



Australian Government

Department of Health

Office of the Gene Technology Regulator

Licence for inadvertent dealings

Licence Number:

Licence holder:

**Inadvertent dealings with petunia genetically modified for altered
flower colour**

Issue date

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. The Act says:

40A Licences relating to inadvertent dealings

(1) If the Regulator is satisfied that a person has come into possession of a GMO inadvertently the Regulator may, with the agreement of the person, treat the person as having made an inadvertent dealings application.

(2) To avoid doubt, subsection (1) does not prevent a person from making an application under section 40 in respect of a GMO that has inadvertently come into the person's possession.

Section 49 has 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. The Act says:

49 Division does not apply to an application relating to inadvertent dealings

Despite section 48, this Division does not apply to an application for a GMO licence if the Regulator is satisfied that:

- (a) the dealings proposed to be authorised by the licence are limited to one or more of the following for purposes relating to disposing of a GMO:
 - (i) conducting experiments with the GMO;
 - (ii) propagating the GMO;
 - (iii) growing, raising or culturing the GMO;
 - (iv) transporting the GMO;
 - (v) any other dealings to be undertaken for the purposes of, or for purposes relating to, disposing of the GMO; and
- (b) the applicant for the licence came into possession of the GMO inadvertently.

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.

'GM' means genetically modified.

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

'Petunia' means plants of the species *Petunia hybrida*.

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 covers the period specified unless cancelled or surrendered.
5. The holder of this licence ('the licence holder') is specified in each licence.
6. The licence holder must immediately notify the Regulator via OGTR.M&C@health.gov.au if their contact details change.
7. Persons covered by the licence are any persons in possession or control of the GMOs.
8. 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: An example of conducting experiments with the GMOs for purposes relating to disposal is testing suspected GMOs to determine whether they are GMOs and need to be destroyed. An example of growing the GMOs for purposes relating to disposal is watering GM plants prior to applying herbicide, if the herbicide is not effective on water-stressed plants. An example of transporting the GMOs for purposes relating to disposal is taking GM seeds to a facility which has an incinerator.

9. Methods permitted for disposal of the GMOs are:
 - (a) in the case of live GM plants any method of disposal including:
 - (i) application of a herbicide that is effective in killing Petunia plants;
 - (ii) uprooting;
 - (iii) desiccation;
 - (iv) incineration;
 - (v) any method expected by a person growing Petunia to kill Petunia plants;
 - (b) in the case of viable GM seeds:
 - (i) incineration;
 - (ii) autoclaving;
 - (iii) boiling in water for at least 20 minutes;
 - (iv) heating, for instance in an oven, to a temperature of at least 150°C for at least 30 minutes;
 - (v) microwaving at a power of at least 800W for at least 10 minutes;
 - (vi) deep burial at biosecurity waste class 8.2 site approved by the Department of Agriculture and Water Resources.
10. Dealings with the GMOs may be conducted in all areas of Australia.
11. The GMOs covered by this licence are described in Attachment A of the licence.

2.1 Obligations of the Licence Holder

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.

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.

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.
14. 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

15. 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 petunia genetically modified for altered flower colour

Organisation Details

Postal address:

Phone number:

GMO Description**GMOs covered by this licence**

Petunia hybrida cultivar 'African Sunset' and any other petunia cultivar containing the same introduced genetic modifications.

Parent Organism

Common Name: Petunia

Scientific Name: *Petunia hybrida*

Modified traits

Category: Altered flower colour

Antibiotic resistance

Genes responsible for conferring the modified traits:

Gene	Encoded protein	Function	Source
<i>A1</i>	Dihydroflavonol 4-reductase	Altered flower colour	<i>Zea mays</i>
<i>nptII</i>	Neomycin phosphotransferase II	Antibiotic resistance marker gene	<i>Escherichia coli</i>

Purpose of the dealings with the GMO

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