



**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 149**

**Licence holder: Nuseed Pty Ltd**

**Title: Limited and controlled release of Indian mustard (*Juncea canola*) genetically modified for altered oil content**

Issued: 14 February 2017

**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.**

### **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 activities involving 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 and the Department of Agriculture. 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 declaring areas to be GM, GM free, or both, for marketing purposes.

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.

### **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](#).

## 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.

**'Burial Site'** means a place where the GMO is Destroyed by burial.

**'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 in that area, to the reasonable satisfaction of the Regulator; or
- (b) in relation to Equipment, the removal and Destruction of the GMOs 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 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; 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) cutting
- (c) shredding/mulching
- (d) treatment with herbicide;
- (e) burning/incineration;

- (f) burial, but only subject to the conditions of this licence;
- (g) Tillage, but only subject to the conditions of this licence;
- (h) autoclaving; or
- (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, used individually, treatment by cutting or mowing may not be sufficient to kill the GMO remaining after harvest and additional treatment(s) may be required.*

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

**'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

- (a) the genetically modified organisms that are the subject of the dealings authorised by this licence and includes viable GM Plant Material such as live plants, root stock that is able to grow into live plants, and viable seed; and
- (b) where there is any uncertainty about viability, any Plant Materials from the GMOs.

*Note: The effect of the above definition is that Plant Material incapable of being identified as viable or not must be treated in the same manner as Plant Material which is indisputably viable.*

**'Insect-proof'** means sufficient to prevent the entry of insects that commonly pollinate Juncea Canola flowers.

**'Isolation Zone'** means an area of land extending outwards from the outer edge of the Planting Area, or the outer edge of the Pollen Trap with respect to a Planting Area when a Pollen Trap is employed. The Isolation Zone must be kept free of deliberately planted Related Species while the GMOs are growing in the Planting Area.

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

**'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:

- (a) at least 10 m in all directions from the outer edge of a Planting Area if all GM Juncea Canola is contained under an Insect-proof tent when flowering (Figure 1A); or
- (b) at least 50 m in all directions from the outer edge of a Planting Area, or the outer edge of a Pollen Trap with respect to a Planting Area when a Pollen Trap is employed (Figure 1B).

**'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 GM and non-GM Juncea Canola plants or non-GM canola plants 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 Juncea Canola plants or non-GM canola plants grown in a Planting Area or in the Pollen Trap with respect to 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.

**‘Pollen Trap’** means an area of land extending at least 15 metres (m) in all directions from the outer edge of a Planting Area and which is planted with Pollen Trap Plants.

**‘Pollen Trap Plants’** means non-GM Juncea Canola plants grown in a Pollen Trap.

**‘Regulator’** means the Gene Technology Regulator.

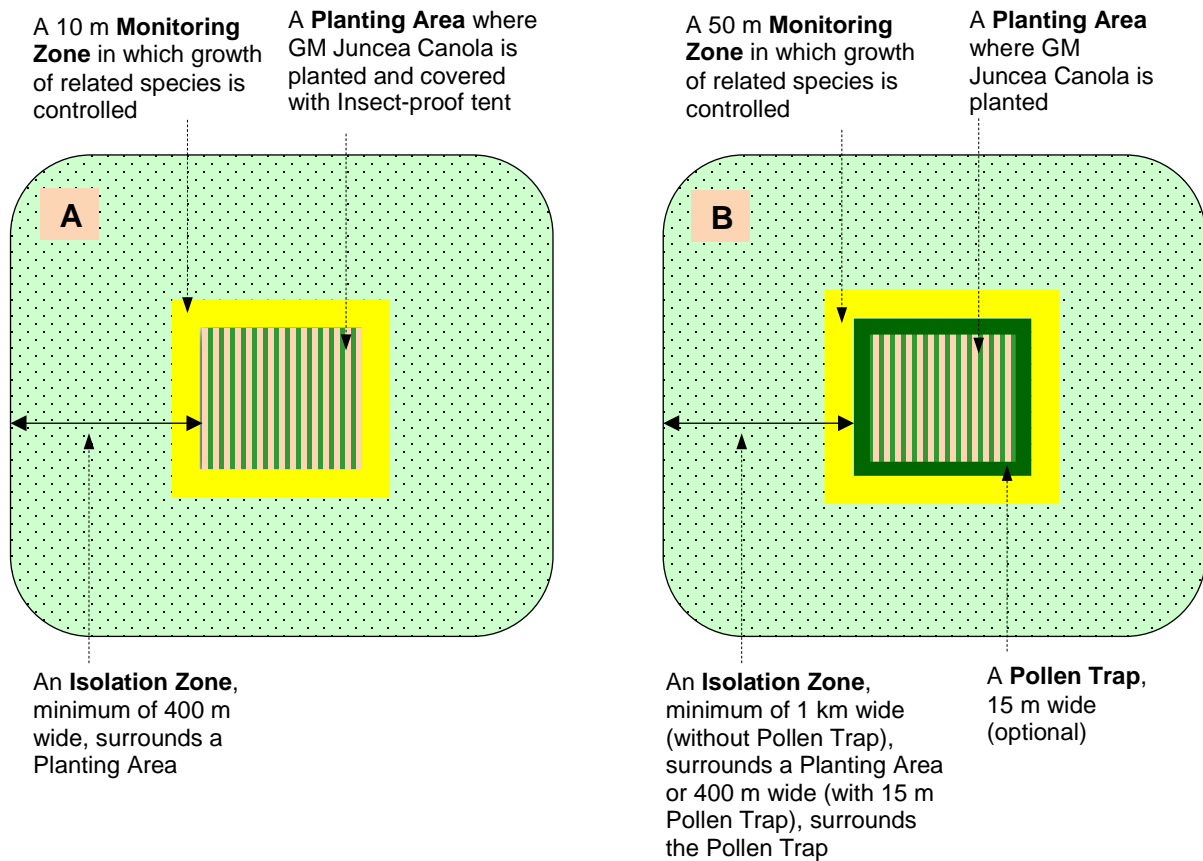
**‘Related Species’** means plants of the species *Brassica juncea*, *B. napus*, or *B. rapa*, but does not include the GMO or non-GM Juncea Canola plants planted and grown according to this licence.

**‘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 Juncea Canola plants or non-GM canola plants, which have not been intentionally grown.

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



**Figure 1. Diagrams showing the relationship between a Planting Area, a Pollen Trap, a Monitoring Zone and an Isolation Zone (not drawn to scale).**

**A:** controls imposed when Insect-proof tents are used; **B:** controls imposed without Insect-proof tents. Note that Isolation Zones vary depending on whether a Pollen Trap is planted or not. See Section 3 on containment measures for detailed conditions.

## 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 Nuseed Pty Ltd (Nuseed).
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, import, 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 in writing 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 and control all Planting Areas, Pollen Traps, 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.

*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 and control all Planting Areas, Pollen Traps, 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 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 Juncea Canola plants;
- (c) non-GM canola (*Brassica napus*); and
- (d) plants approved in writing by the Regulator.

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

## Area and duration

Maximum size of any Planting Area	Maximum number of Planting Areas per year	Period
2 ha	4	April 2017 – March 2018
5 ha	10	April 2018 – March 2019
10 ha	15	April 2019 – May 2022

## Local Government Areas in which Planting Areas may be located

New South Wales	Victoria	Queensland
Albury	Ararat	Lockyer Valley
Balranald	Ballarat	Southern Downs
Berrigan	Benalla	Toowoomba
Bland	Bendigo	Western Downs
Blayney	Buloke	
Boorowa	Campaspe	
Cabonne	Central Goldfields	
Conargo	Colac-Otway	
Coolamon	Corangamite	
Coonamble	Gannawarra	
Cootamundra	Geelong	
Corowa	Glenelg	
Cowra	Golden Plains	
Deniliquin	Hepburn	
Dubbo	Hindmarsh	
Forbes	Horsham	
Gilgandra	Indigo	
Griffith	Latrobe	
Gundagai	Loddon	
Gunnedah	Macedon Ranges	
Gwydir	Melton	
Harden	Mildura	
Hay	Mitchell	
Hume	Moira	
Jerilderie	Moorabool	
Junee	Mount Alexander	
Lachlan	Moyne	
Leeton	Murrindindi	
Liverpool Plains	Northern Grampians	
Lockhart	Pyrenees	
Mid Western	Shepparton	
Moree Plains	South Gippsland	
Murray	Southern Grampians	
Murrumbidgee	Strathbogie	
Muswellbrook	Surf Coast	

New South Wales	Victoria	Queensland
Narrabri	Swan Hill	
Narrandera	Towong	
Narromine	Wangaratta	
Orange	Warrnambool	
Parkes	Wellington	
Tamworth	West Wimmera	
Temora	Wodonga	
Tumbarumba	Wyndham	
Tumut	Yarriambiack	
Upper Hunter		
Urana		
Wagga Wagga		
Wakool		
Walgett		
Warren		
Warrumbungle		
Weddin		
Wellington		
Young		

24. Subject to Condition 25, the GMOs or 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. Non-viable products derived from the GMOs may be fed to animals 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.

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

- (a) a Planting Area, Pollen Trap or Monitoring Zone prior to post-harvest Cleaning; or
- (b) 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 beyond the limits imposed on the trial and during other activities.*

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

27. The outer edge of a Planting Area, or a Pollen Trap if employed, must be at least 50 m away from Waterways and be confined to areas not subject to flooding.

28. For each Planting Area, one of the following measures to limit gene flow must be adopted:

- (a) cover all GMOs with Insect-proof tents from at least 7 days prior to flowering and until all GMOs have completed flowering, and surround the Planting Area with an Isolation Zone of at least 400 m (Figure 1A); or
- (b) surround the Planting Area by a Pollen Trap and an Isolation Zone of at least 400 m (Figure 1B); or
- (c) surround the Planting Area by an Isolation Zone of at least 1 km (Figure 1B).

29. A Planting Area, or a Pollen Trap if employed, must be surrounded by a Monitoring Zone.

30. If a Pollen Trap surrounds a Planting Area:

- (a) the Pollen Trap must be planted only to Pollen Trap Plants and maintained in such a way as to:
  - i) have a reasonably dense and vigorous growth; and
  - ii) be Flowering at the same time as the GMOs; and
  - iii) form a continuous barrier at least 15 m wide around the Planting Area while the GMOs are Flowering, although allowance may be made for a path of up to 3 m in width in order to access the Planting Area; and
- (b) Pollen Trap Plants and Plant Material from Pollen Trap Plants must be handled and controlled as if they were the GMOs or Plant Material from the GMOs.

*Note: If large irrigation equipment is moved into or out of a Planting Area, wheel tracks may be left through the Pollen Trap in addition to the path permitted by Condition 30(a)(iii). This is not considered to be a breach of Condition 30(a)(iii).*

31. The Monitoring Zone must be maintained in a manner appropriate to allow the identification and/or Destruction of Related Species whilst the GMO is growing in the Planting Area and until the Planting Area is Cleaned.

*Note: Measures to achieve this could include maintaining the area free of vegetation and/or keeping vegetation mown. Condition 52(d) of this licence requires details of current land use and recent land management practices to be recorded upon inspection of the Monitoring Zone.*

32. The GMOs must not be planted in a Planting Area if any Related Species are being grown, or are intended to be grown, in the Monitoring or Isolation Zones while the GMOs are in the Planting Area.

*Note: Refer to Condition 11 and 12(c) regarding access and control of areas*

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

Area	Period of inspection	Inspection frequency	Inspect for	Action
Planting Area and Pollen Trap (if applicable)	<b>From</b> 14 days prior to the expected commencement of Flowering of any GMOs* <b>until</b> the Planting Area, Pollen Trap and Monitoring Zone are Cleaned	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	Damage that may render tents non insect-proof	Repair any damage
Monitoring Zone	<b>From</b> 14 days prior to the expected commencement of Flowering of any GMOs* <b>until</b> the Planting Area, Pollen Trap and Monitoring Zone are Cleaned	At least once every 35 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 35 days	Intentionally planted Related Species	Destroy before Flowering or prevent from Flowering

*\*Condition 54(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 52.*

34. Non-GM Juncea Canola plants or non-GM canola plants and Plant Material from non-GM Juncea Canola plants or non-GM canola plants grown in a Planting Area must be handled as if they were the GMOs or Plant Material from the GMOs.

35. GMOs must be harvested separately from any other crop.

36. If windrowing is employed, 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 Juncea Canola 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 flood or wind-prone areas.*

37. If seed harvested from the GMOs is threshed other than in accordance with NLRD requirements, it must be threshed separately from any other crop, and threshing must take place on a Planting Area, a Pollen Trap or in a facility approved in writing by the Regulator.

38. If GMOs growing/planted in a Planting Area 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. Areas of land used in connection with the GMOs must be Cleaned as follows:

Areas to be Cleaned	When
(a) Planting Area, Pollen Trap and Monitoring Zone	Within 14 days after harvest of the GMOs
(b) any area where the GMOs have dispersed during planting, growing or harvesting (c) any area used to Clean any Equipment used in connection with the GMOs (d) any area used to Destroy any GMOs	As soon as practicable
(e) any facility used to store or experiment with the GMO	As soon as practicable and before use for any other purpose

*Note: Areas of land that have been Cleaned, or from which the GMOs have been harvested, are also subject to inspections (Condition 47), and Cleaning activities must be recorded and provided to the Regulator (Condition 54(e)). Facilities used for storage or experimentation with the GMOs would not be subject to post-cleaning inspections.*

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

41. If Destruction of the GMOs occurs by burial, the licence holder must:

- (a) bury the GMOs in a pit dug into the ground in such a way that the GMOs are covered by a layer of soil at least 1 m in depth, the top of which is no higher than the soil surface surrounding the Burial Site; and
- (b) within 14 days of burial, provide the Regulator a written notice indicating the precise location of the Burial Site (GPS coordinates and either a street address or other directions) and the date on which burial occurred; and
- (c) subject to Condition 42, inspect the Burial Site at least once every 3 months until Sign-off, to identify Volunteers and any significant disturbance that may affect the emergence of Volunteers, and:
  - i) if disturbance is identified, take appropriate remedial action and notify the Regulator of the disturbance and the remedial action taken; and
  - ii) if Volunteers are identified, Clean the Burial Site as soon as practicable.

*Note: Results of inspection activities are required to be recorded in a Logbook and provided to the Regulator (Condition 52).*

42. Monitoring and Sign-off of the Burial Site is not required if burial takes place at a Municipal or commercial land fill and the Regulator is provided with a written notice from the manager of the land fill undertaking:

- (a) to bury the GMOs on the day of delivery; and
- (b) not to disturb the Burial Site for a period of at least 2 years from the date of burial; and
- (c) to notify both the licence holder and the Regulator in writing of any significant disturbance of the Burial Site.

43. Any extreme weather event that could potentially cause the dispersal of or has already led to the dispersal of GMOs from a Planting Area while the GMOs are growing or from any area while subject to Cleaning and 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 51).*

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

44. If transport or storage is not conducted in accordance with NLRD requirements, it must be conducted in accordance with Conditions 45 and 46.

*Note: Dealings conducted in accordance with NLRD requirements must be assessed by an IBC before commencement, must comply with the requirements of the Gene Technology Regulations 2001, and are not subject to conditions of this licence.*

45. Transport and storage of the GMOs 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.

46. Methods and procedures used for any transportation of GMOs must be recorded, and must be provided to the Regulator, if requested.

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

47. After Cleaning, areas of land must be inspected by people trained to recognise Volunteers. 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, Monitoring Zone, and other areas of land that have been Cleaned (except facilities used for storage or experimentation)	From the day of Cleaning, until: i. the area is replanted with the GMOs; or ii. the Regulator has issued a Sign-off for the area	At least once every 35 days	Volunteers	Destroy before Flowering
Fence (if used) as per Conditions 49 and 50	During any period when livestock are grazing in the Monitoring Zone	Weekly	Damage	Repair as soon as practical to maintain exclusion of livestock
Burial Site	As per Conditions 41 and 42			

### Use of areas after post-harvest Cleaning

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) the following areas must be Tilled within 60 days of harvest of the GMO at a Planting Area, unless otherwise approved in writing by the Regulator:
  - i) the Planting Area;
  - ii) the Pollen Trap, if any;
  - iii) 5 m around each Planting Area, or around the Pollen Trap if used;
  - iv) any areas of land used to Clean Equipment used in connection with the GMO;
  - v) any other areas of land onto which the GMOs were dispersed;
  - vi) any areas used to Destroy the GMO, other than a Burial Site; and

*Note: Delaying the first Tillage until at least 28 days after harvest may result in reduced persistence of seed in the soil, but Tillage may be carried out earlier.*

- (c) any Tillage of an area must not bury the GMO to a depth of more than 5 cm; and
- (d) all areas requiring Tillage according to Condition 48(b) must also be Tilled at least once within the 12 months prior to submission of a Sign-off application in conditions where germination of Volunteers is reasonably likely to ensue (e.g. immediately before or after rain or irrigation); and

*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.*

*Note: Additional Tillage [other than that required by Condition 48(d)] need not be undertaken when conditions are conducive to germination. However, Tillage in*



*conditions of adequate soil moisture will promote germination of residual seed and reduce the size of the soil seed bank.*

- (e) no plants may be intentionally grown in the area unless:
- i) the plants are those specified in Condition 22 and planted in accordance with the conditions of this licence; or
  - ii) the plants are plants that 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 and satisfy Condition 48(a); or
  - iii) written approval is given by the Regulator for the plants to be grown in the area; or
  - iv) the Regulator has issued a Sign-off for the area.

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

49. Subject to Condition 50, livestock may be introduced into the Monitoring Zone for grazing only if:

- (a) a fence at least 1 metre high capable of excluding livestock surrounds the following areas:
  - i) the Planting Area plus 5m around the Planting Area; and
  - ii) the Pollen Trap, if any, plus 5m around the Pollen Trap; and
  - iii) any area within the Monitoring Zone used to Clean Equipment; and
  - iv) any area where the GMO was dispersed during sowing, harvest or threshing; and
  - v) any area used to Destroy the GMO, including a Burial Site; and
- (b) any gates in the fence are secured so as to exclude livestock when not being accessed by persons covered by this licence.

*Note: Grazing of the Monitoring Zone post-harvest may delay Site Sign-off (see the note for Condition 53). Fencing must also be inspected (Condition 47). Notices must be provided to the Regulator in relation to grazing of the Monitoring Zone [Condition 54(f)].*

50. Livestock must not be permitted:

- (a) within the Monitoring Zone during the period from 2 weeks prior to the projected flowering of GMO in the Planting Area until the Planting Area, Pollen Trap and Monitoring Zone have been Cleaned; and
- (b) in the Planting Area or Pollen Trap at any time prior to the Regulator issuing a Sign-off for these areas.

### **Contingency plan**

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

### **Records of inspection**

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

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

*Note: this may also include irrigation, spraying or maintenance measures used to facilitate inspections for Volunteers/Related Species.*

- (e) Details of the developmental stage of the GMOs while they are being grown;
- (f) details of any post-harvest rainfall events, including measurements at or near the area, or any irrigation events;
- (g) details of any Volunteers or Related Species observed during inspections or during land-management activities, including number, developmental stage and approximate position of the Volunteers or Related Species within each area inspected<sup>⌘</sup>;
- (h) date(s) and method(s) of Destruction, including destruction of volunteers during land-management activities, or preventing flowering of any plants;
- (i) details of any damage and any repairs to the Insect-proof tents.
- (j) details of any damage and any repairs to the fence (if used).

<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 54(g)]. The Regulator has developed a standardised proforma for recording inspection activities. This is available upon request.*

## **Section 4 Sign off**

53. 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 24 months on the area and all associated areas of land; and
- (b) conditions have been conducive for germination and detection; and
- (c) no Volunteers have occurred on these areas in the most recent 12 month inspection period.

*Note: Associated areas refer 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 two Tillage events prior to a Sign-off application (see Condition 48).*

*The Regulator will take into account the management and inspection history for the Planting Area and associated areas, 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. Additionally, as stock grazing in the Monitoring Zone may remove Volunteers before they are observed, a site will generally not be signed off if grazing has occurred in the required 12 month Volunteer-free period.*

## Section 5 Reporting and Documentation

The following licence conditions are imposed to demonstrate compliance with other conditions, facilitate monitoring of compliance by staff of the OGTR, and emphasise appropriate selection of the Planting Area.

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

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 and street address or other directions</li> <li>ii. The measures intended to manage pollen movement (ie use of Insect-proof tent or pollen trap, size of the Monitoring and Isolation Zones) for each Planting Area</li> <li>iii. Identity of the GMOs to be planted at the Planting Area</li> <li>iv. Date on which the GMOs will be planted</li> <li>v. Period when the GMOs and Pollen Trap Plants are expected to Flower</li> <li>vi. Period when windrowing (if applicable) and harvesting are expected to commence and the likely method of harvesting</li> <li>vii. How all areas requiring post-harvest inspections are intended to be used until sign off, including the proposed post-harvest crop(s) (if any)</li> <li>viii. Details on how you propose to manage inspection activities, including strategies for the detection and destruction of volunteer GMOs</li> <li>ix. History of how the site has been used for the previous two years</li> </ul>	At least 7 days prior to each planting (to be updated immediately if the notified intended planting dates 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 55 (a).</li> </ul>	Within 7 days of any planting
(c) Windrowing (if applicable)	<ul style="list-style-type: none"> <li>i. Actual date(s) of windrowing and details of measures used to minimise dispersal of the GMOs during windrowing and harvesting (Condition 36).</li> </ul>	Within 7 days of commencement of windrowing
(d) Harvest	<ul style="list-style-type: none"> <li>i. Actual date(s) of harvesting the GMOs</li> </ul>	Within 7 days of commencement of any Harvesting
(e) Cleaning	<ul style="list-style-type: none"> <li>i. Actual date(s) on which any areas needing Cleaning were Cleaned.</li> <li>ii. Method of Cleaning.</li> </ul>	Within 7 days of completion of any Cleaning
(f) Grazing (if applicable)	<ul style="list-style-type: none"> <li>i. Actual date(s) on which grazing commenced or ceased</li> </ul>	Within 7 days of commencement and within 7 days of cessation of grazing in a Monitoring Zone
(g) Inspection activities	<ul style="list-style-type: none"> <li>ii. Information recorded in a Logbook as per the inspection requirement tables.</li> </ul>	Within 35 days of Inspection

*Note: Other reports and documents that may need to be sent to the Regulator are listed in Attachment B.*

**DIR No: 149**

**Full Title:** Limited and controlled release of Indian mustard (*Juncea canola*) genetically modified for altered oil content

### **Organisation Details**

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

Phone No: (03) 9282 1359

### **IBC Details**

IBC Name: Nuseed Institutional Biosafety Committee

### **GMO Description**

#### **GMOs covered by this licence:**

*Brassica juncea* (L.) Czern. & Coss. genetically modified by introduction of only the genes and genetic elements listed below.

#### **Parent Organisms:**

Common Names: Indian mustard (*Juncea Canola*)

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

#### **Modified traits:**

Categories: Composition – food (human nutrition)  
Composition – animal nutrition  
Selectable marker

Description: *Juncea Canola* plants have been genetically modified for production of long chain polyunsaturated fatty acids in the seed. All plants also contain a selectable marker.

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

Nuseed Pty Ltd has applied for a licence to release genetically modified (GM) *Juncea Canola* into the environment on a limited scale and under controlled conditions. The purpose of the release is to evaluate to evaluate the agronomic characteristics and oil content of the GM *Juncea Canola* plants under field conditions. The GM *Juncea Canola* is not permitted to be used for human food or animal feed but GM material generated from this field trial may be used in small-scale animal nutrition studies.

#### **Commercial confidential information (CCI)**

Details of the genes and genetic elements inserted into the GM *Juncea Canola* lines were declared CCI under Section 185 of the *Gene Technology Act 2000*.

## 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	54(a)	At least 7 days prior to any planting
Planting	Planting	54(b)	Within 7 days of any planting
	Windrowing (if applicable)	54(c)	Within 7 days of commencement of windrowing
	Harvest	54(d)	Within 7 days of commencement
Post-Cleaning	Cleaning	54(e)	Within 7 days of completion
	Grazing (if applicable)	54(f)	Within 7 days of commencement and within 7 days of cessation of grazing in a Monitoring Zone
	Inspection	54(g)	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 practicable
	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
	Burial location and date (if applicable)	41(b)	Within 14 days of burial
	Extreme weather conditions	43	As soon as practically and reasonably possible, if expected or occurs
	Methods and procedures for transport	46	If and when requested