

Australian Government

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

Licence for inadvertent dealings

Licence number: ID-08

Licence holder: Syngenta Australia Pty Ltd

Inadvertent dealings with genetically modified maize

Issued: 18 December 2024 Expiry: 17 December 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* (Commonwealth) and corresponding State and Territory legislation form part of a nationally consistent regulatory system controlling activities involving 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.

Section 40A of the Act provides that the Regulator may issue a licence to authorise dealings with a GMO that has come into the possession of a person inadvertently.

Sections 46A and 49 have the effect that the Regulator may expedite consideration of an application to dispose of a GMO that has come into a person's possession inadvertently, when they would otherwise require a licence for dealings not involving intentional release or for dealings involving intentional release.

Before issuing an inadvertent dealings licence, the Regulator is not required to prepare a risk assessment and risk management plan, or undertake the public consultation procedures, otherwise required for dealings involving the intentional release of a GMO into the environment.

This licence authorises the licence holder and persons covered by the licence to conduct specified dealings which are directed to the disposal of the GMOs listed in Attachment A of the licence.

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.

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 Gene Technology Regulations 2001;
 - (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 standard conditions to the extent of any inconsistency.
- 2. In this licence:

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

'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 and viable seed.

'Maize' means plants of the species Zea mays L. subspecies mays.

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

'Regulator' means the Gene Technology Regulator.

'Volunteers' means GM or non-GM Maize plants, which have not been intentionally grown.

Section 2 Licence 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.
- 4. 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.
- 5. This licence covers the period 18 December 2024 to 17 December 2025 unless cancelled or surrendered.
- 6. The licence holder is Syngenta Australia Pty Ltd.
- 7. The persons covered by the licence are any persons in possession or control of the GMOs.

2.1 Obligations of the Licence Holder

- 8. 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.

Note: For example, the licence holder must inform any employee instructed to destroy the GMOs of the permitted methods of disposal.

2.2 Provision of new information to the Regulator

- 9. 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.
- 10. If at any time the Regulator requests the licence holder to collect and provide information about any matter to do with the dealings authorised by this licence, including but not confined to steps taken by the licence holder to dispose of the GMOs, 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.

2.3 Obligations of persons covered by the licence

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

2.4 Dealings with GMOs permitted by the licence

- 12. The GMOs with which dealings are authorised by this licence are those listed at **Attachment A**.
- 13. The dealings authorised by the licence are:
 - (a) disposing of the GMOs;
 - (b) conducting experiments with the GMOs for purposes relating to disposing of the GMOs;
 - (c) growing the GMOs for purposes relating to disposing of the GMOs;
 - (d) transporting the GMOs for purposes relating to disposing of the GMOs; and
 - (e) possession or supply of the GMOs for purposes relating to disposing of the GMOs.

Note: an example of transporting the GMOs for purposes relating to disposal is taking GM seeds to a facility that has an incinerator.

- 14. Intentional planting of GM Maize seed is prohibited.
- 15. All GM Maize plants that are growing in fields when the licence is issued must be disposed of before the plants flower, by a method that prevents the plants from flowering, in accordance with condition 17.
- 16. All GM Maize seed must be disposed of as soon as practicable, in accordance with condition 17.

Note: This condition includes any GM Maize seed in the possession of farmers who planted the GM Maize in 2024. Any person in possession of the GMOs is a person covered by the licence (condition 7) and the licence holder is required to inform any person covered by the licence of their obligations under the licence (condition 8).

- 17. Disposal of the GMOs must be undertaken by one or a combination of the following methods:
 - mechanical removal of plants, such as uprooting, tilling, or root cutting and shredding/mulching;

- (b) treatment with herbicide, other than glyphosate or glufosinate, in a manner which kills Maize plants;
- (c) burning/incineration;
- (d) milling, crushing or grinding of seed; or
- (e) destructive analysis.
- 18. The licence holder must ensure that transport of the GMOs for purposes related to disposal follows these sub-conditions:
 - (a) the GMOs must be contained within sealed, unbreakable primary and secondary containers sufficient to prevent any GMOs from escaping, with the outer packaging labelled to indicate at least:
 - i. that it contains GMOs;
 - ii. the contact details for the licence holder; and
 - iii. instructions to notify the licence holder in case of a loss or spill of the GMOs; and instructions on how to clean up a spill; and
 - (b) any container used must be visually inspected and all GMOs removed before use of the container for any other purpose; and
 - (c) access to the GMOs must be restricted to authorised persons; and
 - (d) procedures must be in place to ensure that GMOs can be accounted for and that a loss of GMOs during transport or failure to be delivered can be detected.
- 19. The dealings with the GMOs authorised in condition 13 may be conducted in all areas of Australia.

2.5 Inspection and reporting requirements

20. Areas of land where the GM Maize was planted in 2024 must be inspected by experienced people able to recognise Maize. Actions must be taken as follows:

Area	Period of inspection	Inspection frequency	Inspect for	Action
Areas of land where the GM Maize was planted and grown, and other areas where GM Maize seed may have been dispersed during planting or harvesting	 From the day of: a) Issue of the licence, for any areas that were harvested prior to issue of the licence, or b) Disposal of the GM Maize crop in accordance with Condition 15 Until 30 November 2025 	At least once every 35 days	Volunteers	Dispose of before flowering

Note: details of any inspection activity must be recorded in a Logbook (Condition 24) and reported to the Regulator (Condition 23) by the licence holder.

- 21. Areas of land where the GM Maize was planted in 2024 must not be replanted with Maize before 30 November 2025.
- 22. Areas of land where the GM Maize was planted in 2024 must not be used for grazing livestock before 30 November 2025.
- 23. The licence holder must send notifications 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. People covered by the licence	 Name, position title and contact details for the contact person for the licence holder who will be responsible for managing all activities required by this licence Detail of how the persons covered by the 	As soon as practicable after issue of the licence
	licence will be informed of licence conditions	
b. Changes to contact details	Changes to any of the details for the contact person for the licence holder	As soon as practicable after any changes occur
c. Location of properties	Locations and sizes of all areas of land where the GMOs were planted in 2024	As soon as practicable after issue of the licence
covered by this licence	Note: Examples of suitable location information would be GPS coordinates, or local government area and street address	
d. Notification of disposal of a GM Maize	 Date of disposal of a GM Maize crop in accordance with Condition 15 Location of disposal 	Within 7 days after disposing of the GMOs
crop	iii. Method used for disposal	
e. Inspection activities	Information recorded in a Logbook in accordance with Condition 24.	Within 35 days of inspection

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

- (a) location of the inspections; and
- (b) date of the inspections; and
- (c) current land use of the area inspected including any crops planted after harvest or disposal of the GM Maize; and
- (d) if Volunteers are found:
 - i. number of Maize plants found during inspections; and
 - ii. developmental stage of the Maize plants found during inspections; and
 - iii. date and method of disposal of the Maize plants found during inspections.

Note: Details of inspection activities must be provided to the Regulator (Condition 23).

Licence for Inadvertent Dealings

Full Title: Inadvertent dealings with genetically modified maize

Organisation Details

Postal address:	Syngenta Australia Pty Ltd
	Level 1, 2-4 Lyonpark Road
	Macquarie Park
	NSW 2113

GMO Description

GMOs covered by this licence

Maize seeds or plants containing the introduced regulatory elements below.

Parent Organism

Common Name:	Maize
Scientific Name:	Zea mays L. subspecies mays

Modified traits

Category: Unknown

Regulatory elements present in the GM maize

Element	Function	Source
355	Promoter	Cauliflower mosaic virus
nos	Terminator	Agrobacterium tumefaciens