

# Licence for inadvertent dealings

**Licence No.: ID-07** 

Licence holder: P Brodie Holdings Pty Ltd t/a PB Agrifood

Inadvertent dealings with genetically modified soybean

Issued: 4 April 2023

## 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 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 Gene Technology 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 dealings involving intentional release, respectively.

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

The licence authorises the licence holder and persons covered by the licence to conduct specified dealings which are directed to the disposal of the GMO listed in Attachment A 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. 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* (Cth) or the corresponding State legislation under which this licence is issued.

'GM' means genetically modified.

**'GMOs'** means the genetically modified Soybeans that are the subject of the dealings authorised by this licence. This definition includes all pbAMAXX Soybeans and seeds. The terms 'GMO' and 'pbAMAXX Soybeans' are used interchangeably throughout this licence.

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

'Regulator' means the Gene Technology Regulator.

'Soybean' means plants of the species Glycine max.

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

## **Section 2** Licence conditions and obligations

- 3. 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.
- 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 4 April 2023 to 3 April 2024 unless cancelled or surrendered.
- 6. The holder of this licence ('the licence holder') is P Brodie Holdings Pty Ltd t/a PB Agrifoods.
- 7. The licence holder must as soon as practicable notify the Regulator via OGTR.M&C@health.gov.au if their contact details change.
- 8. Persons covered by the licence are any persons in possession or control of the GMOs.

#### 2.1 Obligations of the Licence Holder

- 9. 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

The following condition requires that any new information that may affect the risks (if any) posed by the dealings to the health and safety of people and the environment, is communicated to the Regulator.

- 10. 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.
- 11. 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

12. 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

- 13. The GMOs covered by this licence are described in Attachment A of the licence.
- 14. The dealings permitted 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: growing the GMOs does not include deliberate planting, but refers to any GMOs growing as volunteers after harvest of previous crops.

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

- 15. It is prohibited to plant and grow Soybeans on areas where pbAMAXX Soybeans were grown in the previous two growing seasons.
- 16. Intentional planting and growing the GMOs is prohibited.
- 17. The licence holder must inform all growers of pbAMAXX Soybeans that:
  - (a) any seed from pbAMAXX Soybeans in the previous two growing seasons may be a GMO;
  - (b) in accordance with condition 9 of this licence any persons in possession or control of the GMOs are persons covered by the licence; and

- (c) seed retained from pbAMAXX Soybeans must be returned to PB Agrifood for destruction.
- 18. Planting seed saved from Soybean crops grown in fields in which pbAMAXX was cultivated the previous two years is prohibited unless it is verified that the seed is not GM.

Note: crops established using saved seed prior to issuing of this licence may continue to be cultivated but seed must not be saved for later sowing.

- 19. All pbAMAXX Soybean must be disposed of as soon as practicable, in accordance with condition 20.
- 20. Methods permitted for disposal of the GMOs are:
  - (a) mechanical removal, such as uprooting, root cutting, shredding, mulching or tilling;
  - (b) application of herbicide other than glyphosate, sulfonylurea-based herbicides;
  - (c) burning or incineration in accordance with all federal, state and local laws, ordinances and permits;
  - (d) milling, crushing or grinding of seed; or
  - (e) destructive analysis.
- 21. The licence holder must ensure that transport of the GMOs for the purpose of disposal follows these sub-conditions:
  - (a) only occur to the extent necessary to conduct the dealings permitted by this licence; and
  - (b) be contained within sealed, unbreakable primary and secondary containers sufficient to prevent any GM material 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
  - (c) any containers used must be visually inspected and all GMOs removed before use of the container for any other purpose; and
  - (d) access to the GMOs must be restricted to authorised persons (i.e. the GMOs are within a locked vehicle or unit, or an area which has restricted access). This includes situations where containers are left for collection in a loading area, or left unattended prior to decontamination; and
  - (e) 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; and
  - (f) where transport takes place entirely within a building and the GMOs are accompanied by authorised persons for whom condition 9 has been met, conditions 21(b)iii. and 21(e) do not apply.
- 22. The dealings with the GMOs authorised in condition 14 may be conducted in all areas of Australia.

#### 2.5 Inspection and reporting requirements

23. Areas of land where pbAMAXX Soybean was grown in the 2020/21 or 2021/22 growing seasons must be inspected by experienced people able to recognise Soybean. Actions must be taken as follows:

Area	Period of inspection	Inspection frequency	Inspect for	Action
Areas on which pbAMAXX Soybean was grown, and other areas of land where the GMO may have been dispersed	From the day of licence issue until the end of this licence or 2 years after harvest, whichever is sooner	At least once every 6 weeks	Volunteers	Destroy before seed set or as soon as practical

Note: details of any inspection activity must be recorded in a Logbook (Condition 25) and reported to the Regulator (Condition 24) by the licence holder.

Note: areas of land where the GMO may have been dispersed includes land where seed may have been dispersed outside the growing area of the crop, such as during harvesting or bagging of seed.

24. The licence holder must send notifications to the Regulator as follows:

Note: please send all correspondence related to the licence to <u>OGTR.M&C@health.gov.au</u>.

Notice	Content of notice	Timeframe
a. Changes to contact details	Changes to any of the details for the organisation contact person	As soon as practicable
b. People covered by the licence	<ul> <li>i. Name and position title for the contact person for the licence holder who will be responsible for managing all activities required by this licence, with a description of their responsibilities; and</li> <li>Note: Examples of functions or positions are</li> </ul>	As soon as practicable
	'grower liaison' etc.  ii. detail of how the persons covered by the licence will be informed of licence conditions.	
c. Location of properties covered by this licence	Locations of all sites where the GMOs have been planted in growing seasons 2020/21 and 2021/22 and other areas of land where the GMO may have been dispersed.	Within 35 days of issue of this licence
	Note: Examples of suitable location information would be GPS coordinates, or local government area and street address for the areas planted with pbAMAXX in those seasons.	
d. Inspection	Information related to inspection activities:	Within 35 days of inspection
activities	i. location of inspection; and	
	ii. date of inspection; and	
	iii. whether Soybean any volunteers were found; and	
	iv. if volunteers were found, confirmation of destruction.	
	Other information related to inspection activities as outlined in Condition 23 or recorded in the Logbook (Condition 25).	If requested by the Regulator.

- 25. 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) details of areas inspected including current land use and details of any crops planted after harvest of pbAMAXX Soybeans; and
  - (d) if Soybeans are found:
    - i. details of the number of Soybean plants found during inspections and, if tested for genetic modifications, the results of these tests; and
    - ii. whether the Soybean plants found during inspections had set seed; and
    - iii. confirmation of Destruction of any Soybean plants found during inspections, including destruction of Soybean plants during land-management activities.

Note: Details of inspection activities must be provided to the Regulator (Condition 24).

## **Licence for Inadvertent Dealings**

Full Title: Inadvertent dealings with genetically modified Soybean

## **Organisation Details**

Postal address: P Brodie Holdings Pty Ltd t/a PB Agrifood

PO Box 9169 Wilsonton Qld 4350

## **GMO Description**

## **GMOs** covered by this licence

Glycine max seeds or plants containing the identified introduced regulatory elements.

## **Parent Organism**

Common Name: Soy, Soybean Scientific Name: Glycine max

## **Modified traits**

Category: Regulatory elements

## Regulatory elements responsible for conferring the modified traits:

Element	Function	Source
FMV	Promoter	Figwort mosaic virus

## Purpose of the dealings with the GMO

The purpose of the dealings is to enable disposal of the GMO.