



**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 188**

**Licence Holder: Nuseed Pty Ltd**

**Limited and controlled release of canola and Indian mustard genetically  
modified for altered oil content and herbicide tolerance**

Issued: 8 June 2022

### ***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 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 *Gene Technology Act 2000* 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, Water and the Environment. 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 188***

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](#) 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](#).

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## 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.

**‘Canola’** means plants of the species *Brassica napus* L.

**‘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 canola and Indian mustard plants, if present, to the reasonable satisfaction of the Regulator, and
  - ii. remove canola and Indian mustard 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 38.*

**‘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) cutting and shredding/mulching;

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- (c) Tillage, but only in accordance with condition 38;
  - (d) treatment with herbicide;
  - (e) burning/incineration;
  - (f) autoclaving;
  - (g) crushing or grinding of seed;
  - (h) burial, but only in accordance with condition 39;
  - (i) 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.

**'Indian mustard'** means plants of the species *Brassica juncea* (L.) Czern. & Coss.

**'Insect-proof'** means sufficient to prevent the entry of insects that commonly pollinate canola and Indian mustard flowers.

**'Isolation Zone'** means an area of land extending outwards from the outer edge of the 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 from the outer edge of the Planting Area, or the outer edge of a Pollen Trap if a Pollen Trap is employed, 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 canola and Indian mustard are intentionally planted and grown pursuant to this licence, but does not include the Pollen Trap.

**'Plant Material'** means any part of the GM or non-GM canola and Indian mustard plants grown at a Planting Area or Pollen Trap, whether viable or not, or any product of these plants.

**'Pollen Trap'** means an area of land extending outwards at least 15 metres from the outer edge of a Planting Area, where only Pollen Trap Plants are grown, as shown in Figure 1.

**'Pollen Trap Plants'** means non-GM canola grown in a Pollen Trap.

**'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.

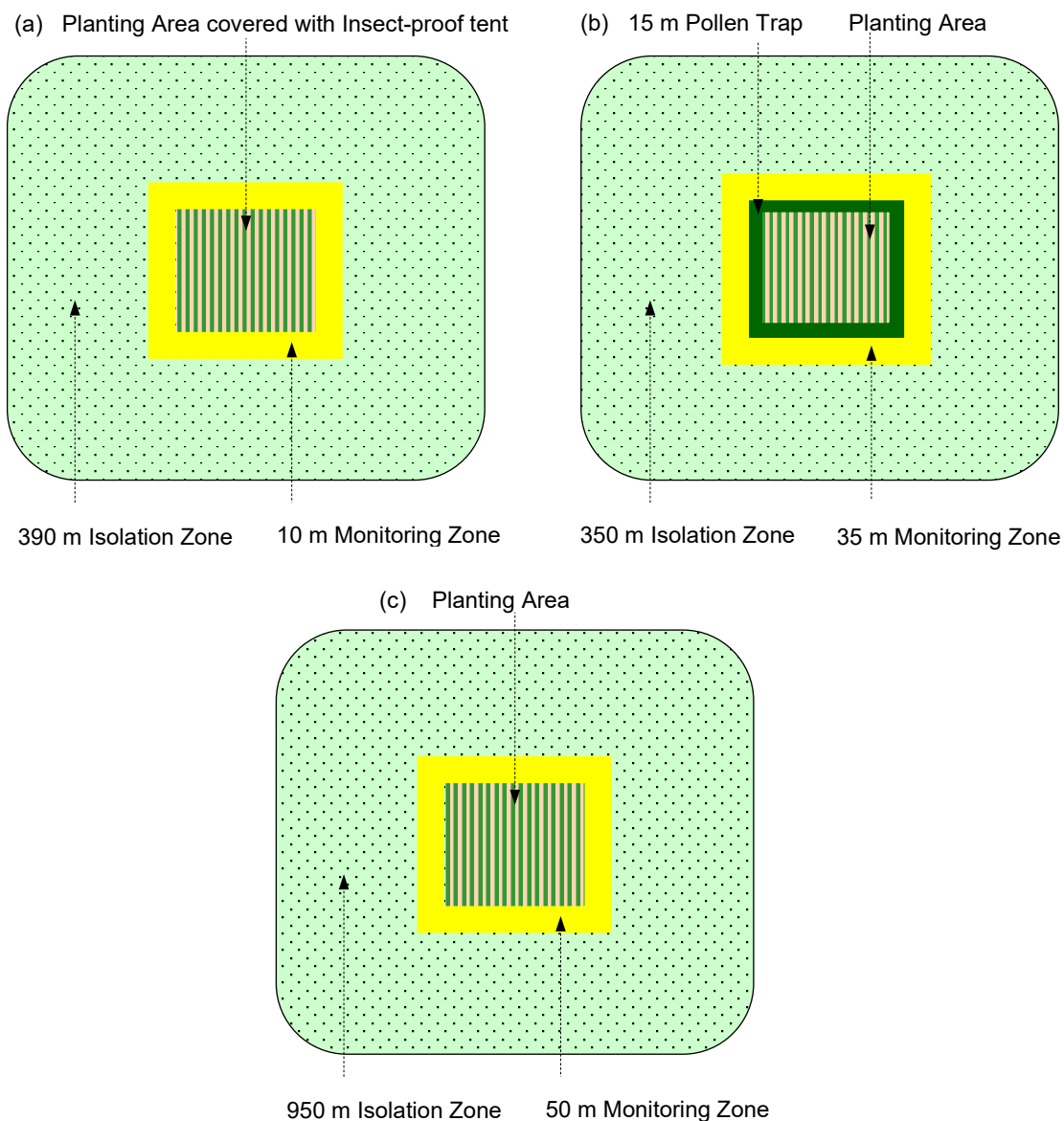
**'Related Species'** means plants of the species *Brassica napus*, *B. rapa*, *B. juncea*, *B. oleracea*, *Hirschfeldia incana*, *Raphanus raphanistrum* or *Sinapis arvensis*, but does not include plants intentionally grown in the Planting Area or Pollen Trap in accordance with licence conditions.

**'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.

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

*Note: Tillage must be in accordance with condition 38.*

**'Volunteers'** means GM or non-GM canola or Indian mustard plants, which have not been intentionally grown.



**Figure 1. Diagrams (not to scale) showing the relationships between Planting Area, Pollen Trap, Monitoring Zone and Isolation Zone.** Site layout (a) with Insect-proof tent, (b) without Insect-proof tent and with Pollen Trap, and (c) without Insect-proof tent or Pollen Trap. Monitoring and Isolation Zones must be kept free of Related Species.

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## 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 Nuseed 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) import the GMOs;
  - (g) transport the GMOs;
  - (h) 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, Pollen Traps, Monitoring 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 47(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 released 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 canola and Indian mustard; and
  - (c) plants approved in writing by the Regulator.
17. Non-GM canola and Indian mustard 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	Number of Planting Areas per year	Maximum size of each Planting Area
November 2022 to January 2028	20	5 ha for 10 Planting Areas 10 ha for 10 Planting Areas

#### Local government areas in which Planting Areas may be located

New South Wales	Victoria	Queensland
Albury City Council	Ararat Rural City Council	Goondiwindi Regional Council
Balranald Shire Council	Ballarat City Council	Lockyer Valley Regional Council
Berrigan Shire Council	Benalla Rural City Council	Somerset Regional Council
Bland Shire Council	Buloke Shire Council	Southern Downs Regional Council
Blayney Shire Council	Campaspe Shire Council	Toowoomba Regional Council

<b>New South Wales</b>	<b>Victoria</b>	<b>Queensland</b>
Cabonne Shire Council	Central Goldfields Shire Council	Western Downs Regional Council
Carrathool Shire Council	Colac-Otway Shire Council	
Coolamon Shire Council	Corangamite Shire Council	
Coonamble Shire Council	Gannawarra Shire Council	
Cootamundra- Gundagai Regional Council	Glenelg Shire Council	
Cowra Shire Council	Golden Plains Shire Council	
Dubbo Regional Council	Greater Bendigo City Council	
Edward River Council	Greater Geelong City Council	
Federation Council	Greater Shepparton City Council	
Forbes Shire Council	Hepburn Shire Council	
Gilgandra Shire Council	Hindmarsh Shire Council	
Greater Hume Shire Council	Horsham Rural City Council	
Griffith City Council	Indigo Shire Council	
Gunnedah Shire Council	Latrobe City Council	
Gwydir Shire Council	Loddon Shire Council	
Hay Shire Council	Macedon Ranges Shire Council	
Hilltops Council	Melton Shire Council	
Junee Shire Council	Mildura Rural City Council	
Lachlan Shire Council	Mitchell Shire Council	
Leeton Shire Council	Moira Shire Council	
Liverpool Plains Shire Council	Moorabool Shire Council	
Lockhart Shire Council	Mount Alexander Shire Council	
Mid-Western Regional Council	Moyne Shire Council	
Moree Plains Shire Council	Murrindindi Shire Council	
Murray River Council	Northern Grampians Shire Council	
Murrumbidgee Council	Pyrenees Shire Council	
Muswellbrook Shire Council	South Gippsland Shire Council	
Narrabri Shire Council	Southern Grampians Shire Council	
Narrandera Shire Council	Strathbogie Shire Council	
Narromine Shire Council	Surf Coast Shire Council	
Orange City Council	Swan Hill Rural City Council	
Parkes Shire Council	Towong Shire Council	
Snowy Valleys Council	Wangaratta Rural City Council	
Tamworth Regional Council	Warrnambool City Council	
Temora Shire Council	Wellington Shire Council	
Upper Hunter Shire Council	West Wimmera Shire Council	
Wagga Wagga City Council	Wodonga City Council	
Walgett Shire Council	Wyndham City Council	
Warren Shire Council	Yarriambiack Shire Council	



New South Wales	Victoria	Queensland
Warrumbungle Shire Council		
Weddin Shire Council		

### 3.2 Control measures

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

#### Restrictions on GMOs in food or feed

19. Subject to conditions 20 and 21, 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.
20. Non-viable products derived from the GMOs may be fed to rodents, chickens or farmed fish species for experimental purposes, subject to those experiments being approved by an Animal Ethics Committee operating under the Australian Code for the Care and Use of Animals for Scientific Purposes.
21. Oil from 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.

#### Conditions to restrict pollen flow

22. For each Planting Area, one of the following measures to limit gene flow must be adopted, either:
  - (a) Cover every GMO planted in the Planting Area with Insect-proof tents from at least seven days prior to Flowering and until all GMOs have completed Flowering, and surround the Planting Area with a Monitoring Zone of at least 10 metres, and surround the Monitoring Zone with an Isolation Zone of at least 390 metres (as shown in Figure 1a); or
  - (b) surround the Planting Area with a Pollen Trap of at least 15 metres, and surround the Pollen Trap with a Monitoring Zone of at least 35 metres, and surround the Monitoring Zone with an Isolation Zone of at least 350 metres (as shown in Figure 1b); or
  - (c) surround the Planting Area with a Monitoring Zone of at least 50 metres, and surround the Monitoring Zone with an Isolation Zone of at least 950 metres (as shown in Figure 1c).
23. If a Pollen Trap is used in accordance with condition 22, Pollen Trap Plants must:
  - (a) have a reasonably dense and vigorous growth; and
  - (b) be Flowering at the same time as the GMOs; and
  - (c) form a continuous barrier at least 15 metres wide around the Planting Area while the GMOs are Flowering, although one path of up to 3 metres in width is allowed in order to access the Planting Area; and
  - (d) be handled as if they were the GMOs.
24. The Monitoring Zone must be maintained in a manner appropriate to allow the identification and Destruction of Related Species while the GMOs are growing in the Planting Area.
 

*Note: Measures to achieve this could include maintaining the area free of vegetation and/or keeping vegetation mown. Condition 48 requires details of current land use and recent land management practices to be recorded upon inspection of the Monitoring Zone.*
25. The GMOs must not be planted in a Planting Area if any Related Species are being grown at the same time in the Monitoring or Isolation Zones.

*Note: Refer to Condition 11 regarding access and control of areas.*

26. While the GMOs are growing in a Planting Area, associated areas and Insect-proof tents must be inspected by people trained to recognise plants of Related Species, and actions must be taken as follows:

Area	Period of inspection	Inspection frequency	Inspect for	Action
Planting Area, Pollen Trap (if applicable) and Monitoring 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 or Destroyed	At least once every 35 days	Related Species	Destroy before Flowering or prevent from Flowering
Insect-proof tents	While tents are in place	At least once every 14 days and after any Extreme Weather event	Damage that may render tents not Insect-proof	Repair any damage or replace if repair not possible
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 35 days	Intentionally planted Related Species	Destroy before Flowering or prevent from Flowering or Destroy the GMOs in the Planting Area

*\*Condition 47(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 48) and reported to the Regulator (Condition 47).*

### Conditions to restrict seed dispersal

27. 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.

28. Planting Areas and Pollen Traps 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.*

29. Planting Areas and Pollen Traps must not be located in flood prone areas.

30. If the GMOs are windrowed, the licence holder must take, or have taken, measures to minimise the likelihood of dispersal of the GMOs by wind or rain. Appropriate measures may include:

- (a) ensuring high density planting and growth of the GMOs prior to windrowing; or
- (b) cutting/windrowing to allow maximum stubble height; or
- (c) use of windrow roller; or
- (d) appropriate site selection.

*Note: Appropriate site selection includes avoidance of windy areas. Windrowing dates and details of measures used to minimise dispersal of GMOs must be reported to the Regulator (Condition 47d).*

### Conditions relating to harvesting

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

32. 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 47). Areas of land that have been Cleaned are subject to inspections (Condition 36).*

33. The GMOs must be harvested and threshed separately from any other crop.

34. 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**

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

Areas of land to be Cleaned	When
i. Planting Area ii. Pollen Trap, if used iii. 10 metres around each Planting Area, or around the Pollen Trap, if used (innermost 10 metres of Monitoring Zone)	Within 14 days after harvest of the GMOs
Any other area used to Clean any Equipment used in connection with the GMOs	As soon as practicable
Any other area where the GMOs have dispersed, e.g. during planting, growing, harvesting or Destruction	As soon as practicable

*Note: Cleaning activities must be reported to the Regulator (Condition 47). Areas of land that have been Cleaned are subject to inspections (Condition 36).*

36. After Cleaning, areas of land must be inspected by people trained to recognise canola and Indian mustard. Inspections must cover the entirety of areas to be inspected. Actions must be taken as follows:

Area	Period of inspection	Inspection frequency	Inspect for	Action
Planting Area, Pollen Trap, innermost 10 metres of Monitoring Zone and other areas of land that were Cleaned in accordance with Condition 35	From the day of Cleaning, until: i. the area is planted as a new Planting Area in accordance with condition 16; or ii. the Regulator has issued a Sign off for the area	i. At least once every 30 days if any Indian mustard was grown on the Planting Area; or ii. at least once every 35 days if only canola was grown on the Planting Area	Volunteers	Destroy before Flowering

*Note: Details of any inspection activity must be recorded in a Logbook (Condition 48) and reported to the Regulator (Condition 47).*

37. While post-Cleaning inspection requirements apply to an area:

- (a) the area must be Tilled within 60 days of harvest of the GMOs at a Planting Area, unless otherwise approved in writing by the Regulator; and

*Note: If Tillage is used as a method of Cleaning, the Tillage done as Cleaning also meets the requirements for a Tillage within 60 days of harvest.*

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- (b) within the 12 months prior to submission of a Sign off application, the area must be Tilled and then receive a watering event as described in **Attachment B**; and
  - (c) the area must be maintained in a manner appropriate to allow identification of Volunteers; and
  - (d) the area must not be used for grazing livestock; and
  - (e) no plants may be intentionally grown in the area unless:
    - i. the area is planted as a new Planting Area in accordance with condition 16; or
    - ii. the plants are listed as post-harvest crops permitted for GM Brassica field trial sites in the OGTR Policy on Post Harvest Crops as current at the time of planting; or
    - iii. the plants are agreed to in writing by the Regulator.

*Note: The OGTR's Policy on Post Harvest Crops can be found on the [OGTR website](#).*

### **Tillage**

38. Any Tillage of the Planting Area and the Pollen Trap must be to a depth no greater than five centimetres.

### **Destruction by burial**

39. 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 two years 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 35, 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 47g).*

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

40. Treatment, threshing 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 Pollen Trap before Cleaning; or
- (c) the innermost 10 m of a Monitoring Zone before Cleaning; or
- (d) a facility approved in writing by the Regulator.

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

41. Within a facility approved in writing by the Regulator in accordance with Condition 40, any area that is used for treatment, threshing, 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**

42. 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, or to the extent necessary to enable export of the GMOs; 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).*

43. 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 44).*

### Contingency plan

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

## Section 4. Sign off

45. 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:

- (a) post-Cleaning inspection activities have been conducted on the area for at least 36 months if any Indian mustard was grown on the Planting Area, or at least 24 months if only canola was grown on the Planting Area; and
- (b) conditions have been conducive for germination and detection of Volunteers; and
- (c) prior to the Sign-off request, no Volunteers have been detected in the area for at least 18 months if any Indian mustard was grown on the Planting Area, or at least 12 months if only canola was grown on the Planting Area.

*Note: The licence requires two Tillages and a watering event prior to a Sign off application (Condition 37).*

*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.*

46. 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	i. any relevant conviction of the licence holder; or 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; or iii. any event or circumstances that would affect the capacity of the licence holder to meet the conditions of the licence; and	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	i. 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> ii. detail of how the persons covered by the licence will be informed of licence conditions	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 canola and Indian mustard 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	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 ii. any contraventions of the licence by a person covered by the licence; or iii. any unintended effects of the dealings authorised by the licence <i>Note: The Act requires, for the purposes of the condition 46.g, that:</i> <ul style="list-style-type: none"> <li>• the licence holder will be taken to have become aware of additional information of a kind mentioned in Condition 46.g if he or she was reckless as to whether such information existed; and</li> <li>• the licence holder will be taken to have become aware of contraventions, or unintended effects, of a kind mentioned in Condition 46.g, if he or she was reckless as to whether such</li> </ul>	Without delay after becoming aware of any new information  <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, 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</i>

	<i>contraventions had occurred, or such unintended effects existed</i> <i>Note: Contraventions of the licence may occur through the action or inaction of a person.</i>	
h. Further details regarding additional information	Any further details requested by the Regulator in relation to information provided under condition 46.g	Within the timeframe stipulated by the Regulator

47. 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	<ul style="list-style-type: none"> <li>i. Details of the Planting Area including size, the local government area, GPS coordinates, a street address, a diagrammatical representation of the trial site (e.g. Google Maps) and any other descriptions</li> <li>ii. Whether an Insect-proof tent or Pollen Trap will be used</li> <li>iii. Details of how the licence holder will access and control the Planting Area and the associated Pollen Trap, Monitoring Zone and Isolation Zone, in accordance with condition 11 <i>Note: this should include a description of any contracts, agreements, or other enforceable arrangements.</i></li> <li>iv. Whether any Indian mustard will be planted in the Planting Area</li> <li>v. Date on which the GMOs will be planted</li> <li>vi. Period when the GMOs are expected to Flower</li> <li>vii. Period when windrowing (if intended) is expected to commence</li> <li>viii. Period when harvesting is expected to commence</li> <li>ix. How all areas requiring post-Cleaning inspections are intended to be used until Sign off, including proposed post-harvest crops (if any)</li> <li>x. Details of how inspection activities will be managed, including strategies for the detection and Destruction of Volunteers</li> <li>xi. History of how the trial site has been used for the previous two years</li> </ul>	At least 7 days prior to each planting (to be updated as soon as practicable if the notified details change)
b. Planting	<ul style="list-style-type: none"> <li>i. Actual date(s) of planting the GMOs</li> <li>ii. Any changes to the details provided under part (a) of this condition</li> </ul>	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 44).</i>	As soon as practicable
d. Windrowing	Actual date(s) of windrowing and details of measures used to minimise dispersal of the GMOs during windrowing (Condition 30).	Within 7 days of commencement of windrowing

Notice	Content of notice	Timeframe
e. Harvest	Actual date(s) of harvesting the GMOs	Within 7 days of commencement of any harvesting
f. 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
g. 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 39	Within 7 days of burial of any GMOs
h. Inspection activities	Information recorded in a Logbook as per the inspection requirements (Conditions 26, 36 and 48).	Within 35 days of inspection

*Note: Additional records must be provided to the Regulator, if requested, in accordance with condition 43.*

48. 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 canola, Indian mustard and/or Related Species, 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 and/or Related Species observed during inspections or during land-management activities, including number, developmental stage and approximate position of the Volunteers and/or Related Species within each area inspected<sup>†</sup>; and
- (h) date(s) and method(s) of Destruction of or preventing Flowering of any Volunteers and/or Related Species, including destruction of Volunteers and/or Related Species during land-management activities; and
- (i) details of any damage and any repairs to the Insect-proof tents, while Insect-proof tents are required.

<sup>†</sup> *Examples of acceptable ways to record the positional information for Volunteers and/or Related Species 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 47). The Regulator has developed a standardised proforma for recording inspection activities. This can be made available on request.*



**DIR No: 188**

**Full Title:** Limited and controlled release of canola and Indian mustard genetically modified for altered oil content and herbicide tolerance

**Organisation Details**

Postal address: Nuseed Pty Ltd  
103-105 Pipe Road  
Laverton North, VIC 3026

Phone No: (03) 9282 1000

**IBC Details**

IBC Name: Nuseed Institutional Biosafety Committee

**GMO Description****GMOs covered by this licence**

Canola and Indian mustard plants genetically modified by introduction of only the genes and genetic elements listed below.

**Parent Organisms**

Common Names: Canola and Indian mustard

Scientific Names: *Brassica napus* L. and *Brassica juncea* (L.) Czern. & Coss.

**Modified traits**

Category: Composition – food (human nutrition)  
Composition – animal nutrition  
Herbicide tolerance

Description: Canola and Indian mustard plants have been genetically modified by introduction of up to seven genes involved in fatty acid biosynthesis. The GMOs are intended to produce  $\omega$ -3 long-chain polyunsaturated fatty acid in seed oil. The GMOs may also contain a selectable marker gene that confers herbicide tolerance. The introduced genes are listed in Table 1 and the associated regulatory sequences are listed in Table 2.

**Purpose of the dealings with the GMO**

The purpose of the release is to evaluate the altered oil content trait under field conditions. The GM canola and Indian mustard are not permitted to be used for human food or animal feed except in specified animal feeding experiments and human sensory testing, including taste testing.

**Table 1.** Introduced genes in the GM canola and Indian mustard

Gene	Source organism	Description of encoded protein
<i>LackI-Δ12D</i>	<i>Lachancea kluyveri</i>	Fatty acid Δ12-desaturase
<i>Picpa-ω3D</i>	<i>Pichia pastoris</i>	Fatty acid ω-3 desaturase
<i>Micpu-Δ6D</i>	<i>Micromonas pusilla</i>	Fatty acid Δ6-desaturase
<i>Pyrco-Δ6E</i>	<i>Pyramimonas cordata</i>	Fatty acid Δ6-elongase
<i>Pavsa-Δ5D</i>	<i>Pavlova salina</i>	Fatty acid Δ5-desaturase
<i>Pyrco-Δ5E</i>	<i>Pyramimonas cordata</i>	Fatty acid Δ5-elongase
<i>Pavsa-Δ4D</i>	<i>Pavlova salina</i>	Fatty acid Δ4-desaturase
<i>pat</i>	<i>Streptomyces viridochromogenes</i>	Enzyme for glufosinate herbicide tolerance

**Table 2.** Introduced regulatory sequences in the GM canola and Indian mustard

Sequence	Source	Intended function
PRO_Arath-FAE1	Promoter of <i>Arabidopsis thaliana</i> fatty acid elongase 1	Seed specific promoter
PRO_Brana-FP1	Promoter of <i>Brassica napus</i> napin	Seed specific promoter
PRO_Linus-Cnl1	Promoter of <i>Linum usitatissimum</i> conlinin1	Seed specific promoter
PRO_Linus-Cnl2	Promoter of <i>Linum usitatissimum</i> conlinin2	Seed specific promoter
PRO_35S×2	Promoter of Cauliflower mosaic virus 35S RNA	Constitutive promoter
Tobacco mosaic virus 5' UTR leader	Enhancer from Tobacco mosaic virus 59	Increase gene expression
MAR_Nicta- RB7	Rb7 matrix attachment region from <i>Nicotiana tabacum</i>	Increase gene expression
TER_Agrtu-NOS	Terminator of <i>Agrobacterium tumefaciens</i> nopaline synthase	Terminator
TER_Glyma-Lectin	Terminator of <i>Glycine max</i> lectin <i>Le1</i>	Terminator
TER_Linus-Cnl1	Terminator of <i>Linum usitatissimum</i> conlinin1	Terminator
TER_Linus-Cnl2	Terminator of <i>Linum usitatissimum</i> conlinin2	Terminator

A watering event is irrigation or natural rainfall that provides sufficient soil moisture to promote germination of canola and Indian mustard 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 two days; or
- At least 30 millimetres of rainfall over three 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 37 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.