



**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 163**

**Licence holder: Nuseed Pty Ltd**

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

Issued: 6 September 2018

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 and Water Resources. 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.

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 in this licence have the same meaning as they do in the Act and the Regulations;
  - a. words importing a gender include any other gender;
  - b. words in the singular include the plural and words in the plural include the singular;
  - c. words importing persons include a partnership and a body whether corporate or otherwise;
  - d. 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;
  - e. 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;
  - f. 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 buried for the purposes of Destruction.

**'Canola'** means plants of the species *Brassica napus* L.

**'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/or 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/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 **'Destroyed'** or **'Destruction'**) means, as the case requires, killed by one or more of the following methods:

- a. cutting;
- b. shredding/mulching;
- c. treatment with herbicide;
- d. burning/incineration;
- e. burial, but only subject to the conditions of this licence;
- f. Tillage, but only subject to the conditions of this licence;

- g. autoclaving;
- h. in the case of a Facility, removal of the GMOs; 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 (e.g. bags, containers, trucks), clothing, footwear and tools.

**'Extreme Weather Event'** includes, but is not limited to, fires, flooding, cyclones, earthquakes, torrential rain, that could disperse GMOs.

**'Facility'** means a facility approved in writing by the Regulator.

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

**'GM'** means genetically modified.

**'GMOs'** means the genetically modified organisms that are the subject of the dealings authorised by this licence. GMOs include live plants and viable seed.

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

**'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, as indicated 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 GM and 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 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 m in all directions from the outer edge of a Planting Area.

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

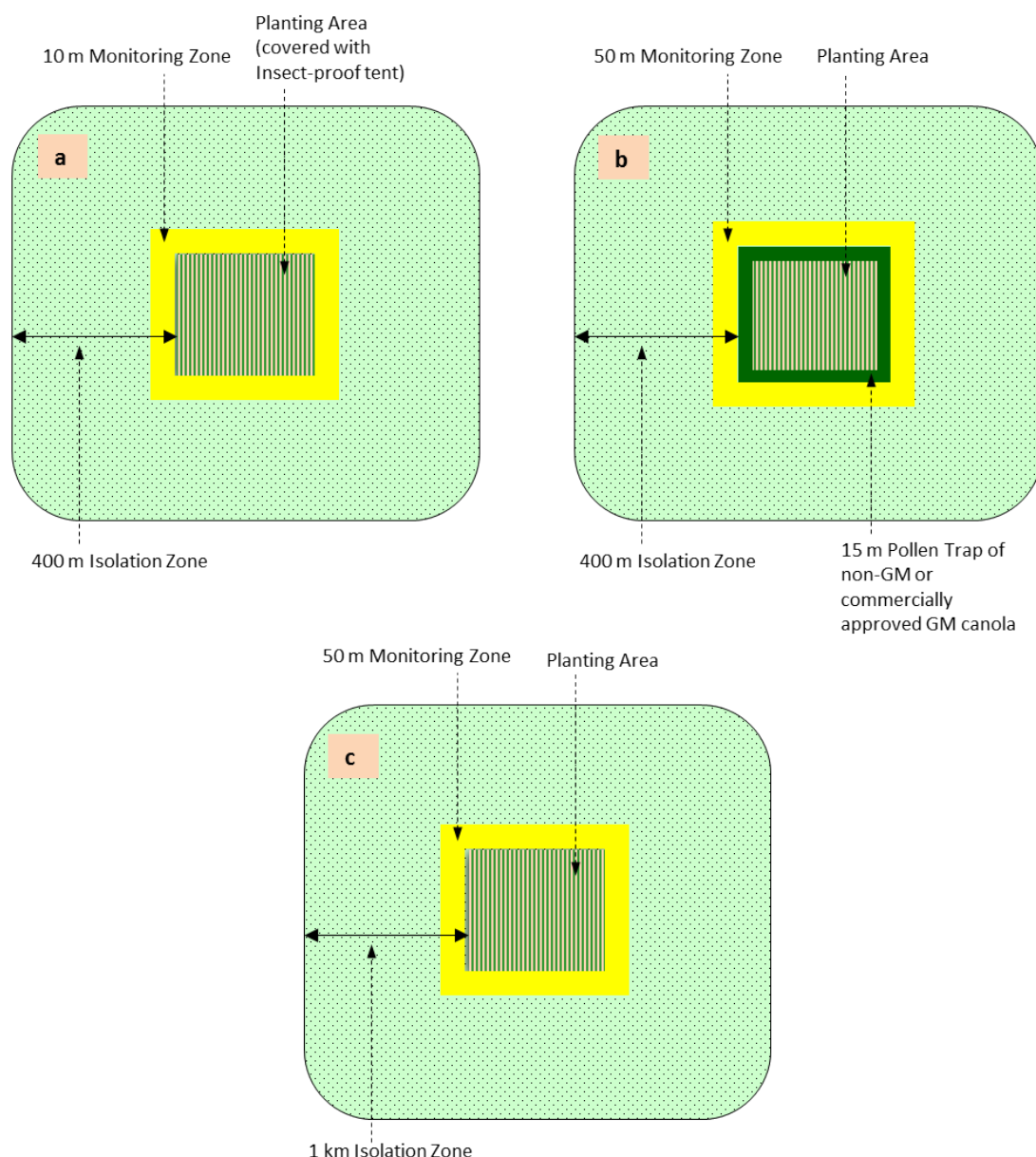
**'Related Species'** means plants of the species *Brassica napus*, *B. rapa*, *B. juncea*, *B. oleracea*, *Hirschfeldia incana*, *Raphanus raphanistrum* or *Sinapis arvensis*, but does not include the GMO or non-GM Canola plants planted and grown according to this licence.

**‘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 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). 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 (Conditions 32, 33 and 34).

## 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 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.
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 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 as soon as practically possible if any of the contact details of the project supervisor change from that notified in the licence application or subsequently.

*Note: please address correspondence to [ogtr.applications@health.gov.au](mailto:ogtr.applications@health.gov.au).*

*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 by the Regulator, 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 Facilities approved in accordance with Condition 38 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 planting 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 'Project supervisor', '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 the Planting Areas, Pollen Traps, Monitoring Zones, Isolation Zones and Facilities approved in accordance with Condition 38 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 GMO and the presence of the genetic modifications described in this licence in a recipient organism. The detection method must be capable of distinguishing between categories of GMOs approved for release to the satisfaction of the Regulator; and
- e. a 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 and 17.c, 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 flowers, 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 within a day 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, such 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.

*Note: Under the Act a place, including an area of land, is defined as a premises.*

### **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. The only plants that may be intentionally grown at a Planting Area are:
  - a. the GMOs covered by this licence as described in Attachment A of the licence;
  - b. non-GM canola plants; and
  - c. plants approved in writing by the Regulator.
23. Planting and growing of the GMOs may only occur within the following limits:



- a. Up to 20 sites, with a total maximum Planting Area of 150 ha per year, as listed in the table below

**Area and duration**

Maximum size of any Planting Area	Maximum number of Planting Areas per year	Period
5 ha	10	Nov 2018 - December 2023
10 ha	10	Nov 2018 - December 2023

- b. sites may be located in the following local government 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	Southern Downs Regional Council
Bland Shire Council	Greater Bendigo City Council	Toowoomba Regional Council
Blayney Shire Council	Buloke Shire Council	Western Downs Regional Council
Hilltops Council: Boorowa, Harden Shire and Young Shire Councils	Campaspe Shire Council	
Cabonne Shire Council	Central Goldfields Shire Council	
Carrathool Shire Council	Colac-Otway Shire Council	
Edward River Council: Conargo Shire and Deniliquin Councils	Corangamite Shire Council	
Coolamon Shire Council	Gannawarra Shire Council	
Coonamble Shire Council	Greater Geelong City Council	
Gundagai Council: Cootamundra and Gundagai Shire Councils	Glenelg Shire Council	
Federation Council: Corowa and Urana Shire Councils	Golden Plains Shire Council	
Cowra Shire Council	Hepburn Shire Council	
Forbes Shire Council	Hindmarsh Shire Council	
Gilgandra 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	
Greater Hume Shire Council	Melton Shire Council	
Murrumbidgee Council: Murrumbidgee and Jerilderie Shire Councils	Mildura Rural City Council	
Junee Shire Council	Mitchell Shire Council	
Lachlan Shire Council	Moirra Shire Council	
Leeton Shire Council	Moorabool Shire Council	

New South Wales	Victoria	Queensland
Liverpool Plains Shire Council	Mount Alexander Shire Council	
Lockhart Shire Council	Moyne Shire Council	
Mid-Western Regional Council	Murrindindi Shire Council	
Moree Plains Shire Council	Northern Grampians Shire Council	
Murray River Council: Murray Shire Council and The Council of the Shire of Wakool	Pyrenees Shire Council	
Muswellbrook Shire Council	Greater Shepparton City Council	
Narrabri Shire Council	South Gippsland Shire Council	
Narrandera Shire Council	Southern Grampians Shire Council	
Narromine Shire Council	Strathbogie Shire Council	
Orange City Council	Surf Coast Shire Council	
Parkes Shire Council	Swan Hill Rural City Council	
Tamworth Regional Council	Towong Shire Council	
Temora Shire Council	Wangaratta Rural City Council	
Snowy Valleys Council: Tumbarumba and Tumut Shire Councils	Warrnambool City Council	
Upper Hunter Shire Council	Wellington Shire Council	
Wagga Wagga City Council	West Wimmera Shire Council	
Walgett Shire Council	Wodonga City Council	
Warren Shire Council	Wyndham City Council	
Warrumbungle Shire Council	Yarriambiack Shire Council	
Weddin Shire Council		
Dubbo Regional Council: Dubbo City and Wellington Councils		

24. Subject to Conditions 25 and 26, 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. Oil from the GMOs may be used in taste testing, subject to those experiments being subject to 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.

### **Control measures**

*The following licence conditions maintain the risk assessment context within which the application was assessed by restricting spread and persistence of the GMOs.*

### **Controls to minimise 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 1c).
29. If a Pollen Trap surrounds a Planting Area:
  - a. the Pollen Trap must be planted only to non-GM canola or GM canola approved for commercial release by the Regulator 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, with the exception of a path of up to 3 m in width in order to access the Planting Area and for wheel tracks from large irrigation equipment; and
  - b. Plant Material from the Pollen Trap must be handled and controlled as if they were the GMOs or Plant Material from the GMOs.
30. A Planting Area, or a Pollen Trap if employed, must be surrounded by a Monitoring Zone.
31. The 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 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 Pollen Trap with respect to a Planting Area when a Pollen Trap is employed (Figure 1b); or
  - c. at least 50 m in all directions from the outer edge of a Planting Area without an Insect-proof tent or a Pollen Trap (Figure 1c).
32. The Monitoring Zone must be maintained in a manner appropriate to allow the identification and/or Destruction of Volunteers and Related Species whilst the GMOs are 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 53.d of this licence requires details of current land use and recent land management practices to be recorded upon inspection of the Monitoring Zone.*
33. The GMOs must not be planted or be growing 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 and 12.c regarding access and control of areas*
34. 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 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 or replace if repair not possible
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 or Destroy the GMOs in the Planting Area
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 59.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 53.*

35. If conditions regarding the area of the Isolation Zone defined as the Monitoring Zone are inconsistent with the requirements regarding the Isolation Zone, then the conditions for the Monitoring Zone prevail.

36. Non-GM Canola grown in a Planting Area must be handled as if it were the GMO.

37. The licence holder must notify the Regulator in writing as soon as reasonably practicable of any Extreme Weather Event that could cause or has led to the dispersal of GMOs beyond areas requiring Cleaning.

*Note: The Contingency Plan must be implemented if the GMOs are detected beyond areas requiring Cleaning (Condition 57).*

### **Controls during processing or experimentation with GMOs**

38. If not conducted in accordance with NLRD requirements, the following activities with the GMOs may only be undertaken within:

- a. a Planting Area, Pollen Trap or Monitoring Zone prior to post-harvest Cleaning: experimentation, analysis, threshing or processing; or
- b. a Facility approved in writing by the Regulator: experimentation, analysis, storage, threshing or processing.

*Note: Dealings conducted in accordance with Notifiable Low Risk Dealings (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.*

39. Within a Facility approved under the preceding conditions, any area that is used for experimentation, analysis, threshing, storage or processing of the GMOs must be Cleaned as soon as practicable and before use for any other purpose.

40. GMOs not required for further experimentation, or for future planting under this licence must be Destroyed as soon as practicable.

**Controls to minimise dispersal during harvest**

- 41. GMOs must be harvested separately from any other crop.
- 42. Harvesting must be conducted in a manner that minimises the likelihood of dispersal of GMOs outside the Planting Area.
- 43. 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 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.*

44. If all 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.

**Controls during transport or storage of the GMOs**

- 45. If transport or storage of the GMOs is not conducted in accordance with NLRD requirements, such activities 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; and
  - c. comply with all other conditions of this licence.

*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 the conditions of this licence.*

*Note: Condition 15 requires signed statements for persons transporting or disposing of the GMOs.*

46. Methods and procedures used for any transportation of 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 57).*

**Conditions relating to Cleaning**

47. 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, harvesting or burial	As soon as practicable
c. any area used to Clean any Equipment used in connection with the GMOs	
d. any area used to Destroy any GMOs	

e. any Facility used to store or experiment with the GMO	As soon as practicable and before use for any other purpose
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*Note: Areas of land that have been Cleaned are also subject to inspections (Condition 52), and Cleaning activities must be recorded and provided to the Regulator (Condition 59.e).*

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

*Note: If GM seeds have been dispersed around the burial pit during burial, this area will require cleaning under Condition 47, and post-cleaning licence conditions will apply.*

#### **Conditions relating to Destruction by burial**

49. Burial must be conducted in a manner that minimises the likelihood of dispersal of GMOs outside the Burial Site.

50. If Destruction of the GMOs occurs by burial:

- a. the GMOs must be buried in a pit and 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;
- b. seeds should be sufficiently irrigated at time of burial to encourage decomposition;
- c. within 14 days of burial, the Regulator must be provided a written notice with the precise location of the Burial Site (GPS coordinates and either a street address or other directions), the date on which burial occurred and a broad description of the GMOs buried (Planting Area and year the GMOs were planted);
- d. the Burial Site must not be intentionally disturbed for a period of at least 2 years from the date of burial; and
- e. the Burial Site must be inspected during this period to identify any significant disturbance, and, if disturbance is identified, take appropriate remedial action and notify the Regulator of the disturbance and the remedial action taken.

*Note: Results of inspection activities are required to be recorded in a Logbook and provided to the Regulator (Condition 53).*

51. 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 within the 2 years.

*Note: The Licence cannot be surrendered until Burial site conditions have been satisfied.*

#### **Controls to restrict persistence of the GMOs post-Cleaning**

52. Post-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,	During any period when livestock are grazing in the Monitoring Zone	Weekly	Damage	Repair as soon as practical to maintain exclusion of livestock

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

- a. date of the inspections;
- b. name of the person(s) conducting the inspections;
- c. details of the experience, training or qualification that enables the person(s) to recognise Volunteers, 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 spraying or maintenance measures used to facilitate inspections for Volunteers*

- 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 observed during inspections or during land-management activities, including number, developmental stage and approximate position of the Volunteers within each area inspected<sup>†</sup>;
- h. date(s) and method(s) of Destruction of or preventing Flowering of any Volunteers, including destruction of Volunteers during land-management activities;
- i. details of any damage and any repairs to the Insect-proof tents, and
- 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 59.h). The Regulator has developed a standardised proforma for recording inspection activities. This can be made available on request.*

### **Use of areas post-Cleaning**

54. 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 54.b must also be Tilled at least once within the 12 months prior to submission of a Sign-off application. This Tillage must occur 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 54.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 54.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.*

- 55. Subject to Condition 56, livestock may be introduced for grazing in the Isolation Zone only if:
  - a. a fence at least 1 metre high capable of excluding livestock surrounds the following areas:
    - i. the Planting Area plus 5 m around the Planting Area; and
    - ii. the Pollen Trap, if any, plus 5 m around the Pollen Trap; and
    - iii. any area which required cleaning under condition 47; and
  - b. any gates in the fence are secured so as to exclude livestock.

*Note: Grazing of the Monitoring Zone post-harvest may delay Site Sign-off (see the note for Condition 58). Fencing must also be inspected (Condition 52). Notices must be provided to the Regulator in relation to grazing of the Monitoring Zone (Condition 59.g).*



56. 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

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

### Section 4 Sign off

58. 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. all post-Cleaning inspection activities have been conducted for at least 24 months on all areas,
- b. conditions have been conducive for germination and detection of Volunteers; and
- c. no Volunteers have been detected on this area for at least 12 months of the inspection period immediately prior to the Sign off request.

*Note: A Planting Area and the aggregate of all other areas of land requiring Cleaning will be signed-off as a group rather than individually. Licence conditions require two Tillage events prior to a Sign-off application (see Condition 54).*

*The Regulator will take into account the management and inspection history for the Planting Area and other areas required 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. 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.*

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

Notice	Content of notice	Timeframe
a. Intention to Plant	<ol style="list-style-type: none"> <li>i. Details of the Planting Area including size, the local government area, GPS coordinates, a street address, a diagrammatical representation of the trial sites (e.g. Google Maps) and any other descriptions.</li> <li>ii. The measures intended to manage pollen movement (e.g. 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 (e.g. lines or construct details).</li> <li>iv. Date on which the GMOs will be planted.</li> <li>v. Period when the GMOs and Pollen Traps 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> </ol>	At least 7 days prior to each planting (to be updated immediately if the notified details change)

Notice	Content of notice	Timeframe
	<ul style="list-style-type: none"> <li>vii. How all areas requiring post-Cleaning inspections are intended to be used until sign-off, including the proposed post-harvest crop(s) (if any).</li> <li>viii. Details of how the inspection activities will be managed, 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>	
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. 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 43).</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. Burial	<ul style="list-style-type: none"> <li>i. Actual date(s) and precise location of Burial.</li> <li>ii. Broad description of the GMOs buried (Condition 50.c).</li> <li>iii. Record of any disturbance to the Burial Site and remedial actions taken.</li> <li>iv.</li> </ul>	<p>Within 14 days of any burial</p> <p>As soon as practicable</p>
g. 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
h. Inspection activities	<ul style="list-style-type: none"> <li>i. Information recorded in a Logbook as per the inspection requirement table.</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 to the licence.*

**DIR No: 163**

**Full Title:** Limited and controlled release of canola 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 1359

### **IBC Details**

IBC Name: Nuseed Institutional Biosafety Committee

### **GMO Description**

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

*Brassica napus* L. genetically modified by introduction of only the genes or genetic elements listed below.

#### **Parent Organisms:**

Common Name: Canola

Scientific Name: *Brassica napus* L.

#### **Modified traits:**

Categories: Composition – food (human nutrition)  
Composition – animal nutrition  
Selectable marker - herbicide  
Selectable marker – antibiotic  
Herbicide tolerance

Description: Canola plants have been genetically modified with the introduction of genes for production of long chain polyunsaturated fatty acids in the seed.

GM canola plants contain up to two selectable marker genes. Some GM canola categories might also contain a herbicide tolerance gene.

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

Seven of the introduced genes for production of long chain polyunsaturated fatty acids in the seed are listed in Table 1; the other four have been declared Confidential Commercial Information (CCI) under section 185 of the *Gene Technology Act 2000*. The identity of the herbicide tolerance gene has also been declared CCI.

Associated regulatory sequences for the genes are listed in Table 2. The selectable marker genes used are the *pat* gene from *Streptomyces viridochromogenes* for glufosinate tolerance and the *nptII* gene from *Escherichia coli* for kanamycin tolerance.

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

Nuseed Pty Ltd has applied for a licence to release genetically modified (GM) canola into the environment on a limited scale and under controlled conditions. The purpose of the release is to gather data under field conditions for agronomic performance, oil profile and content, nutritional assessment, compositional analysis, molecular analysis and genetic stability. The GM canola grown in this field trial would not be used in commercial human food and animal feed.

**Table 1.** Genes introduced into the category 1 GM canola.

Gene	Encoded protein	Source organism	Intended function*
<i>Lackl-Δ12D</i>	Δ12-desaturase	Yeast <i>Lachancea kluyveri</i>	Convert OA to LA
<i>Picpa-ω3D</i>	Δ15-/ω-3 desaturase	Yeast <i>Pichia pastoris</i>	Convert LA to ALA
<i>Micpu-Δ6D</i>	Δ6-desaturase	Microalgae <i>Micromonas pusilla</i>	Convert ALA to SDA
<i>Pyrco-Δ6E</i>	Δ6-elongase	Microalgae <i>Pyramimonas cordata</i>	Convert SDA to ETA
<i>Pavsa-Δ5D</i>	Δ5-desaturase	Microalgae <i>Pavlova salina</i>	Convert ETA to EPA
<i>Pyrco-Δ5E</i>	Δ5-elongase	Microalgae <i>Pyramimonas cordata</i>	Convert EPA to DPA
<i>Pavsa-Δ4D</i>	Δ4-desaturase	Microalgae <i>Pavlova salina</i>	Convert DPA to DHA

\*ALA, α-linolenic acid (18:3<sup>Δ9,12,15</sup>); DHA, docosahexaenoic acid (22:6<sup>Δ4,7,10,13,16,19</sup>); DPA, docosapentaenoic acid (22:5<sup>Δ7,10,13,16,19</sup>); EPA, eicosapentaenoic acid (20:5<sup>Δ5,8,11,14,17</sup>); ETA, eicosatetraenoic acid (20:4<sup>Δ8,11,14,17</sup>); LA, linoleic acid (18:2<sup>Δ9,12</sup>); OA, oleic acid (18:1<sup>Δ9</sup>); SDA, stearidonic acid (18:4<sup>Δ6,9,12,15</sup>).

**Table 2.** Regulatory sequences present in the GM canola.

Sequence	Intended function	Source organism
Tobacco mosaic virus 5' UTR leader	Translational enhancer	Tobacco mosaic virus (TMV) 59
MAR_Nicta- RB7	Rb7 matrix attachment region (MAR) for increasing gene expression	<i>Nicotiana tabacum</i>
PRO_Arath- FAE1	Seed specific promoter	<i>FAE1</i> gene from <i>Arabidopsis thaliana</i>
PRO_Brana-FP1	Seed specific promoter	<i>napA</i> gene from <i>Brassica napus</i>
PRO_Linus- Cn1	Seed specific promoter	<i>conlinin1</i> gene from <i>Linum usitatissimum</i>
PRO_Linus- Cn2	Seed specific promoter	<i>conlinin2</i> gene from <i>L. usitatissimum</i>
PRO_35S×2	Constitutive promoter	35S RNA gene from Cauliflower mosaic virus (CaMV)
TER_Agrtu- NOS	Terminator	nopaline synthase <i>gene from Agrobacterium tumefaciens</i>
TER_Linus- Cn1	Terminator	<i>conlinin1</i> gene from <i>L. usitatissimum</i>
TER_Linus-Cn2	Terminator	<i>L. usitatissimum conlinin2</i>
TER_Glyma-Lectin	Terminator	<i>Glycine max lectin</i>

## 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	59(a)	At least 7 days prior to any planting
Planting	Planting	59(b)	Within 7 days of any planting
	Windrowing (if applicable)	59(c)	Within 7 days of commencement of windrowing
	Harvest	59(d)	Within 7 days of commencement
Post-Cleaning	Cleaning	59 (e)	Within 7 days of completion
	Burial	59(f)i and ii 59(f)iii	Within 14 days of burial As soon as practicable
	Grazing (if applicable)	59(g)	Within 7 days of commencement and within 7 days of cessation of grazing in a Monitoring Zone
	Inspection	59(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
	Extreme weather conditions	37	As soon as practically and reasonably possible, if expected or occurs
	Methods and procedures for transport	46	If and when requested