



**Australian Government**

**Department of Health, Disability and Ageing**  
Office of the Gene Technology Regulator

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

**Licence number: DIR 211**

**Licence holder: Miruku Australia Pty Ltd**

**Limited and controlled release of safflower genetically modified for dairy protein production and altered fat composition**

**Issued: 29 May 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* (Cth) (the Act) and corresponding state and territory legislation form part of a nationally consistent regulatory system controlling activities involving genetically modified (GM) organisms.

This licence is issued by the Gene Technology Regulator (the Regulator) in accordance with the Act and, as applicable, corresponding State law.

The 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 GM organisms into the Australian environment.

Other agencies that also regulate GM organisms or GM products include Food Standards Australia New Zealand, Australian Pesticides and Veterinary Medicines Authority, Therapeutic Goods Administration, Australian Industrial Chemicals Introduction Scheme and the Department of Agriculture, Fisheries and Forestry. 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.

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.

### ***Further Information on Licence DIR 211***

More information about the decision to issue this licence is contained in the Risk Assessment and Risk Management Plan prepared in connection with this licence. This document can be obtained from the [Office of the Gene Technology Regulator \(OGTR\) website](#) or by telephoning the Office on 1800 181 030.

Information about where the GMOs have been planted pursuant to this licence can be accessed on the [OGTR website](#).

# Chapter 1 Proposed licence conditions

## Section 1 Interpretations and definitions

1. In this licence:

- (a) unless defined otherwise, words and phrases used in this licence have the same meaning as they do in the Act and the Regulations;
- (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 general conditions to the extent of any inconsistency.

2. In this licence:

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

**‘Clean’** means, as the case requires:

- (a) in relation to Equipment or a facility, remove and/or Destroy the GMOs; or
- (b) in relation to an area of land specified in this licence as requiring Cleaning:
  - i. Destroy Safflower plants, if present, to the reasonable satisfaction of the Regulator, and
  - ii. remove Safflower seeds from the soil surface to the reasonable satisfaction of the Regulator.

*Note: The intent of removing seeds from the soil surface is to minimise seed dispersal. One method of removing seeds from the soil surface is Tillage, which moves seeds to under the soil. Tillage must be in accordance with Condition 41.*

**‘Contingency Plan’** means a written plan detailing measures to be taken in the event of the unintended presence of the GMOs 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/or Destroy the GMOs to the reasonable satisfaction of the Regulator; and
- (c) inspect for and Destroy any Volunteers that may exist as a result of the event to the reasonable satisfaction of the Regulator.

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

- (a) uprooting;
- (b) root cutting and shredding/mulching;
- (c) Tillage, but only in accordance with Condition 41;

- (d) treatment with herbicide;
- (e) burning/incineration;
- (f) autoclaving;
- (g) milling/hammer milling;
- (h) crushing or grinding of seed;
- (i) burial, but only in accordance with Condition 42;
- (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, treatment with herbicide would not successfully kill GM seeds.*

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

**'Extreme Weather'** includes, but is not limited to, fires, flooding, cyclones or torrential rain, that could disperse GMOs or affect the licence holder's ability to comply with licence conditions.

**'Flowering'** is taken to begin when any plant of the class of plants referred to in a particular condition first has an open flower, 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. GMOs include live plants and viable seed.

**'Inspection Zone'** means an area of land extending outwards at least 50 metres or at least 190 metres from the outer edge of a Monitoring Zone as specified elsewhere in this licence, as shown in Figure 1.

**'Isolation Zone'** means an area of land extending outwards at least 590 metres from the outer edge of a Monitoring Zone, as shown in 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 Regulator on request.

**'Monitoring Zone'** means an area of land extending outwards at least 10 metres from the outer edge of a Planting Area, as shown in Figure 1. If multiple Planting Areas are present in a Site, the Monitoring Zone also includes the areas of land, of any size, between Planting Areas, as shown in Figure 1.

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

**'Personal Information'** means information or an opinion about an identified individual, or an individual who is reasonably identifiable:

- (a) whether the information or opinion is true or not; and
- (b) whether the information or opinion is recorded in a material form or not.

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

**'Plant Material'** means any part of the GM or non-GM Safflower plants grown at a Planting Area, whether viable or not, or any product of these plants.

**'Regulations'** means the Gene Technology Regulations 2001 (Commonwealth) or the corresponding State law under which this licence is issued.

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

**'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.

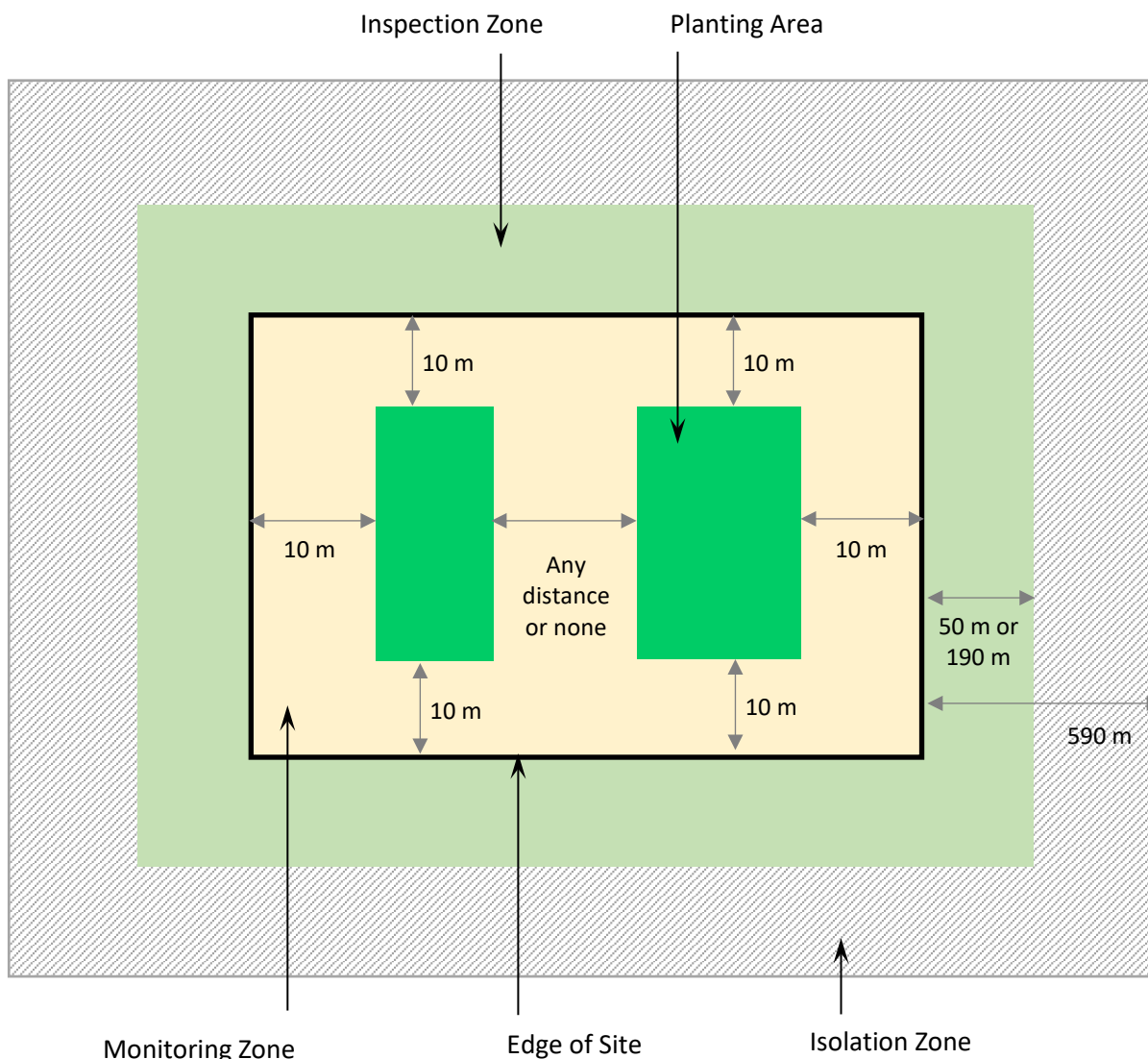
**‘Sign off’** means a notice in writing from the Regulator, in respect of an area, that post-Cleaning obligations no longer apply to that area.

**‘Site’** means an area of land containing one or more Planting Areas and their joint Monitoring Zone, as shown in Figure 1.

**‘Tillage’** means the use of any technique to disturb the soil.

*Note: Tillage must be in accordance with Condition 41.*

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



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

## Section 2 General 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 recognising an area 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.
4. This licence remains in force until it is suspended, cancelled or surrendered. No dealings with the GMOs are authorised during any period of suspension.

*Note: Although this licence has no expiry date, the period when GMOs may be grown is restricted in accordance with Condition 18.*

5. The licence holder is Miruku Australia Pty Ltd.
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 GMOs with which dealings are authorised by this licence are those listed at **Attachment A**.
8. The dealings authorised by the licence are to:
  - (a) conduct experiments with the GMOs;
  - (b) breed the GMOs;
  - (c) propagate the GMOs;
  - (d) use the GMOs in the course of manufacture of a thing that is not the GMOs;
  - (e) grow the GMOs;
  - (f) transport the GMOs;
  - (g) dispose of the GMOs;and the possession, supply or use of the GMOs in the course of any of these dealings.
9. 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.

*Note: Dealings conducted as an NLRD must be assessed by an Institutional Biosafety Committee (IBC) before commencement and must comply with the requirements of the Regulations.*

#### **General obligations of the licence holder**

10. The licence holder must, at all times, remain an accredited organisation in accordance with the Act and must comply with its instrument of accreditation.
11. The licence holder must be able to access and control all Planting Areas, Monitoring Zones, Inspection Zones, Isolation Zones and approved facilities to the extent necessary to comply with this licence.

*Note: Arrangements to access and control these areas must be notified to the Regulator as part of each planting notification (Condition 50(a)).*

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;
  - (b) the cancellation or suspension of the licence;
  - (c) the surrender of the licence.
13. The licence holder must not permit a person covered by this licence to conduct any dealing with the GMOs 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.

14. The licence holder must inform the persons covered by this licence that any Personal Information relevant to the administration and/or enforcement of the licence may be disclosed to the Regulator.

### **General 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 the licence applies to the dealing by the 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.

*Note: Under the Act, the definition of premises includes a building, area of land or vehicle.*

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

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

*The following licence conditions impose limits on where and when the GMOs may be grown.*

16. The only plants that may be intentionally grown at a Planting Area are:
- (a) the GMOs covered by this licence; and
  - (b) non-GM Safflower; and
  - (c) plants approved in writing by the Regulator.
17. Non-GM Safflower plants grown in a Planting Area must be handled as if they were the GMOs.
18. Planting and growing of the GMOs may only occur within the following limits:

#### **Area and duration**

Period	Maximum number of Sites per calendar year	Maximum combined area of Planting Areas in each Site
2025	2	0.5 ha
2026	5	1 ha
2027	10	5 ha
2028	15	5 ha
2029	20	5 ha

#### **Local Government Areas in which Sites may be located**

New South Wales	Victoria	Western Australia	South Australia
Berrigan	Ararat	Albany	Adelaide Plains
Bland	Ballarat	Beverley	Barossa
Blayney	Benalla	Boddington	Light
Cabonne	Buloke	Boyup Brook	Wakefield
Coolamon	Campaspe	Bridgetown-Greenbushes	
Coonamble	Central Goldfields	Brookton	
Cootamundra-Gundagai	Colac Otway	Broomehill-Tambellup	
Cowra	Corangamite	Carnamah	
Dubbo	Gannawarra	Coorow	
Edward River	Glenelg	Corrigin	
Federation	Golden Plains	Cranbrook	
Forbes	Greater Bendigo	Cuballing	
Gilgandra	Greater Geelong	Cunderdin	
Greater Hume	Greater Shepparton	Dalwallinu	
Griffith	Hepburn	Denmark	

New South Wales	Victoria	Western Australia	South Australia
Gunnedah	Hindmarsh	Donnybrook-Balingup	
Gwydir	Horsham	Dowerin	
Hay	Indigo	Dumbleyung	
Hilltops	Loddon	Esperance	
Inverell	Macedon Ranges	Gnowangerup	
Junee	Mildura	Goomalling	
Leeton	Mitchell	Greater Geraldton	
Liverpool Plains	Moirra	Jerramungup	
Lockhart	Moorabool	Katanning	
Mid-Western	Mount Alexander	Kent	
Moree Plains	Moyne	Kojonup	
Murray River	Northern Grampians	Manjimup	
Murrumbidgee	Pyrenees	Merredin	
Muswellbrook	Southern Grampians	Mingenew	
Narrabri	Strathbogie	Moora	
Narrandera	Swan Hill	Morawa	
Narromine	Wangaratta	Nannup	
Orange	West Wimmera	Narrogin	
Parkes	Wodonga	Northam	
Snowy Valleys	Wyndham	Perenjori	
Tamworth	Yarriambiack	Pingelly	
Temora		Plantagenet	
Upper Hunter		Quairading	
Wagga Wagga		Ravensthorpe	
Walgett		Tammim	
Warren		Three Springs	
Warrumbungle		Toodyay	
Weddin		Victoria Plains	
		Wagin	
		Wandering	
		West Arthur	
		Wickepin	
		Williams	
		Wongan-Ballidu	
		Woodanilling	
		Wyalkatchem	
		York	

### 3.2 Control measures

*The following licence conditions restrict the spread or persistence of the GMOs and their genetic material in the environment.*

#### **Conditions to restrict exposure to the GMOs**

19. 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 other than that used in any sensory testing (see Condition 20) or feed for animals.
20. Products of the GMOs may be used in human sensory testing which may include taste testing, subject to those experiments being under oversight by a Human Research Ethics Committee, which is required to review and approve the research proposals in accordance with the National Statement on Ethical Conduct in Human Research.



21. The licence holder must not permit a person covered by this licence to conduct any dealing which may expose the person to Plant Material unless the person has provided a statement that the person does not have a known allergy to proteins expressed as a result of the modifications in the GM Safflower.

*Note: The licence holder should document compliance with this condition, as per Condition 13.*

### **Conditions to restrict pollen flow**

22. A Planting Area must be surrounded by a Monitoring Zone (as shown in Figure 1). Multiple Planting Areas may be contained within a single Monitoring Zone. No Planting Area may be less than 10 metres from the outer edge of the Monitoring Zone.
23. The Monitoring Zone must be maintained in a manner appropriate to allow the identification and Destruction of Volunteers while the GMOs are growing in the Planting Areas and until the Planting Areas are Cleaned.

*Note: Acceptable measures to achieve this include keeping land free of vegetation or keeping vegetation mown to a height of less than 10 centimetres. Condition 51 requires details of current land use and recent land management practices to be recorded upon inspection of the Monitoring Zone.*

24. The Monitoring Zone must be surrounded by an Inspection Zone (as shown in Figure 1). The Inspection Zone extends outwards from the outer edge of the Monitoring Zone by at least:
- (a) 190 metres; or
  - (b) 50 metres, if:
    - i. no Safflower Crop has been grown in the innermost 190 m of the Isolation Zone for at least 2 years; or
    - ii. no Safflower has been observed during inspections conducted under Condition 40 in the previous growing season; and
    - iii. it is agreed to in writing by the Regulator.
25. The Inspection Zone must be surrounded by an Isolation Zone (as shown in Figure 1).
26. The GMOs must not be grown in a Planting Area if:
- (a) any Safflower Crop is present in the Monitoring Zone, Inspection Zone or Isolation Zone; or
  - (b) any Safflower, other than plants grown pursuant to this licence, was planted in the Monitoring, Inspection or Isolation Zones in the previous Safflower growing season.
27. While the GMOs are growing in a Planting Area, associated areas must be inspected by people trained to recognise Safflower, and actions must be taken as follows:

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

*\*Condition 50(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 (Condition 51) and reported to the Regulator (Condition 50).*

### **Conditions to restrict seed dispersal**

28. Equipment used in connection with the GMOs must be Cleaned as soon as practicable after use with the GMOs and before use for any other purpose.

29. Planting Areas must be at least 50 metres away from any permanent natural watercourses or man-made drainage features that flow into natural watercourses.

*Note: This includes irrigation channels or storm water drains that flow into a natural watercourse.*

30. Planting Areas must not be located in flood prone areas.

*Note: Acceptable measures to determine if an area is flood prone may include, but are not limited to, the 1 in 100 year flood level of the area or the flooding history of the area.*

31. Measures must be implemented to control rodents within each Planting Area from at least 7 days prior to planting the GMOs, while the GMOs are being grown and until the Planting Area is Cleaned.

*Note: Measures for rodent control may include, but are not limited to, traps and/or poison baits within and/or surrounding the Planting Area.*

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 is Cleaned.

*Note: Acceptable measures to achieve this include keeping land free of vegetation or keeping vegetation mown to a height of less than 10 centimetres.*

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

- (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; or
- (c) surrounded by a 10 m strip of decoy non-GM plants within the innermost 190 m of the Isolation Zone and these plants must bear seed over the same period as the Safflower in the Planting Area; or
- (d) managed so as to minimise bird access to the GMOs by a method approved in writing by the Regulator.

*Note: A combination of measures described in (a), (b), (c) or (d) may be employed at a Planting Area. The purpose of the decoy plants (e.g. sorghum or wheat) is to attract birds away from the GM Safflower. Details of any inspection activity must be recorded in a Logbook as detailed in Condition 51.*

### **Conditions relating to harvesting**

34. All GMOs planted within a Planting Area must be harvested or Destroyed within 8 months after the first planting of any GMO within that Planting Area.

35. If all GMOs in a Planting Area have been Destroyed, then for the purposes of this licence:

- (a) the GMOs are taken to have been harvested; and
- (b) the Planting Area is taken to have been Cleaned.

*Note: Cleaning activities must be reported to the Regulator (Condition 50). Areas of land that have been Cleaned are subject to inspections (Condition 39).*

36. The GMOs must be harvested separately from any other crop.
37. Harvested GM seed not required for experimentation or future planting must be Destroyed as soon as practicable.

**Conditions to restrict persistence of GMOs on trial sites**

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

Areas of land to be Cleaned	When
Planting Area and Monitoring Zone	Within 14 days after harvest of the GMOs
Any area, outside a Planting Area or Monitoring Zone, used to Clean any Equipment used in connection with the GMOs	As soon as practicable
Any area, outside a Planting Area or Monitoring Zone, where the GMOs have dispersed, e.g. during planting, growing, harvest or Destruction	As soon as practicable

*Note: Cleaning activities must be reported to the Regulator (Condition 50). Areas of land that have been Cleaned are subject to inspections (Condition 39).*

39. After Cleaning, areas of land must be inspected by people trained to recognise Safflower. Inspections must cover the entirety of the areas to be inspected. Actions must be taken as follows:

Area	Period of inspection	Inspection frequency	Inspect for	Action
Planting Area, Monitoring Zone and other areas of land that were Cleaned in accordance with Condition 38.	From the day of Cleaning, until: i. the area is planted as a new Planting Area in accordance with Condition 16 and inspections required under Condition 27 commence; or ii. the Regulator has issued a Sign off for the area.	At least once every 35 days	Volunteers	Destroy before Flowering

*Note: Details of any inspection activity must be recorded in a Logbook (Condition 51) and reported to the Regulator (Condition 50).*

40. While post-Cleaning inspection requirements apply to an area:
- the area must be maintained in a manner appropriate to allow identification of Volunteers; and
  - no plants may intentionally be grown in the area unless:
    - the area is planted as a new Planting Area in accordance with Condition 16; or
    - the plants are agreed to in writing by the Regulator; and
  - prior to an application for Sign off, the area must receive at least one watering event, as described in **Attachment B**, occurring within the 6 months prior to submission of the Sign off application; and
  - within the 6 months prior to submission of the Sign off application, and before the final required watering event, the area must be Tilled.

**Tillage**

41. Any Tillage of the Planting Area must be to a depth no greater than 5 centimetres.

### ***Destruction by burial***

42. If Destruction of GMOs occurs by burial:

- (a) the GMOs must be buried in a pit and covered by a layer of soil at least one metre in depth, the top of which is no higher than the surrounding soil surface; and
- (b) seeds must be wet when buried to encourage decomposition; and
- (c) the licence holder must take measures to ensure that the burial site is not disturbed for a period of at least 12 months from the date of burial.

*Note: If GMOs are dispersed on the soil surface during the process of burial, the burial site becomes an area of land that requires Cleaning under Condition 38, and is subject to post-Cleaning requirements.*

*Note: The date and location of burial, and measures used to ensure that the burial site is not disturbed, must be reported to the Regulator (Condition 50(f)).*

### ***Processing or experimentation with the GMOs***

43. Treatment or processing of GM seed or experimentation or analysis with the GMOs may only be undertaken within:

- (a) a Planting Area before Cleaning; or
- (b) a Monitoring Zone before Cleaning; or
- (c) a facility approved in writing by the Regulator.

*Note: This condition does not apply to dealings conducted as an NLRD (see Condition 9).*

44. Within a facility approved in writing by the Regulator in accordance with Condition 43, any area that is used for treatment processing, experimentation or analysis of the GMOs must be Cleaned as soon as practicable and before use for any other purpose.

### ***Transport or storage of the GMOs***

45. Transport or storage of the GMOs must:

- (a) only occur to the extent necessary to conduct the dealings permitted by this licence or other valid authorisation under the Act; 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; and
- (c) comply with all other conditions of this licence.

*Note: Activities with the GMOs within a Planting Area prior to Cleaning are not regarded as transport or storage.*

*Note: Condition 13 requires signed statements for persons transporting the GMOs.*

*Note: This condition does not apply to dealings conducted as an NLRD (see Condition 9).*

46. Methods and procedures used to transport GMOs must be recorded, and must be provided to the Regulator, if requested.

*Note: The Contingency Plan must be implemented if the GMOs are detected outside areas under inspection (Condition 47).*

### ***Contingency plan***

47. If any unintentional presence of the GMOs is detected outside the areas requiring Cleaning, the Contingency Plan must be implemented.

## Section 4 Sign off

48. The licence holder may make written application to the Regulator that planting restrictions and inspection requirements no longer apply to the Planting Area and other areas requiring Cleaning if:
- post-Cleaning inspection activities have been conducted for at least 12 months on the area; and
  - conditions have been conducive for germination and detection of Volunteers; and
  - no Volunteers have been detected in the area during the 6 months prior to the Sign off request.

*Note: An area requires Tillage and one watering event prior to a Sign off application (Condition 40).*

*Note: The Regulator will take into account the management and inspection history for the Planting Area and other areas requiring Cleaning, including post-harvest crops planted (if any), Tillage, irrigation, rainfall, application of herbicide and occurrence of Volunteers, in deciding whether or not 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 facilitate monitoring of compliance by staff of the OGTR.*

49. General notifications must be sent to the Regulator as follows:

*Note: please send all correspondence related to the licence to [OGTR.M&C@health.gov.au](mailto:OGTR.M&C@health.gov.au).*

Notice	Content of notice	Timeframe
a. Changes to contact details	Changes to any of the contact details of the project supervisor that were notified in the licence application or subsequently	As soon as practicable
b. Ongoing suitability to hold a licence	<ol style="list-style-type: none"> <li>any relevant conviction of the licence holder; or</li> <li>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; or</li> <li>any event or circumstances that would affect the capacity of the licence holder to meet the conditions of the licence; and</li> </ol>	As soon as practicable after any of these events occur
	iv. any information related to the licence holder's ongoing suitability to hold a licence, that is requested by the Regulator	Within the timeframe stipulated by the Regulator
c. People covered by the licence	<ol style="list-style-type: none"> <li>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 <i>Note: Examples of functions or positions are 'project supervisor', 'site manager', 'farm labourer' etc.</i></li> <li>detail of how the persons covered by the licence will be informed of licence conditions</li> </ol>	At least 14 days prior to conducting any dealings with the GMOs (to be updated within 14 days if the notified details change)
d. Testing methodology	A written methodology to reliably detect the genetic modifications described in this licence. The detection method/s must be capable of identifying each GM Safflower line planted under this licence	At least 14 days prior to conducting any dealings with the GMOs (to be updated within 14 days if the notified details change)

e. Contingency plan	A Contingency Plan to respond to inadvertent presence of the GMOs outside an area that must be inspected	At least 14 days prior to conducting any dealings with the GMOs (to be updated within 14 days if the notified details change)
f. Training records	Copies of the signed and dated statements referred to in Condition 13 if requested by the Regulator	Within the timeframe stipulated by the Regulator
g. Additional information required by the Act	<p>i. 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</p> <p>ii. any contraventions of the licence by a person covered by the licence; or</p> <p>iii. any unintended effects of the dealings authorised by the licence</p> <p><i>Note: The Act requires, for the purposes of the Condition 49(g), that:</i></p> <ul style="list-style-type: none"> <li><i>the licence holder will be taken to have become aware of additional information of a kind mentioned in Condition 49(g) if he or she was reckless as to whether such information existed; and</i></li> <li><i>the licence holder will be taken to have become aware of contraventions, or unintended effects, of a kind mentioned in Condition 49(g), if he or she was reckless as to whether such contraventions had occurred, or such unintended effects existed</i></li> </ul> <p><i>Note: Contraventions of the licence may occur through the action or inaction of a person.</i></p>	<p>Without delay after becoming aware of any new information</p> <p><i>Note: An example of notification without delay is contact made within a day of a contravention of the licence via the OGTR free call phone number 1800 181 030 or email to OGTR.M&amp;C@health.gov.au. Notification without delay will allow the OGTR to conduct a risk assessment on the incident and attend the location, if required</i></p>
h. Further details regarding additional information	Any further details requested by the Regulator in relation to information provided under Condition 49(g)	Within the timeframe stipulated by the Regulator

50. Notifications relating to each trial site must be sent to the Regulator as follows:

*Note: please send all correspondence related to the licence to [OGTR.M&C@health.gov.au](mailto:OGTR.M&C@health.gov.au).*

Notice	Content of notice	Timeframe
a. Intention to plant	<p>i. Details of the Planting Area including size, the local government area, GPS coordinates, a street address, a diagrammatical representation of the Site (e.g. Google Maps) and any other descriptions</p> <p>ii. Detail of how the licence holder will access and control the Planting Area and the associated Monitoring Zone, Inspection Zone and Isolation Zone, in accordance with Condition 11</p> <p><i>Note: this should include a description of any contracts, agreements, or other enforceable arrangements.</i></p> <p>iii. Identity of the GMOs to be planted at the Planting Area (e.g. inserted vector name)</p> <p>iv. Date on which the GMOs will be planted</p> <p>v. Period when the GMOs are expected to Flower</p>	At least 7 days prior to each planting (to be updated as soon as practicable if the notified details change)

Notice	Content of notice	Timeframe
	vi. Period when harvesting is expected to commence vii. Confirmation that no Safflower Crops other than the GMOs, were grown in the Monitoring, Inspection or Isolation Zones in the preceding growing season viii. How all areas requiring post-Cleaning inspections are intended to be used until Sign off, including proposed post-harvest crops (if any) ix. Details of how inspection activities will be managed, including strategies for the detection and Destruction of Volunteers x. History of how the Site has been used for the previous 2 years	
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. Extreme Weather	Any Extreme Weather event that is expected to affect or has already affected an area where the GMOs are or may be present.  <i>Note: The Contingency Plan must be implemented if the GMOs are detected outside areas requiring Cleaning (Condition 47).</i>	As soon as practicable
d. Harvest	Actual date(s) of harvesting the GMOs	Within 7 days of commencement of any harvesting
e. Cleaning	i. Date(s) on which required Cleaning was performed on any areas of land ii. Method(s) of Cleaning	Within 7 days of completion of Cleaning
f. Destruction by burial	Date of burial, location of burial including GPS co-ordinates, and details of measures used to ensure that the burial site will not be disturbed for the period required by Condition 42	Within 7 days of burial of any GMOs
g. Inspection activities	Information recorded in a Logbook as per the inspection requirements (Conditions 27, 33, 39 and 51).	Within 35 days of inspection

**Note: Additional records must be provided to the Regulator, if requested, in accordance with Condition 46.**

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

- (a) date of the inspections; and
- (b) name of the person(s) conducting the inspections; and
- (c) details of the experience, training or qualification that enables the person(s) to recognise Safflower, if not already recorded in the Logbook; and
- (d) details of areas inspected including current land use (including any post-harvest crops) and recent management practices applied; and

*Note: management practices include Tillage events, spraying or maintenance measures used to facilitate inspections.*

- (e) details of the developmental stage of the GMOs while they are being grown; and
- (f) details of any post-Cleaning rainfall events including measurements at or near the area, or any irrigation events; and

- (g) details of any Volunteers observed during inspections or during land-management activities, including number, developmental stage and approximate position of the Volunteers within each area inspected<sup>†</sup>; and
- (h) date(s) and method(s) of Destruction of or preventing Flowering of any Volunteers, including destruction of Volunteers during land-management activities; and
- (i) details of rodent control methods used and any evidence of rodent activity, while rodent control methods are required; and
- (j) details of any measures taken to deter birds (including use of bird netting, bird scarers or a decoy crop; details of damage/repair to netting; and if a decoy crop planting is used, observations of seed production in the decoy crop 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 a corresponding map/sketch.*

*Note: Details of inspection activities must be provided to the Regulator (Condition 50). The Regulator has developed a standardised proforma for recording inspection activities. This can be made available on request.*



## ATTACHMENT A

DIR No: 211

**Full Title:** Limited and controlled release of Safflower genetically modified for dairy protein production and altered fat composition

### Licence holder

Miruku Australia Pty Ltd

### GMO Description

#### GMOs covered by this licence

Safflower plants genetically modified by introduction of only the genes and genetic elements listed below.

#### Parent Organism

Common Name: Safflower

Scientific Name: *Carthamus tinctorius* L.

#### Modified traits

Category: Composition – food (processing)  
Reporter gene expression  
Selectable marker – antibiotic  
Selectable marker – herbicide

Description: Safflower plants have been genetically modified for production of a chimeric dairy protein, in combination with altered fatty acid composition in some lines. All lines contain either a herbicide tolerance, antibiotic resistance, or visual reporter selectable marker gene. The introduced genes are listed in Table 1 and the associated genetic elements are listed in Table 2.

**Table 1.** Introduced genes in the GM Safflower

Genetic element	Source organism	Encoded protein	Intended function
<i>bar</i>	<i>Streptomyces hygroscopicus</i>	Phosphinothricin acetyltransferase	Herbicide resistance
<i>BCN2</i>	<i>Bos taurus</i>	Miruku $\beta$ -casein (CSN2) variant 2	$\beta$ -casein production
<i>BCN3</i>	<i>Bos taurus</i>	Miruku $\beta$ -casein (CSN2) variant 3	$\beta$ -casein production
<i>CCI gene*</i>	<i>CCI*</i>	CCI*	CCI*
<i>CCI gene*</i>	<i>CCI*</i>	CCI*	CCI*
<i>CtFAD2.2</i> fragments	<i>Carthamus tinctorius</i>	Hairpin RNA targeting <i>FAD2.2</i> desaturase for RNAi-mediated gene silencing	<i>FAD2.2</i> down-regulation
<i>Cat-1</i> intron	<i>Ricinus communis</i>		
<i>CtSAD</i> fragments	<i>Carthamus tinctorius</i>	Hairpin RNA targeting <i>SAD</i> desaturase for RNAi-mediated gene silencing	<i>SAD</i> down-regulation
<i>Cat-1</i> intron	<i>Ricinus communis</i>		
<i>GUSPlus™</i>	<i>Staphylococcus</i> sp.	Codon-optimised $\beta$ -glucuronidase derived from <i>gusA</i> gene	Visual selectable marker

Genetic element	Source organism	Encoded protein	Intended function
<i>hph</i>	<i>Streptomyces hygroscopicus</i>	Hygromycin B phosphotransferase	Antibiotic resistance

\*This information has been declared Confidential Commercial Information (CCI) under s185 of the Act

**Table 2.** Introduced regulatory sequences in the GM Safflower

Genetic element	Source	Intended function
<i>AtCel1</i> cell wall signal	Cell wall signal from <i>Arabidopsis thaliana</i> <i>CEL1</i> gene	Cell wall targeting sequence
<i>CaMV35S</i> 3'UTR	Cauliflower mosaic virus	Terminator and polyadenylation signal
<i>CaMV35S</i> promoter	Cauliflower mosaic virus	Constitutive promoter
CCI 3'UTR 1*	<i>Glycine max</i>	Terminator and polyadenylation signal
CCI 3'UTR 2*	<i>Phaseolus vulgaris</i>	Terminator and polyadenylation signal
CCI 3'UTR 3*	<i>Linum usitatissimum</i>	Terminator and polyadenylation signal
CCI promoter 1*	<i>G. max</i>	Seed-specific promoter
CCI promoter 2*	<i>P. vulgaris</i>	Seed-specific promoter
CCI promoter 3*	<i>L. usitatissimum</i>	Seed-specific promoter
CCI promoter 4*	<i>Brassica napus</i>	Seed-specific promoter
<i>CT-CVS</i> C-terminus	C-terminal beta-conglycinin vacuolar sequence from <i>Glycine max</i>	Terminator
ER Retention	C-terminal H/KDEL tag sequence from <i>A. thaliana</i>	Endoplasmic reticulum retention
<i>GmCVS</i> vacuolar signal	Vacuole signal from <i>G. max</i> beta-conglycinin gene	Vacuole targeting sequence
<i>Goshu-lectin</i> 3'UTR	<i>Dioscorea batatas</i>	Terminator and polyadenylation signal
<i>HvAVSP</i> vacuolar signal	Vacuole signal from <i>Hordeum vulgare</i> aleurain gene	Vacuole targeting sequence
<i>Prr</i>	<i>Nicotiana tabacum</i>	Cell wall targeting sequence
<i>nos</i> 3'UTR	<i>Agrobacterium tumefaciens</i>	Terminator and polyadenylation signal
<i>nos</i> promoter	<i>A. tumefaciens</i>	Constitutive promoter

\*This information has been declared Confidential Commercial Information (CCI) under s185 of the Act

## ATTACHMENT B

A watering event is irrigation or natural rainfall that provides sufficient soil moisture to promote germination of Safflower seeds on a trial site.

Examples of acceptable watering events are:

- At least 26 millimetres of rainfall over one day; or
- At least 28 millimetres of rainfall over 2 days; or
- At least 30 millimetres of rainfall over 3 days; or
- At least 32 millimetres of rainfall over four days; or
- Irrigation that provides equivalent levels of soil moisture to one of the examples of rainfall above.

Rainfall measurements must be taken on the site or within 3 km of the site. An irrigation or natural rainfall that matches one of the examples listed above, and occurs during the time period specified for a watering event in Condition 40 of the licence, is considered a valid watering event. The licence holder should keep records of the date/s and amount of water applied during the watering event, and provide this information when requesting Sign off of the relevant site.

If an irrigation or natural rainfall does not match one of the examples listed above, the licence holder may submit a request to the Regulator for it to be considered a watering event. The request should provide:

- evidence of amount of water applied, such as rainfall measurements on the site or within 3 km of the site, and
- evidence that resultant soil moisture is suitable for germination, such as photos of germinating plants on the site.

It is recommended that any requests that an irrigation or natural rainfall be considered a watering event be submitted at the time of the event, to minimise potential delays to Sign off of the site.