



Australian Government

Department of Health

Office of the Gene Technology Regulator

Licence for inadvertent dealings

Licence No.: ID06

Licence holder: PGG Wrightson Seeds (Australia) Pty Ltd.

Inadvertent dealings with genetically modified alfalfa

Issued: 21 July 2021

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;
- (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.

2. In this licence:

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

'Alfalfa' means plants of the species *Medicago sativa*.

'GM' means genetically modified.

'GMOs' means the genetically modified organisms that are the subject of the dealings authorised by this licence.

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 21 July 2021 to 20 July 2022 unless cancelled or surrendered.
- 6. The holder of this licence ('the licence holder') is PGG Wrightson Seeds (Australia) Pty Ltd.
- 7. The licence holder must immediately 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.
- 9. The dealings permitted by the licence are:
 - (a) disposing of the GMOs;
 - (b) transporting the GMOs for purposes relating to disposing of the GMOs; and

- (c) 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.

10. Methods permitted for disposal of the GMOs are:

- (a) incineration;
- (b) autoclaving;
- (c) boiling in water for at least 20 minutes;
- (d) heating, for instance in an oven, to a temperature of at least 180°C for at least 30 minutes; or
- (e) microwaving at a power of at least 850W for at least 10 minutes.

11. Transport of the GMOs for the purpose of disposal must:

- (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 decontaminated prior to and after any transport if necessary, visual inspection may be used to determine whether decontamination is necessary; 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) GMOs must be accounted for during transport such that a spill or loss can be identified; and
- (f) 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
- (g) where transport takes place entirely within a building and the GMOs are accompanied by authorised persons for whom condition 14 has been met, conditions 11(b)iii. and 11(f) do not apply.

12. The dealings with the GMOs authorised in condition 9 may be conducted in all areas of Australia.

13. The GMOs covered by this licence are described in Attachment A of the licence.

2.1 Obligations of the Licence Holder

14. 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.

15. 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.
16. 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 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

17. 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.

Licence for Inadvertent Dealings**Full Title:** Inadvertent dealings with genetically modified alfalfa**Organisation Details**

Postal address: PGG Wrightson Seeds
 4 Black Swamp Road
 Leigh Creek
 VIC 3352

Phone number: (03) 5334 7871

GMO Description**GMOs covered by this licence**

Medicago sativa seeds containing one or more identified introduced regulatory elements.

Parent Organism

Common Name: alfalfa, lucerne

Scientific Name: *Medicago sativa*

Modified traits

Category: Regulatory elements

Regulatory elements responsible for conferring the modified traits:

Element	Function	Source
35S	Promoter	Cauliflower mosaic virus
FMV	Promoter	Figwort mosaic virus

Purpose of the dealings with the GMO

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