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 216

Licence Holder: Bayer CropScience Pty Ltd

Commercial release of cotton genetically modified for insect resistance and herbicide tolerance (Bollgard® 3 ThryvOn® cotton with XtendFlex® Technology)

Issued: 7 October 2025

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 (GM) 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.

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 GM organisms into the Australian environment.

Other agencies that also regulate GM 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, Water and the Environment. Dealings conducted under any licence issued by the Regulator may also be subject to regulation by one or more of these agencies. It is recommended that the licence holder consult the relevant agency (or agencies) about their regulatory requirements.

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

Further information on licence DIR 216

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.

Section 1 Interpretations and Definitions

1. 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 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* (Cth) or the corresponding State legislation under which this licence is issued.

‘**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.

‘**Regulator**’ means the Gene Technology Regulator.

Section 2 Licence conditions and obligations

3. This licence does not authorise dealings with the GMO 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 GMO are authorised during any period of suspension.

5. The licence holder is Bayer CropScience Pty Ltd.

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

7. Except as restricted by condition 3, all dealings with the GMO are permitted.

8. Dealings with the GMO may be conducted in all areas of Australia.

9. This licence authorises dealings with the GMO described in **Attachment A**.

2.1 General obligations of the licence holder

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

Note: please address correspondence to OGTR.Applications@health.gov.au.

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

11. The licence holder must:

    (a) inform the Regulator as soon as practicable after any of these events occur:

        i. any relevant conviction of the licence holder; or

        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

        iii. any event or circumstances that would affect the capacity of the licence holder to meet the conditions of the licence; and

    (b) provide any information related to the licence holder's ongoing suitability to hold a licence, if requested by the Regulator, within the timeframe stipulated by the Regulator.

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); and

    (b) the cancellation or suspension of the licence; and

    (c) the surrender of the licence.

2.2 Provision of new information to the Regulator

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

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

    (a) additional information as to any risks to the health and safety of people, or to the environment, associated with the dealings authorised by the licence; or

    (b) any contraventions of the licence by a person covered by the licence; or

    (c) any unintended effects of the dealings authorised by the licence.

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

(a) *the licence holder will be taken to have become aware of additional information of a kind mentioned in condition 13 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 condition 13, if he or she was reckless as to whether such contraventions had occurred, or such unintended effects existed.*

Note: Contraventions of the licence may occur through the action or inaction of a person.

14. If the licence holder is required to inform the Regulator under condition 13, the Regulator must be informed without delay.

Note: An example of informing without delay is contact made within a day of becoming aware of new information via the OGTR free call phone number 1800 181 030 or email to OGTR.M&C@health.gov.au.

15. 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 13(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 13(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 13(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, for a nominated period;

(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 to the progress of the dealings with the GMO.

2.3 Obligations of persons covered by the licence

16. 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.

Section 3 Reporting and documentation

3.1 Annual Report

17. The licence holder must provide an annual report to the Regulator by the end of September each year covering the previous financial year. An annual report must include:

(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, in each State and Territory for each growing season in the period; and

(c) information about the volumes of the GMO grown for non-commercial (e.g. research) purposes in each State and Territory for each growing season in the period.

Note: nil plantings should also be reported under sub-conditions (b) and (c).

Note: Please address correspondence to OGTR.M&C@health.gov.au.

ATTACHMENT A

DIR No: 216

Full Title: Commercial release of cotton genetically modified for insect resistance and herbicide tolerance (Bollgard® 3 ThryvOn® cotton with XtendFlex® Technology)

Licence holder: Bayer CropScience Pty Ltd

GMO Description

GMO covered by this licence

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

Parent Organism

Common Name: Cotton

Scientific Name: *Gossypium hirsutum* L.

Modified traits

Category: Insect resistance

Herbicide tolerance

Selectable marker – Antibiotic resistance

Selectable marker – Reporter gene expression

Description: The GMO has been genetically modified by the introduction of genes involved in herbicide tolerance and insect resistance. The GMO also contains antibiotic resistance and reporter genes as selectable markers. The event names, introduced genes, and selectable markers are listed in Table 1. The GMO proposed for release will also contain short regulatory elements (Table 2).

Table 1 Introduced genes in the GMO

GM event	Gene	Source	Protein function
MON-887Ø2-4	*mCry51Aa2*	*Bacillus thuringiensis*	hemipteran and thysanopteran insect resistance
MON-15985-7	*cry1Ac*	*B. thuringiensis*	lepidopteran insect resistance
	cry2Ab	*B. thuringiensis*	lepidopteran insect resistance
	aad	*Escherichia coli*	selectable marker – antibiotic resistance (streptomycin)
	nptII	*E. coli*	selectable marker – antibiotic resistance (kanamycin)
	uidA	*E. coli*	selectable marker – reporter
SYN-IR1Ø2-7	*vip3Aa19*	*B. thuringiensis*	lepidopteran insect resistance
	aph4	*E. coli*	selectable marker – antibiotic resistance (hygromycin)
MON-88913-8	*cp4 epsps*	*Agrobacterium sp.* strain CP4	glyphosate herbicide tolerance

GM event	Gene	Source	Protein function
MON-887Ø1-3	*bar*	*Streptomyces hygroscopicus*	glufosinate herbicide tolerance
	dmo	*Stenotrophomonas maltophilia*	dicamba herbicide tolerance

Table 2 Introduced regulatory sequences in the GMO

GM event	Element function	Genetic element	Source organism
MON-887Ø2-4	Enhancer	*FMV*	*Figwort mosaic virus (FMV)*
	Promoter and 5' UTR leader sequence	*Hsp81-2*	*Arabidopsis thaliana*
	3' UTR	*35S*	*Cauliflower mosaic virus (CaMV)*
MON-15985-7	Promoter	*Tn7*	*Escherichia coli*
	Terminator	*7S 3'*	*Glycine max*
SYN-IR1Ø2-7	Promoter	*actin 2/ ubiquitin 3*	*A. thaliana*
	Additional element	*ubi3 intron*	*A. thaliana*
MON-88913-8	Promoter	*P-FMV*	*FMV*
	Promoter	*TSF2/ACT8*	*A. thaliana*
	Terminator	*Rbcs-E9*	*Pisum sativum – pea*
MON-887Ø1-3	Promoter	PC1SV	*Peanut chlorotic streak caulimovirus*
	Terminator	E6 3'	*Gossypium barbadense*
MON-15985-7; MON-88913-8; MON-887Ø1-3	Promoter	*35S*	*CaMV*
MON-15985-7; SYN-IR1Ø2-7	Terminator	*nos*	*Agrobacterium tumefaciens*
MON-15985-7; MON-887Ø1-3	Additional element	*PetHSP70*	*Petunia x hybrida*
MON-15985-7; MON-88913-8	Additional element	*Ctp2*	*A. thaliana*