Words in the singular include the plural and words in the plural include the singular.

Words importing persons include a partnership and a body whether corporate or otherwise.

References to any statute or other legislation (whether primary or subordinate) is to a statute or other legislation of the Commonwealth of Australia as amended or replaced from time to time unless the contrary intention appears.

Where any word or phrase is given a defined meaning, any other part of speech or other grammatical form in respect of that word or phrase has a corresponding meaning.

In this licence:

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

‘Covered Vehicles’ means vehicles that use tight fitting covers to prevent spillage of the load during transporting (for example a trailer with sides moulded to the base fitted with a roll-over tarp).

‘Deal with’ has the same meaning as under the *Gene Technology Act 2000* in which ‘deal with’, in relation to the GMO, means the following;

- a) conduct experiments with the GMO;
- b) make, develop, produce or manufacture the GMO;
- c) breed the GMO;
- d) propagate the GMO;
- e) use the GMO in the course of manufacture of a thing that is not the GMO;
- f) grow, raise or culture the GMO;
- g) import the GMO;

and includes the possession, supply, use, transport or disposal of the GMO for the purpose of or in the course of, a dealing mentioned in any of paragraphs (a) to (g).

‘Feral cotton’ means naturalised, self-perpetuating populations of unmodified *Gossypium hirsutum* L. and/or *Gossypium barbadense* L.

‘GM’ means genetically modified.

‘GMO’ means genetically modified organism authorised for release by this licence.

‘OGTR’ means the Office of the Gene Technology Regulator.

‘Restricted Zone’ means north of latitude 22° South in NT, QLD and WA.

‘Technology User’s Agreement’ means the licence issued by the licence holder for use of the GMO.

‘Volunteer plant’ means progeny of the GMO.

PART 3 CONDITIONS OF LICENCE

The licence holder and persons covered by this licence must comply with the conditions of this licence. The reasons for the specific conditions are set out in the Summary Table presented in Chapter 2 of the risk assessment and risk management plan.

SECTION 1: GENERAL CONDITIONS

Informing people of their obligations

1. The licence holder must inform each person covered by this licence of the obligations imposed on them as a result of the conditions in this licence.

Reporting

2. The licence holder must immediately notify the Regulator in writing 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.

3. 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 notification of any adverse impacts on human health and safety or the environment, caused as a result of the GMOs.

Material changes in circumstances

4. The licence holder must immediately notify the Regulator in writing 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 Commonwealth, 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 this licence to meet the conditions in it.

Remaining an accredited organisation

5. The licence holder must, at all times, remain an accredited organisation in accordance with the Act and comply with any conditions of accreditation set out in the OGTR Guidelines for Accreditation of Organisations.

Changes to details

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

SECTION 2: SPECIFIC CONDITIONS

Restrictions on growing of the GMOs

7. The licence holder must not enter into a Technology User's Agreement or any other agreement which would permit the GMO to be grown *outside* of the traditional cotton-growing areas of New South Wales and Queensland south of latitude 22° South or north of 22° South.

Transport of GM whole cotton seed *into* the Restricted Zone

8. The licence holder must provide written notification to cotton gins from which GM whole cotton seed will be transported into the Restricted Zone stating the requirements for transportation *into* the Restricted Zone required by Condition 11. The licence holder must also maintain a record of this action.
9. The licence holder must prepare and distribute to cotton gins from which GM whole cotton seed will be transported *into* the Restricted Zone sufficient copies of the sign required by Condition 11(b). This sign must accompany each shipment of cotton seed into the restricted Zone, as required by condition 11.
10. Cotton gins from which GM whole cotton seed is transported *into* the Restricted Zone must convey the information in the notification prepared by the licence holder under Condition 8 to transporters of GM whole cotton seed *into* the Restricted Zone, provide transporters with a sign to accompany *every* shipment of cottonseed into the restricted Zone, and must maintain a record of this action.
11. Transporters of GM whole cotton seed to destinations within the Restricted Zone must:
 - (a) only transport the GM whole cotton seed in Covered Vehicles;
 - (b) sign Covered Vehicles to indicate that they contain GM whole cotton seed, and with instructions to contact the licence holder in the event that the GM whole cotton seed is spilt or misdirected, including telephone contact numbers.

Use of GM whole cotton seed *within* the Restricted Zone

12. The licence holder must, in consultation with the OGTR, develop a communication strategy, including a document for distribution, to convey the importance of appropriate control of cotton volunteers, to all recipients of GM whole cotton seed.
13. The licence holder must provide a written request to cotton gins from which GM whole cottonseed is transported *into* the Restricted Zone that the cotton gins attach the document required by Condition 12 to bill of loading/invoice/weighbridge certificate, such that recipients of GM whole cotton seed in the Restricted Zone will receive a copy of the document.
14. The licence holder must take all reasonable steps to distribute the document specified in condition 12 to:
 - (a) the cotton gins from which GM whole cotton seed is sourced for transport *into* the Restricted Zone;
 - (b) the transporters of GM whole cotton seed *into* the Restricted Zone; and

- (c) all recipients of GM whole cotton seed *within* the Restricted Zone, including retailers and the end users of the GM whole cotton seed.

Research

- 15. The licence holder must, in consultation with the OGTR, conduct a survey of non-crop areas for the incidence of Roundup Ready[®] and Roundup Ready[®]/INGARD[®] cotton volunteers.
- 16. The licence holder must, in consultation with the OGTR, conduct an annual survey within the Restricted Zone of:
 - (a) the incidence of volunteer cotton in areas where stock are fed GM whole cotton seed;
 - (b) the incidence of volunteer cotton in areas where stock graze after being fed GM whole cotton seed; and
 - (c) the extent to which the communication strategy, required in conditions 12 – 14, has been effective.
- 17. Each of the key geographic regions where GM whole cotton seed is used as stock feed in northern Australia (eg. Atherton Tablelands, Eungella, Katherine, Broome) must be represented in the annual survey required in Condition 16.
- 18. The findings of research, required in Condition 15 – 17, must be included in the licence holder's annual report to the OGTR.

Compliance management plan

- 19. Prior to planting 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 to document that compliance.

Testing Methodology

- 20. 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 any transferred genetically modified material that might be present in a recipient organism. The instrument must be provided within 30 days of planting the GMOs.