



**Australian Government**

**Department of Health**

Office of the Gene Technology Regulator

# **Licence for dealings involving an intentional release of a GMO into the environment**

**Licence No.: DIR 121**

**Licence holder: The Commonwealth Scientific and Industrial Research Organisation**

**Title: Limited and controlled release of safflower genetically modified for increased levels of oleic acid**

Issued: 22 July 2013

Varied: 19 August 2013

Varied: 9 April 2014

**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 website at <http://www.ogtr.gov.au>, or by telephoning the Office on 1800 181 030.**

## **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.

The Gene Technology 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 GMOs into the Australian environment.

Other agencies that also regulate GMOs or GM products include Food Standards Australia New Zealand, Australian Pesticides and Veterinary Medicines Authority, Therapeutic Goods Administration, National Industrial Chemicals Notification and Assessment Scheme, National Health and Medical Research Council and the Department of Agriculture, Fisheries and Forestry Biosecurity. 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.

The licence authorises the licence holder and persons covered by the licence to conduct specified dealings with the genetically modified organism(s) 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.

### **Note about where dealings with GMOs are being undertaken pursuant to this licence**

Information about where the GMOs have been planted pursuant to this licence can be accessed on the OGTR website at <http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/dir121>

## **Section 1 Interpretations and Definitions**

1. In this licence:

- (a) unless defined otherwise, words and phrases used have the same meaning as they do in the Act and the Gene Technology Regulations 2001;
- (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* (Commonwealth) or the corresponding State legislation under which this licence is issued.

**‘Clean’** (or **‘Cleaned’**) means, as the case requires:

- (a) in relation to an area specified in this licence as requiring Cleaning, the Destruction of the GMOs and Plant Material in that area, to the reasonable satisfaction of the Regulator; or
- (b) in relation to Equipment, the removal and Destruction of the GMOs and Plant Material from the Equipment, to the reasonable satisfaction of the Regulator.

**‘Contingency Plan’** means a written plan detailing measures to be taken in the event of the unintended presence of the GMOs or Plant Material outside an area that must be inspected. A Contingency Plan must include procedures to:

- (a) ensure the Regulator is notified immediately if the licence holder becomes aware of the event; and
- (b) recover and Destroy any of the GMOs or Plant Material; and
- (c) inspect for and Destroy any Volunteers that may exist as a result of the event.

**‘Destroy’** (or **‘Destroyed’** or **‘Destruction’**) means, as the case requires, killed by one or more of the following methods:

- (a) uprooting;
- (b) Tilling, but only subject to the conditions of this licence;
- (c) treatment with herbicide;
- (d) burning/incineration;
- (e) autoclaving;
- (f) deep burial to a depth greater than 1 m;

*Note: any areas where viable seeds are Destroyed by burial are subject to Cleaning requirements under Condition 40 and inspection requirements under Condition 46.*

- (g) crushing or grinding of seed;
- (h) heat treatment that renders seed non-viable;
- (i) gamma irradiation that renders seed non-viable; or
- (j) a method approved in writing by the Regulator.

*Note: 'As the case requires' has the effect that, depending on the circumstances, one or more of these techniques may not be appropriate. For example, in the case of plants with mature seed heads still attached, tilling would not be appropriate due to the possible introduction of large numbers of viable seeds into the seedbank.*

**'Equipment'** includes, but is not limited to, seeders, plot harvesters, threshers, storage equipment, transport equipment (e.g. bags, containers, trucks), clothing and tools.

**'Exclusion Zone'** means an area of land extending outwards at least 400 m in all directions from the outer edge of the Isolation Zone (see Figure 1).

**'Flowering'** is taken to begin when any plant of the class of plants referred to in a particular condition first flowers, and is taken to end when all plants in the class of plants no longer have flowers.

**'GM'** means genetically modified.

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

**'Isolation Zone'** means an area of land extending outwards at least 190 m in all directions from the outer edge of the Monitoring Zone (see Figure 1).

**'Logbook'** means a written or electronic record containing information required to be collected and maintained by this licence and which is able to be presented to the OGTR on request.

**'Monitoring Zone'** means an area of land extending outwards at least 10 m in all directions from the outer edge of the Planting Area (see Figure 1).

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

**'Personal Information'** means information or an opinion (including information forming part of a database), whether true or not, and whether recorded in a material form or not, about an individual whose identity is apparent, or can reasonably be ascertained, from the information or opinion.

**'Planting Area'** means an area of land where GM and non-GM Safflower plants are intentionally planted and grown pursuant to this licence.

**'Plant Material'** means any part of the GM or non-GM Safflower plants grown in a Planting Area, whether viable or not, including but not limited to seed, stubble and pollen, whether from the plant itself or derived from or produced by the plant.

**'Regulator'** means the Gene Technology Regulator.

**'Related Species'** means plants from the genus *Carthamus* except for plants of the species *Carthamus tinctorius* L.

**'Safflower'** means plants of the species *Carthamus tinctorius* L.

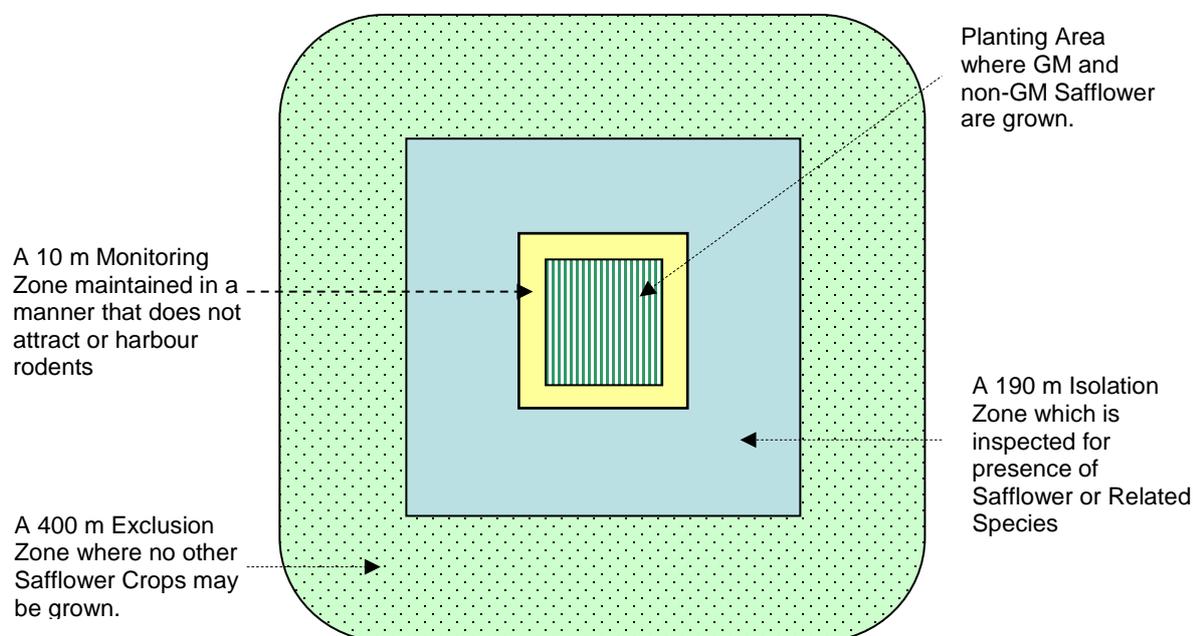
**'Safflower Crop'** means Safflower plants that are intentionally planted and grown for commercial, breeding or experimental purposes.

**‘Sign-off’** means a notice in writing from the Regulator, in respect of an area, that post-harvest obligations no longer apply in respect of that area.

**‘Tillage’** (or **‘Tilled’** or **‘Tilling’**) means the use of any technique to disturb the soil.

**‘Volunteers’** means GM or non-GM Safflower plants, which have not been intentionally grown.

**‘Waterways’** means all permanent natural waterways and man-made waterways that flow into natural waterways.



**Figure 1.** Diagram showing the relationship between a Planting Area, Monitoring Zone, Isolation Zone and Exclusion Zone (not drawn to scale).

## **Section 2 General 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 remains in force until it is suspended, cancelled or surrendered. No dealings with GMOs are authorised during any period of suspension.
5. The holder of this licence ('the licence holder') is the Commonwealth Scientific and Industrial Research Organisation (CSIRO).
6. The persons covered by this licence are the licence holder and employees, agents or contractors of the licence holder and other persons who are, or have been, engaged or otherwise authorised by the licence holder to undertake any activity in connection with the dealings authorised by this licence.
7. The only permitted dealings authorised by this licence are to conduct experiments with the GMOs, breed, propagate, grow, culture, transport and dispose of the GMOs, and the possession, supply and use of the GMOs in the course of any of these dealings.

### ***Obligations of the Licence Holder***

8. The licence holder must notify the Regulator as soon as practically possible if any of the contact details of the project supervisor change.

*Note: please address correspondence to the Director, Monitoring Section of the OGTR.*

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

9. The licence holder must, at all times, remain an accredited organisation in accordance with the Act and must comply with its instrument of accreditation.

10. The licence holder must:

(a) inform the Regulator immediately in writing, of:

- i. any relevant conviction of the licence holder occurring after the commencement of this licence; and
- 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; and
- iii. any event or circumstances occurring after the commencement of this licence that would affect the capacity of the holder of this licence to meet the conditions in it; and

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

11. The licence holder must be able to access all Exclusion Zones, and to access and control all Planting Areas, Monitoring Zones, Isolation Zones and approved facilities to the extent necessary to comply with this licence, for the duration of the life of the licence.

*Note: The purpose of access to an Exclusion Zone is to ensure that a Safflower Crop is not being grown (Conditions 30 and 31). If the licence holder has sufficient access to determine that part of an Exclusion Zone is occupied by a land use where a Safflower Crop would not be present (e.g. a lake or urban residential housing), the licence holder is not required to further enter and inspect this land use.*

*The following conditions seek to ensure that persons conducting the dealings are aware of the licence conditions and appropriate processes are in place to inform people of their obligations.*

12. Prior to conducting any dealings with the GMOs, the licence holder must provide to the Regulator:

(a) names of all organisations and persons or functions or positions of the persons who will be covered by the licence, with a description of their responsibilities; and

*Note: Examples of functions or positions are 'Site manager', 'Farm labourer' etc.*

(b) detail of how the persons covered by the licence will be informed of licence conditions; and

(c) detail of how the licence holder will access all Exclusion Zones, and access and control all Planting Areas, Monitoring Zones, Isolation Zones and approved facilities for the duration of the licence; and

*Note: this may include a description of any contracts, agreements, or other enforceable arrangements.*

- (d) written methodology to reliably detect the GMOs, the genetic modifications and distinguish between categories of GMOs approved for release (if relevant); and
- (e) Contingency Plan to respond to inadvertent presence of the GMOs outside an area that must be inspected.

13. Any changes to the information provided under the immediately preceding condition must be communicated in writing to the Regulator within 14 days of the changes occurring.

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.

15. The licence holder must not permit a person covered by this licence to conduct any dealing unless:

- (a) the person has been informed of any applicable licence conditions, including any variation of them; and
- (b) the licence holder has obtained from the person a signed and dated statement that the person:
  - i. has been informed by the licence holder of the licence conditions, including any variation of them; and
  - ii. has understood and agreed to be bound by the licence conditions, or variation.

16. The licence holder must:

- (a) inform the persons covered by this licence that any Personal Information relevant to the administration and/or enforcement of the licence may be released to the Regulator; and
- (b) provide the Regulator, if requested, with copies of the signed and dated statements referred to in the immediately preceding condition.

### ***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.*

17. 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 paragraph 17(a) 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 paragraph 17(b) 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. For example if it is a condition of the licence that volunteers are destroyed prior to flowering and a volunteer does flower, then the person responsible for controlling volunteers will have contravened that licence condition.*

18. If the licence holder is required to inform the Regulator under the immediately preceding condition, the Regulator must be informed without delay.

*Note: An example of informing without delay is contact made at the time of the incident via the OGTR free call phone number 1800 181 030, which provides emergency numbers for incidents that occur out of business hours. Notification without delay will allow the OGTR to conduct a risk assessment on the incident and attend the location if required.*

19. If the licence holder informs the Regulator under the immediately preceding condition and the Regulator requests further information, the further information must be provided in a manner, and within the time period, stipulated by the Regulator.

### ***Obligations of persons covered by the licence***

20. Persons covered by this licence must not deal with the GMOs except as expressly permitted by this licence.

21. 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.

## **Section 3 Limits and control measures**

### ***Limits on the release***

*The following licence conditions maintain the risk assessment context within which the application was assessed, by imposing limits on where and when the GMOs may be grown, and on other activities that can be undertaken.*

22. While GMOs are being grown, the only plants that may be intentionally grown in a Planting Area are:

- (a) the GMOs covered by this licence as described in Attachment A of the licence; and
- (b) non-GM Safflower plants.

23. Planting and growing of the GMOs may only occur within the following limits:

Local government area	Maximum number of active Planting Areas	Maximum size of Planting Areas	Duration
Australian Capital Territory	1	1 ha	September 2013 – March 2016, inclusive
Narrabri Shire, NSW	1	1 ha	June 2014 – March 2016, inclusive
Wagga Wagga, NSW	1	1 ha	June 2014 – March 2016, inclusive
Wyndham-East Kimberley, WA	1	1 ha	March 2014 – March 2016, inclusive

*Note: An active Planting Area is an area where GMOs are being intentionally grown, excluding post-harvest or post-Destruction Planting Areas. In the event of crop failure, the GMOs in a Planting Area may be Destroyed, then GMOs may be replanted in the same or a new Planting Area in the same LGA in that season.*

23A. The cumulative area of Planting Areas throughout the period of the licence must not exceed 7 ha.

24. Plant Material must not be used, sold or otherwise disposed of for any purpose which would involve or result in its use as food for humans or feed for animals.

25. If experimentation or analysis with the Plant Material is not conducted in accordance with notifiable low risk dealing (NLRD) requirements, experimentation or analysis with the Plant Material may only be undertaken within:

- (a) a Planting Area or Monitoring Zone prior to post-harvest Cleaning; or
- (b) the CSIRO Animal, Food and Health Sciences Werribee facility (non-viable Plant Material only); or
- (c) a facility approved in writing by the Regulator.

*Note: Dealings conducted in accordance with NLRD requirements must be assessed by an institutional biosafety committee (IBC) before commencement and must comply with the requirements of the Gene Technology Regulations 2001.*

### **Containment measures**

*The following licence conditions restrict spread and persistence of the GMOs or Plant Materials from the GMOs beyond the limits imposed on the trial and during other activities.*

### **Pollen and seed dispersal during cultivation**

26. The outer edge of a Planting Area must be at least 50 m away from Waterways.

27. A Planting Area must be surrounded by a Monitoring Zone.

28. A Monitoring Zone must be surrounded by an Isolation Zone.

29. An Isolation Zone must be surrounded by an Exclusion Zone.
30. The GMOs must not be planted in a Planting Area if:
- (a) any Safflower Crop is present in the Monitoring, Isolation or Exclusion Zones; or
  - (b) any Safflower Crop, other than plants grown pursuant to this licence, was planted in the Monitoring, Isolation or Exclusion Zones in the previous Safflower growing season.
31. While the GMOs are growing in a Planting Area, associated areas must be inspected by people trained to recognize Safflower and Related Species plants, and actions taken, as follows:

Area	Period of inspection	Inspection frequency	Inspect for	Action
Monitoring Zone	<b>From</b> 14 days prior to the expected commencement of Flowering of any GMOs* <b>until</b> the Planting Area and Monitoring Zone are Cleaned	At least once every 14 days	Volunteers and Related Species	Destroy before Flowering or prevent from Flowering
Isolation Zone	<b>From</b> 14 days prior to the expected commencement of Flowering of any GMOs* <b>until</b> all GMOs in the Planting Area have finished Flowering	At least once every 14 days	Volunteers and Related Species	Destroy before Flowering or prevent from Flowering
Exclusion Zone	<b>From</b> 14 days prior to the expected commencement of Flowering of any GMOs* <b>until</b> all GMOs in the Planting Area have finished Flowering	At least once every 35 days	Any Safflower Crop	Destroy before Flowering or prevent from Flowering; or Destroy the GMOs before Flowering

*\*Condition 51(a) requires the licence holder to provide information to the Regulator on the expected flowering period, however the inspection period should be based on the observed development of the GMOs, so that inspections commence prior to flowering of any GMOs.*

*Note: Details of any inspection activity must be recorded in a Logbook as detailed in Condition 47.*

32. The Monitoring Zone must be maintained in a manner that does not attract or harbour rodents while the GMOs are being grown at a Planting Area and until the Planting Area and Monitoring Zone are Cleaned.

*Note: Measures to achieve this could include areas of land free of any vegetation and/or vegetation kept mown to a height of less than 10 centimetres.*

33. Measures must be implemented to control rodents within the Planting Area while GMOs are being grown and until the Planting Area is Cleaned. Measures may include, but are not limited to, traps and/or poison bait within and/or surrounding the Planting Area.

34. During the period from 14 days after commencement of Flowering of the GMOs until the Planting Area is Cleaned, the Planting Area must be either:

- (a) covered with bird netting , which must be maintained in a state adequate to deter birds;
- or

- (b) equipped with bird scarers that are expected to deter the main seed-eating bird species present in the vicinity of the Planting Area.

34A. In the case of a Planting Area located in the shire of Wyndham-East Kimberley, the Planting Area must be surrounded by a strip of sorghum plants within the Isolation Zone. The strip of sorghum plants must be at least 10 m wide, and must bear seed over the same period as the Safflower in the Planting Area.

*Note: The purpose of the sorghum plants is to decoy birds away from the GM Safflower. Details of any inspection activity must be recorded in a Log book as detailed in Condition 47.*

35. Non-GM Safflower plants grown in a Planting Area must be handled as if they were the GMOs.

36. Plant Material must be harvested separately from any other crop.

37. If Plant Material from a Planting Area is harvested, it must be harvested by hand, a mechanical single-row harvester, or a small plot harvester.

*Note: For the purpose of this licence, harvested by hand refers to the cutting of plant stems using an implement such as a hand sickle or secateurs.*

38. If GMOs are Destroyed, they are taken to have been harvested for the purposes of this licence and all conditions applying to post-harvest apply equally to post-Destruction.

39. If seed harvested from the GMOs or Plant Material is threshed, it must be threshed separately from any other crop, and threshing must take place on a Planting Area or in a facility approved in writing by the Regulator.

*Note: Threshing may also be conducted in a certified facility as an NLRD, in accordance with all applicable requirements of the Gene Technology Regulations 2001.*

40. Areas of land used in connection with the GMOs must be Cleaned as follows:

Areas to be Cleaned	When	How
(a) Planting Area and Monitoring Zone	Within 14 days after harvest of the GMOs	Tillage that buries residual seed
(b) any area where Plant Material has dispersed during planting, growing or harvesting	As soon as practicable and before use for any other purpose	Any appropriate method of Destruction
(c) any area used to Clean any equipment used in connection with the GMOs		
(d) any area used to Destroy any Plant Material		
(e) any area of land used to store or experiment with Plant Material		

*Note: Areas of land that have been Cleaned, or from which the GMOs have been harvested, are also subject to inspections (Condition 46), and Cleaning activities must be recorded and provided to the Regulator (Condition 51(d)).*

41. Any Equipment used in connection with the GMOs grown in a Planting Area must be Cleaned within the Planting Area, Monitoring Zone or Isolation Zone, as soon as practicable and before use for any other purpose.

*Note: If Equipment is Cleaned in an area within an Isolation Zone, the area requires Cleaning under Condition 40 and inspections under Condition 46.*

42. Any extreme weather event that is expected to affect or has already affected a Planting Area or Monitoring Zone, while the GMOs are growing or while the Planting Area or Monitoring Zone is subject to inspection requirements, must be notified in writing to the Regulator as soon as practically and reasonably possible.

*Note: The Contingency Plan must be implemented if the GMOs are detected outside areas under inspection (Condition 49).*

### **Dispersal of the GMOs during transport or storage**

43. If transport or storage is not conducted in accordance with NLRD requirements, it must be conducted in accordance with conditions 44 and 45.

*Note: Dealings conducted in accordance with NLRD requirements must be assessed by an IBC before commencement and must comply with the requirements of the Gene Technology Regulations 2001.*

44. Transport and storage of Plant Material outside the Planting Area or Monitoring Zone must:

- (a) only occur to the extent necessary to conduct the dealings permitted by this licence or other valid authorisation; and
- (b) be in accordance with the Regulator's *Guidelines for the Transport, Storage and Disposal of GMOs* for PC2 GM plants as current at the time of transportation or storage.

45. Methods and procedures used for any transportation of Plant Material must be recorded, and must be provided to the Regulator, if requested.

### **Persistence of the GMOs or GM Volunteers post Cleaning**

46. After Cleaning, areas of land must be inspected by people trained to recognize Safflower, and actions taken as follows:

Area	Period of inspection	Inspection frequency	Inspect for	Action
Planting Area, Monitoring Zone, and other areas of land that required Cleaning under Condition 40	From the day of Cleaning, until: <ul style="list-style-type: none"> <li>i. the area is replanted with the GMOs; or</li> <li>ii. the Regulator has issued a Sign-off for the area</li> </ul>	At least once every 35 days	Volunteers	Destroy before Flowering

47. Details of any inspection activity must be recorded in a Logbook and must include:
- (a) date of the inspections;
  - (b) name of the person(s) conducting the inspection;
  - (c) details of the experience, training or qualification that enables the person(s) to recognise Safflower or Related Species, if not already recorded in the Logbook;
  - (d) details of areas inspected including current land use and recent management practices applied;
  - (e) details of any post-harvest rainfall events, including measurements at or near the area, or any irrigation events;
  - (f) details of any post-harvest Volunteers observed, including number, developmental stage and approximate position of the Volunteers within each area inspected<sup>⌘</sup>;
  - (g) date(s) and method(s) of Destruction or preventing flowering of any plants;
  - (h) details of measures taken to control rodents and of any evidence of rodent activity; and
  - (i) details of any measures taken to deter birds (including use of bird netting, bird scarers or sorghum crop; details of damage/repair to netting; and if a sacrificial sorghum planting is used, observations of seed production in the sorghum and GM safflower) and any evidence of bird activity.

<sup>⌘</sup> *Examples of acceptable ways to record the positional information for Volunteers in the Logbook include:*

- *Descriptive text*
- *Marking on a diagram*
- *Indicating grid references on corresponding map/sketch.*

*Note: Details of Inspection activities must be provided to the Regulator (Condition 51(e)).*

48. While post-Cleaning inspection requirements apply to an area:
- (a) the area must be maintained in a manner appropriate to allow identification of Volunteers; and
  - (b) no plants may be intentionally grown in the area unless:
    - i. the plants are the GMOs, or non-GM Safflower, planted in accordance with the conditions of this licence; or
    - ii. written approval is given by the Regulator for the plants to be grown in the area; or
    - iii. the Regulator has issued a Sign-off for the area; and
  - (c) prior to an application for Sign-off, the area must receive at least one irrigation during the first two months of the Volunteer-free period immediately prior to the Sign-off application.

*Note: A period of natural rainfall may be taken as irrigation only with the agreement of the Regulator. Evidence (such as rainfall measurements, photos etc.) that the rainfall has been sufficient to promote germination should be provided.*

## Contingency plan

49. If any unintentional presence of the GMOs or plant material from the GMOs is detected outside the areas requiring inspection, the Contingency Plan must be implemented.

### **Section 4 Sign off**

50. The licence holder may make written application to the Regulator that planting restrictions and inspection conditions no longer apply to an area if:

- (a) all post-Cleaning inspection activities have been conducted for at least 12 months on the area and all associated areas of land; and
- (b) no Volunteers have occurred on these areas in the most recent six month inspection period.

*Note: Associated areas refers to a Planting Area and the aggregate of all other areas of land requiring post-Cleaning inspections in respect of that Planting Area. Associated areas will be signed-off as a group rather than individually. Licence conditions require at least one irrigation or rainfall event for each area prior to Sign-off application. The Regulator will take into account the management and inspection history for all associated areas, including tillage and irrigation regimes and occurrence of Volunteers, in deciding whether or not he is satisfied that no further inspections are required to manage persistence of the GMOs.*

### **Section 5 Reporting and Documentation**

*The following licence conditions are imposed to demonstrate compliance with other conditions and to facilitate monitoring of compliance by staff of the OGTR.*

51. Notifications must be sent to the Regulator as follows:

Notice	Content of notice	Timeframe
(a) Intention to Plant	<ol style="list-style-type: none"><li>i. Details of the Planting Area, including size and GPS coordinates</li><li>ii. Identity of the GMOs to be planted at the Planting Area</li><li>iii. Date on which the GMOs will be planted</li><li>iv. Period when the GMOs are expected to Flower</li><li>v. Period when harvesting is expected to commence</li><li>vi. Confirmation that no other Safflower Crops were grown in the Monitoring, Isolation or Exclusion Zones in the preceding growing season</li><li>vii. If GMOs have previously been planted at the Planting Area, a history indicating how the Planting Area has been used in the preceding 2 years, including details of previous GMOs and post-harvest crops planted</li><li>viii. How the Planting Area is intended to be used during the year following harvest</li><li>ix. If a sacrificial sorghum crop is to be used, the expected dates of seed production for the GMOs and the sorghum.</li></ol>	At least 7 days prior to each planting (to be updated immediately if the notified intended planting dates change)

(b) Planting	i. Actual date(s) of Planting the GMOs ii. Any changes to the details provided under part (a) of this Condition.	Within 7 days of any planting
(c) Harvest	i. Actual date(s) of Harvesting the GMOs.	Within 7 days of commencement of any Harvesting
(d) Cleaning	i. Actual date(s) on which any areas needing Cleaning were Cleaned ii. Details of areas Cleaned and methods of Cleaning.	Within 7 days of completion of any Cleaning
(e) Inspection activities	i. Information recorded in a Logbook as per Condition 47.	Within 35 days of Inspection
(f) Seed set	i. Actual date(s) of GMO seed set (for planting area in WA) ii. Actual date(s) of sorghum seed set.	Within 7 days of seed set

*Note: Other reports and documents that may need to be sent to the Regulator are described under Conditions 10(a), 10(b), 17 and 42.*

**DIR No: 121**

**Full Title:** Limited and controlled release of safflower genetically modified for increased levels of oleic acid

**Organisation Details**

Postal address: CSIRO Plant Industry  
GPO Box 1600  
Canberra ACT 2601

Phone No: (02) 6246 4943

**IBC Details**

IBC Name: IBC 103 (CSIRO Plant Industry)

**GMO Description**

**GMOs covered by this licence:**

*Carthamus tinctorius* L. containing only the genes and genetic elements listed below.

**Parent Organism:**

Common Name: Safflower

Scientific Name: *Carthamus tinctorius* L.

**Modified traits:**

Categories: Oil composition  
Selectable marker – antibiotic  
Visual marker

Description: Safflower plants have been genetically modified for increased levels of oleic acid and decreased levels of other fatty acids. All plants also contain an antibiotic resistance marker and some plants contain a visual marker.

**Genetic elements responsible for conferring the modified trait:**

Genes: Fragment of FATB (palmitoyl-ACP thioesterase) gene from safflower  
Fragment of FAD2 ( $\Delta 12$  desaturase) gene from safflower  
Fragment of another fatty acid biosynthesis gene from safflower  
*hph* (hygromycin phosphotransferase, truncated) from *Escherichia coli*  
*gfp* (green fluorescent protein) from *Aequorea victoria* jellyfish

Promoters for *hph/gfp* 35S from Cauliflower mosaic virus (CaMV 35S)  
enhanced tobacco constitutive ubiquitous promoter (enTCUP)

Terminators for *hph/gfp*: octopine synthase polyA (ocs) from *Agrobacterium tumefaciens*  
nopaline synthase polyA (nos) from *A. tumefaciens*.

Further details of the genetic elements inserted into the GM safflower lines have been declared Confidential Commercial Information (CCI) under section 185 of the Act.

**Purpose of the dealings with the GMOs:**

CSIRO applied for a licence for dealings involving the intentional release of up to 190 GM safflower lines on a limited scale and under controlled conditions.

The primary purpose of the field trial is to evaluate the agronomic performance of the GM safflower under field conditions.

## ATTACHMENT B

### Checklist of documents that must be sent to the Regulator:

When	What	Condition	Timeframe
Prior to conducting any dealings	Details of persons covered	12(a)	
	Plan to inform people covered by the licence	12(b)	
	Plan to ensure control and access to all the Sites	12(c)	
	Detection methodology	12(d)	
	Contingency plan	12(e)	
Prior to planting	Intention to plant	51(a)	At least 7 days prior to any planting
During growing	Planting	51(b)	Within 7 days of any planting
	Harvest	51(c)	Within 7 days of commencement
Post-Cleaning	Cleaning	51(d)	Within 7 days of completion
	Inspection	51(e)	Within 35 days of each inspection
Any time after issue of the licence	Any changes of the project supervisor contact details	8	As soon as practically possible
	Any relevant conviction, revocation, suspension or cancellation of any relevant permit or circumstances that may affect compliance to licence conditions	10 (a)	Immediately, if occurs
	Any information relevant to on-going suitability	10 (b)	If and when requested
	Any changes to details provided under conditions 12(a) - 12(e)	13	Within 14 days of the changes
	Signed statements from persons covered under the licence	16 (b)	If and when requested
	Any additional information regarding health and safety of the people and the environment, contraventions of this licence or any unintended effects of the dealings authorized by the licence	17	As soon as practically and reasonably possible, after becoming aware
	Extreme weather conditions	42	As soon as practically and reasonably possible, if expected or occurs
	Methods and procedures for transport and storage	45	If and when requested