



Australian Government

Department of Health, Disability and Ageing

Office of the Gene Technology Regulator

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

Licence No.: DIR 091

Licence holder: Pioneer Hi-Bred Australia Pty Ltd

Title: Commercial release of cotton genetically modified for insect resistance (WideStrike™ Insect Protection Cotton)

Issued: 25 November 2009

Varied: 4 March 2021

Transferred: 4 September 2026

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

Gene Technology Regulation in Australia

Australia's gene technology regulatory system operates as an integrated legislative framework. The *Gene Technology Act 2000* (Cth) and corresponding state and territory legislation form a substantial part of a nationally consistent regulatory system controlling the development and use of genetically modified organisms (GMOs).

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

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

Other agencies that also regulate GMOs or GM products include Food Standards Australia New Zealand, Australian 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 B of this licence.

Dealings permitted by this licence may also be subject to the operation of State legislation declaring areas to be GM, GM free, or both, for marketing purposes.

Section 1 Interpretations and Definitions

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

2. In this licence:

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

3. In this licence:

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

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

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

'Covered Vehicles' means vehicles that use tight fitting covers to prevent spillage of the seed transported in them (for example, vehicles that contain seed in steel or aluminium bulk bins covered with tight, well fitting weather-proof tarpaulins or similar).

'GM' means genetically modified.

'GMO' means the genetically modified organism that is the subject of the dealings authorised by this licence.

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

'Personal Information' means information or an opinion (including information forming part of a database), whether true or not, and whether recorded in a material form or not, about an individual whose identity is apparent, or can reasonably be ascertained, from the information or opinion.

'Plant Material' means any part of the GM cotton plants, whether viable or not, including, but not limited to, seed, pollen and material cut from plants, whether from the plant itself or derived from or produced by the plant, but not including cotton lint.

'Unbreakable Container' means a container able to maintain integrity under all reasonably expected conditions of transport such as pressures, forces, impacts, temperatures and moisture.

'Volunteer Plant' means the GMO or its progeny that have not been intentionally grown.

Section 2 *Licence conditions*

Duration of licence

4. This licence remains in force until it is suspended, cancelled or surrendered. No dealings with the GMO is authorised during any period of suspension.

Holder of licence

5. The holder of this licence ('the licence holder') is Pioneer Hi-Bred Australia Pty Ltd.

Remaining an accredited organisation

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

Licence holder must provide information on matters related to suitability

7. 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; and
- (c) any event or circumstances occurring after the commencement of this licence that would affect the capacity of the holder of this licence to meet the conditions in it.

8. The licence holder must provide information related to the licence holder's ongoing suitability to hold a licence when requested to do so in writing by the Regulator and must provide the information within a time period stipulated by the Regulator.

Contact details

10. The licence holder must notify the Regulator as soon as practicable if any of its contact details change.

Persons covered by this GMO licence

11. Any person, including the licence holder, may conduct any permitted dealing(s) with the GMO.

Informing people of their obligations

12. 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; and
- (c) the surrender of the licence.

13. The minimum requirement for purposes of providing information under condition 12(a) is compliance with conditions 20, 21 and 22.

People dealing with the GMO must allow auditing and monitoring of the dealing

14. If a person is authorised by this licence to deal with the GMO 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.

GMO covered by this licence

15. The GMO covered by this licence is the organism genetically modified as described in Attachment B.

Permitted dealings

16. This licence permits all dealings with the GMO to be conducted in all areas of Australia south of latitude 22° South.

17. The licence holder and persons covered by this licence must not deal with the GMO north of latitude 22° South except as expressly authorised or contemplated by this licence.

18. The GMO and Plant Material from the GMO may be used as feed for livestock in areas north of latitude 22° South but feeding of whole GM cotton seed must only take place inside stockyards, feedlots or dairies.

19. To the extent that the conditions of any prior licence authorising dealings with the GMO are inconsistent with the conditions of this licence, the conditions of this licence will prevail.

Agreements with growers or others dealing with the GMO

20. Where the licence holder or an agent of the licence holder enters into a written agreement to licence, authorise, or in any other way permit a person to use the GMO, the licence holder or agent must, after having regard to the intended use of the GMO by the person, attach to the agreement a document that:

- (a) states that conditions apply to the transport and use of the GMO and GM cotton seed north of latitude 22° South;
- (b) lists the conditions which will apply, or are likely to apply, to the person;
- (c) explains the listed conditions;
- (d) states that a breach of the conditions is an offence under the Act; and
- (e) indicates that Personal Information collected by the licence holder which is relevant to the administration and/or enforcement of the licence may be released to the Regulator.

Transportation of Plant Material north of latitude 22° South

21. The licence holder must prepare:

- (a) a document that:
 - (i) lists the conditions which apply to cotton gins from which whole cotton seed of the GMO is transported north of latitude 22° South;
 - (ii) lists the conditions which apply to transporters of whole cotton seed of the GMO north of latitude 22° South;
 - (iii) lists the conditions which apply to use of whole cotton seed of the GMO for stock feed north of latitude 22° South;
 - (iv) explains the listed conditions; and

- (v) states that breach of these conditions is an offence under the Act;
and
- (b) signage for transport vehicles, indicating that GM cotton seed is being transported and with instructions to contact the licence holder (including phone numbers) in the event the GM cotton seed is spilt or misdirected;

and must provide a copy of both the document and signage to the Regulator prior to planting of the GMO.

22. The licence holder must provide, to cotton gins from which whole cotton seed of the GMO may be transported north of latitude 22° South, a sufficient number of copies of both the document and signage mentioned in condition 21 to accompany all transport of the seed north of latitude 22° South from the gin.

23. Cotton gins from which whole cotton seed of the GMO is transported north of latitude 22° South must provide transporters with a copy of the signage referred to in condition 21(b) to accompany every shipment of the seed north of latitude 22° South, and must maintain a record of this action.

24. Cotton gins must attach a copy of the document referred to in condition 21(a) to all bills of loading, invoices, weighbridge certificates and other such documents related to transport of whole cotton seed of the GMO north of latitude 22° South.

Note: This is to ensure that recipients of the seed of the GMO receive a copy of the document.

25. Plant Material may be transported north of latitude 22° South but, if it contains whole cotton seed of the GMO, it must be transported in Covered Vehicles or in an Unbreakable Container within a vehicle. The signage mentioned in condition 21(b) must be displayed on the vehicle or on the container.

Research on environmental impacts

26. The licence holder must, in consultation with the Regulator, develop an agreed research programme to monitor the environmental impacts of the GMO. This must include (but need not be limited to) collecting information on:

- (a) the effects of the GMO on key non-target insects in cotton fields in Australia; and
- (b) the incidence of Volunteer plants in areas north of latitude 22° South where livestock were:
 - (i) fed viable GM cotton seed; and
 - (ii) subsequently grazed or housed within two days of being fed the GM cotton seed.

27. The research programme mentioned in the immediately preceding condition must be agreed upon by the Regulator, and must be commenced by the licence holder before a total area greater than 500 ha is planted to the GMO. Progress on the research programme must be provided to the Regulator in the Annual Report.

28. The final results of the agreed research programme mentioned in condition 26, including data analysis, must be provided to the Regulator within five years from the date of the commencement of the programme.

Additional information to be given to the Regulator

29. The licence holder must inform the Regulator immediately if the licence holder becomes aware of any of the following:

- (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;
- (b) any contraventions of the licence by a person covered by the licence; and
- (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 the above condition 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 the above condition if he or she was reckless as to whether such contraventions had occurred, or such unintended effects existed.*

30. The licence holder must provide the information required by paragraphs (a), (b) and (c) of the immediately preceding condition to the Regulator as soon as practically and reasonably possible, and must also include the information in the Annual Report.

31. If at any time the Regulator requests the licence holder to collect and provide information about any matter to do with the progress of the dealings authorised by this licence, including but not confined to:

- (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, whether or not the licence holder has provided information to the Regulator under condition 29 (a);
- (b) any contraventions of the licence by a person covered by the licence, whether or not the licence holder has provided information to the Regulator under condition 29 (b);
- (c) any unintended effects of the dealings authorised by the licence, whether or not the licence holder has provided information to the Regulator under condition 29(c);
- (d) research, including by way of survey, to verify predictions of the risk assessment, or for any purpose related to risks to the health and safety of people, or to the environment;
- (e) scientific literature and reports in respect of the GMO authorised by this licence;
- (f) details of any refusals of applications for licences or permits (however described) to deal with the GMO made pursuant to the regulatory laws of a foreign country;

and the request is reasonable, having regard to consistency with the Act and relevance to its purpose, then the licence holder must collect the information and provide it to the Regulator at a time and in the manner requested by the Regulator.

Note: The Regulator may invite the licence holder to make a submission on the reasonability of a request by the Regulator to collect and provide information relevant the progress of the GMO.

Annual Report

32. The licence holder must provide an Annual Report to the Regulator. An Annual Report must include the following:

- (a) information about any adverse impacts, unintended effects, or new information relating to risks to human health and safety or the environment caused by the GMO or material from the GMO;

- (b) information about the volumes of the GMO grown for commercial purposes, including seed increase operations, in each State and Territory for each growing season in the period;
- (c) information about the volumes of the GMO grown for non-commercial (eg research) purposes in each State and Territory for each growing season in the period;
- (d) the total annual volume of GM cotton seed fed to livestock north of latitude 22° South in each State and Territory;
- (e) results from research on effects on non-target insect(s) (if conducted); and
- (f) results from research on Volunteer incidence in areas north of latitude 22° South after livestock feeding (if conducted).

Testing methodology

33. 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 GMO and the presence of the genetic modifications described in this licence (for details see Attachment B of the licence) in a recipient organism. The instrument must be provided within thirty days of the issuing of this licence.

ATTACHMENT A

DIR No: 091

Full Title: Commercial release of cotton genetically modified for insect resistance (WideStrike™ Insect Protection Cotton)

Organisation Details

Pioneer Hi-Bred Australia Pty Ltd

GMO Description

The GMO covered by this licence:

Gossypium hirsutum L. containing only the transformation events 281-24-236 and 3006-21-23¹. The GMO is known as WideStrike™ cotton. The OECD identifier for WideStrike™ cotton is DAS-21Ø23-5 x DAS-24236-5. The introduced genes, promoters and terminators listed below.

Parent Organism:

Common Name: Cotton

Scientific Names: *Gossypium hirsutum* L.

Modified traits:

Categories: Insect Resistance

Marker gene expression – herbicide tolerance

Description: Cotton plants have been genetically modified for insect resistance. The line contains one copy each of *cry1Ac(synpro)* and *cry1F(synpro)* and two copies and an additional fragment of the *pat* gene. The genetic modification has been detailed in the RARMP prepared for this licence.

Genes responsible for conferring the modified traits:

cry1Ac(synpro) synthetic *cry* gene

cry1F(synpro) synthetic *cry* gene

pat plant-optimised *pat* gene

Promoters and terminators

(4OCS)Δmas2' promoter from *Agrobacterium tumefaciens*

ORF 25 terminator from *A. tumefaciens*

Ubi promoter from *Zea mays*

Purpose of the dealings with the GMO:

Commercially release one genetically modified cotton line into the environment.

¹ GM cotton containing only the *cry1Ac(synpro)* or *cry1F(synpro)* gene in combination with the *pat* gene may occur.