



Australian Government

Department of Health and Aged Care

Office of the Gene Technology Regulator

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

Licence No.: DIR 164

Licence holder: Monsanto Australia Proprietary Limited

Title: Limited and controlled release of canola genetically modified for herbicide tolerance

Issued: 21 November 2018

Varied: 8 March 2022

Varied: 26 July 2022

Varied: 18 August 2022

Gene Technology Regulation in Australia

Australia's gene technology regulatory system operates as part of an integrated legislative framework. The *Gene Technology Act 2000* (Cth) and corresponding state and territory legislation form part of a nationally consistent regulatory system controlling activities involving genetically modified (GM) organisms.

This licence is issued by the Gene Technology Regulator (the Regulator) in accordance with the *Gene Technology Act 2000* and, as applicable, Corresponding State Law.

The Regulator is required to consult with, and take into account advice from, a range of key stakeholders, including other regulatory authorities, on risks to human health and safety and to the environment in assessing applications for dealings involving the intentional release of 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, Australian Industrial Chemicals Introduction Scheme and the Department of Agriculture, Fisheries and Forestry. Dealings conducted under any licence issued by the Regulator may also be subject to regulation by one or more of these agencies. It is recommended that the licence holder consult the relevant agency (or agencies) about their regulatory requirements.

Dealings permitted by this licence may also be subject to the operation of State legislation recognising areas as designated for the purpose of preserving the identity of GM crops, non-GM crops, or both GM crops and non-GM crops, for marketing purposes.

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.

Further Information of Licence DIR 164

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 (OGTR) website or by telephoning the Office on 1800 181 030.

Information about where the GMOs have been planted pursuant to this licence can be accessed on the OGTR website.

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; unless defined otherwise, words and phrases used in this licence have the same meaning as they do in the Act and the Regulations;
- (b) words importing a gender include every other gender;
- (c) words in the singular number include the plural and words in the plural number include the singular;
- (d) expressions used to denote persons generally (such as “person”, “party”, “someone”, “anyone”, “no one”, “one”, “another” and “whoever”), include a body politic or corporate as well as an individual;
- (e) references to any statute or other legislation (whether primary or subordinate) are a reference to a statute or other legislation of the Commonwealth of Australia as amended or replaced from time to time and equivalent provisions, if any, in corresponding State law, unless the contrary intention appears;
- (f) where any word or phrase is given a particular meaning, other grammatical forms of that word or phrase have corresponding meanings;
- (g) specific conditions prevail over general conditions to the extent of any inconsistency.

2. In this licence:

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

‘Burial Site’ means a place where the GMO is Destroyed by burial.

‘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.

'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.

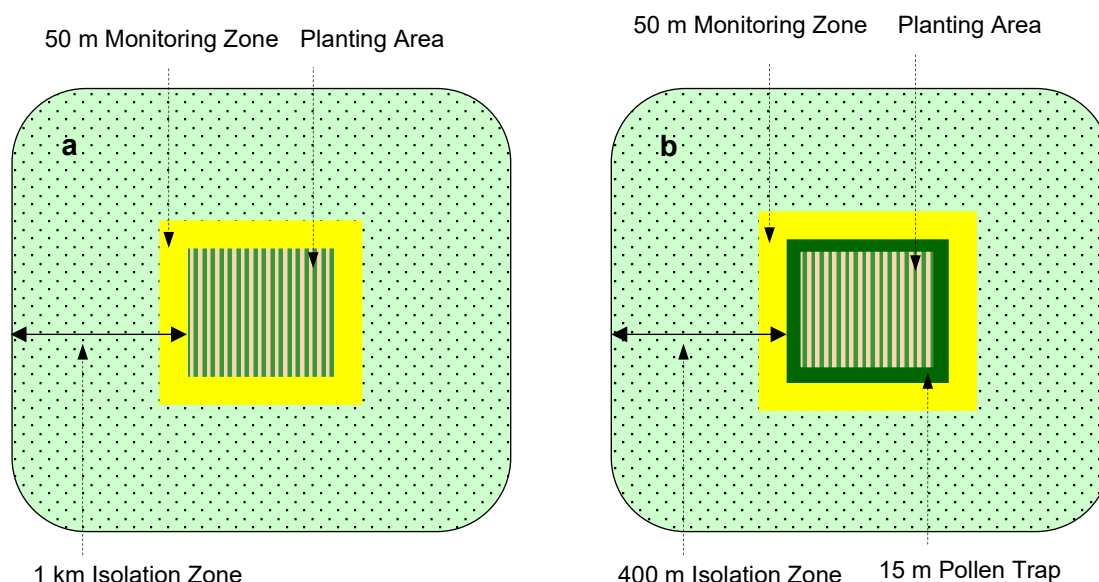


Figure 1. Diagrams showing the relationship between a Planting Area, a Pollen Trap, a Monitoring Zone and an Isolation Zone (not drawn to scale). Site-layout: **(a)** without Pollen Trap; **(b)** with Pollen Trap. Monitoring and Isolation Zones must be kept free of related species (Conditions 30, 31 and 32).

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 Monsanto Australia Proprietary Limited (Monsanto).
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 oqtr.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 licence holder 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 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 '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 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 GMO, and the presence of the genetic modifications described in this licence in a recipient organism. The detection method must be capable of identifying, to the satisfaction of the Regulator, each genetic modification event described in this licence; 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:

- *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*
- *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 100 ha per year, as listed in the table below:

Area and duration

Maximum size of each Planting Area	Maximum combined size of Planting Area per year	Maximum number of Planting Areas per year	Period
2 ha	30 ha	15	2020 - 2021
5 ha	50 ha	20	2022
20 ha	100 ha	20	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	South Australia	Queensland	Western Australia
Berrigan	Ararat	Grant	Goondiwindi	Albany
Bland	Ballarat	Kingston	Lockyer Valley	Beverley
Blaney	Benalla	Mt Gambier	Toowoomba	Boddington
Boorowa	Buloke	Naracoorte	Somerset	Boyup Brook
Cabonne	Bendigo	Robe	Southern Downs	Bridgetown-Greenbushes
Conargo	Central Goldfields	Tatiara	Western Downs	Brookton
Coolamon	Glenelg	Wattle Range		Broomehill
Coonamble	Golden Plains			Carnamah
Cootamundra	Greater Geelong			Coorow

New South Wales	Victoria	South Australia	Queensland	Western Australia
Corowa	Greater Shepparton			Corrigin
Cowra	Hepburn			Cranbrook
Deniliquin	Hindmarsh			Cuballing
Dubbo	Horsham			Cunderdin
Forbes	Indigo			Dalwallinu
Gilgandra	Loddon			Denmark
Greater Hume	Macedon Ranges			Donnybrook-Balingup
Griffith	Mitchell			Dowerin
Gunnedah	Moorabool			Dumbleyung
Gundagai	Mount Alexander			Esperance
Gwydir	Moyne			Gnowangerup
Harden	Northern Grampians			Goomalling
Jerilderie	Pyrenees			Greenough
Junee	Southern Grampians			Jerramungup
Leeton	Wangaratta			Katanning
Liverpool Plains	West Wimmera			Kent
Lockhart	Wodonga			Kojonup
Mid-Western	Wyndham			Majmimup
Moree Plains	Yarriambiack			Mingenew
Murry				Moora
Muswellbrook				Morowa
Narrabri				Mullewa
Narrandera				Narrogin
Narromine				Nannup
Orange				Northam
Parkes				Perenjori
Tamworth				Pingelly
Temora				Plantagenet
Upper Hunter				Quairading
Urana				Ravensthorpe
Wagga Wagga				Tambellup
Wakool				Tammin
Walgett				Three Springs
Warrumbungle				Toodyay
Weddin				Victoria Plains
Wellington				Wagin
Young				Wandering
				West Arthur
				Wickepin
				Williams
				Wongan-Ballidu
				Woodanilling
				Wyalkatchem
				York

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

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

25. 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.
26. For each Planting Area, one of the following measures to limit gene flow must be adopted:
 - (a) surround the Planting Area by an Isolation Zone of at least 1 km (Figure 1a); or
 - (b) surround the Planting Area by a Pollen Trap and an Isolation Zone of at least 400 m (Figure 1b).
 - (c) for Site 4 in 2022 only, surround the Planting Area by a 20 m Pollen Trap, which may exhibit the gaps identified in Attachment C, and an Isolation Zone of at least 825 m.

Note: Site 4 is bound by the following GPS coordinates: -31.0867735 116.4667246, 31.0863747 116.4664856, -31.0860715 116.4685646, -31.0856077 116.4682749

- (d) for Site 6 in 2022 only, surround the Planting Area by a Pollen Trap of at least 19.7 m, which may include patches with poor or no plant growth with a combined area of no more than 2% of the total Pollen Trap, and an Isolation Zone of at least 825 m.

Note: Site 6 is bound by the following GPS coordinates: -34.28782 116.79652, -34.28794 116.79748, -34.28874 116.79740, -34.28867 116.79647

27. 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) subject to Condition 26(c) and (d), have a reasonably dense and vigorous growth; and
 - ii) be Flowering at the same time as the GMOs; and
 - iii) subject to Condition 26(c) and (d), 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.
28. A Planting Area, or a Pollen Trap if employed, must be surrounded by a Monitoring Zone.
29. The Monitoring Zone means an area of land extending outwards:
 - (a) at least 50 m in all directions from the outer edge of a Planting Area without a Pollen Trap (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).
30. 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 51(d) of this licence requires details of current land use and recent land management practices to be recorded upon inspection of the Monitoring Zone.

31. 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.

32. While the GMOs are growing in a Planting Area, associated areas 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)	From 14 days prior to the expected commencement of Flowering of any GMOs* until 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
Monitoring Zone	From 14 days prior to the expected commencement of Flowering of any GMOs* until 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	From 14 days prior to the expected commencement of Flowering of any GMOs* until 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 57(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 51.

33. 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.
34. Non-GM Canola grown in a Planting Area must be handled as if it were the GMO.
35. 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 55).

Controls during processing or experimentation with GMOs

36. 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.

37. 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.
38. GMOs not required for further experimentation or future planting under this licence must be Destroyed as soon as practicable.

Controls to minimise dispersal during harvest

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

42. 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

43. 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.

44. 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 55).

Conditions relating to Cleaning

45. 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

Note: Areas of land that have been Cleaned are also subject to inspections (Condition 50), and Cleaning activities must be recorded and provided to the Regulator [Condition 57(e)].

46. 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 are or might have been dispersed around the burial pit during burial, this area will require cleaning under Condition 45, and post-cleaning licence conditions will apply.

Conditions relating to Destruction by burial

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

48. 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 51).

49. 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

50. 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

51. 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[†];
- (h) date(s) and method(s) of Destruction of or preventing Flowering of any Volunteers, including destruction of Volunteers during land-management activities; and
- (i) details of any damage and any repairs to the fence (if used).

[†] 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 57(h)]. The Regulator has developed a standardised proforma for recording inspection activities. This can be made available on request.

Use of areas post-Cleaning

52. 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 52(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 52(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 52(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.

53. Subject to Condition 54, livestock may be introduced 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 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 45; 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 56). Fencing must also be inspected (Condition 50). Notices must be provided to the Regulator in relation to grazing of the Monitoring Zone [Condition 57(g)].

54. 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

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

Section 4 Sign off

56. 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 the area,
 - (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 consecutive 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 52).

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.

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

Notice	Content of notice	Timeframe
a. Intention to Plant	<ul style="list-style-type: none"> 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. ii. The measures intended to manage pollen movement (e.g. use of pollen trap, size of the Monitoring and Isolation Zones) for each Planting Area 	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"> iii. Identity of the GMOs to be planted at the Planting Area (e.g. lines or construct details). iv. Date on which the GMOs will be planted. v. Period when the GMOs and Pollen Traps are expected to Flower. vi. Period when windrowing (if applicable) and harvesting are expected to commence and the likely method of harvesting. 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). viii. Details of how the inspection activities will be managed, including strategies for the detection and destruction of volunteer GMOs. ix. History of how the site has been used for the previous two years. 	
b. Planting	<ul style="list-style-type: none"> i. Actual date(s) of planting the GMOs. ii. Any changes to the details provided under part (a) of this condition. 	Within 7 days of any planting
c. Windrowing (if applicable)	<ul style="list-style-type: none"> i. Actual date(s) of windrowing and details of measures used to minimise dispersal of the GMOs during windrowing and harvesting (Condition 41). 	Within 7 days of commencement of any windrowing
d. Harvest	<ul style="list-style-type: none"> i. Actual date(s) of harvesting the GMOs. 	Within 7 days of commencement of any harvesting
e. Cleaning	<ul style="list-style-type: none"> i. Actual date(s) on which any areas needing Cleaning were Cleaned. ii. Method of Cleaning. 	Within 7 days of completion of any Cleaning
f. Burial	<ul style="list-style-type: none"> i. Actual date(s) and precise location of Burial. ii. Broad description of the GMOs buried [Condition 48(c)]. iii. Record of any disturbance to the Burial Site and remedial actions taken. 	<p>Within 14 days of any burial</p> <p>As soon as practicable</p>
g. Grazing (if applicable)	<ul style="list-style-type: none"> i. Actual date(s) on which grazing commenced or ceased. 	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"> i. Information recorded in a Logbook as per the inspection requirement table. 	Within 35 days of Inspection

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

DIR No: 164

Full Title: Limited and controlled release of canola genetically modified for herbicide tolerance

Organisation Details

Postal address:

PO Box 6051
St Kilda Road Central, VIC 8008

Phone No: (03) 9522 7122

IBC Details

IBC Name: Monsanto Australia 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:

Category: Herbicide tolerance
Hybrid breeding system

Description: Canola plants have been genetically modified for herbicide tolerance. The dicamba-tolerant line was generated by *Agrobacterium*-mediated transformation and contains the introduced *dmo* gene listed in Table 1. The GM canola line RF3, which is authorised for commercial release under DIR-021/2002, expresses a gene conferring tolerance to the herbicide glufosinate ammonium and a fertility restorer. The GM canola line generated by conventional breeding between the dicamba-tolerant line and MON88302 canola, which contains both the *dmo* and *cp4 epsps* genes (Table 1) for tolerance to both herbicides dicamba and glyphosate, is also authorised for release. The GM canola line generated by conventional breeding between the dicamba-tolerant line, MON88302 and RF3, which contains the *dmo*, *cp4 epsps*, *bar* and *barstar* genes (Table 1) for tolerance to herbicides dicamba, glyphosate and glufosinate ammonium and a fertility restorer, is also authorised for release.

The introduced regulatory sequences in these lines are listed in Table 2.

Purpose of the dealings with the GMOs:

The purpose of the release is to assess agronomic performance of the GM canola plants in all canola growing areas in Australia. The GM canola grown in this field trial is not permitted to be used for human food or animal feed.

Commercial confidential information (CCI)

The unique identifying code for the dicamba-tolerant line and details of the regulatory elements for *dmo* gene expression were declared CCI under Section 185 of the *Gene Technology Act 2000*.

Table 1. Introduced genes in the GM canola lines

Gene	Encoded protein	Source organism
<i>dmo</i>	dicamba mono-oxygenase	<i>Stenotrophomonas maltophilia</i>
<i>cp4 epsps</i>	5-enolpyruvylshikimate-3-phosphate synthase	<i>Agrobacterium</i> sp. strain CP4
<i>bar</i>	Phosphinothricin acetyl transferase	<i>Streptomyces hygroscopicus</i>
<i>barstar</i>	Barstar (RNase inhibitor)	<i>Bacillus amyloliquefaciens</i>

Table 2. Introduced regulatory elements in the GM canola lines

Regulatory element	Source
Regulatory elements for <i>dmo</i> gene - CCI	CCI
Chimeric promoter from FMV 35S transcript and <i>Tsf1</i> gene	Figwort mosaic virus and <i>Arabidopsis thaliana</i>
<i>Tsf1</i> leader and intron	<i>Arabidopsis thaliana</i>
Chloroplast transit peptide coding sequence <i>ctp2</i> from <i>epsps</i> gene	<i>Arabidopsis thaliana</i>
Terminator from rbc small subunit <i>E9</i> gene	<i>Pisum sativum</i> (pea)
<i>PSuAra</i> promoter	<i>Arabidopsis thaliana</i>
<i>3' g7</i> terminator	<i>Agrobacterium tumefaciens</i>
<i>PTa29</i> promoter	<i>Nicotiana tabacum</i>
<i>3'-nos</i> terminator	<i>Agrobacterium tumefaciens</i>

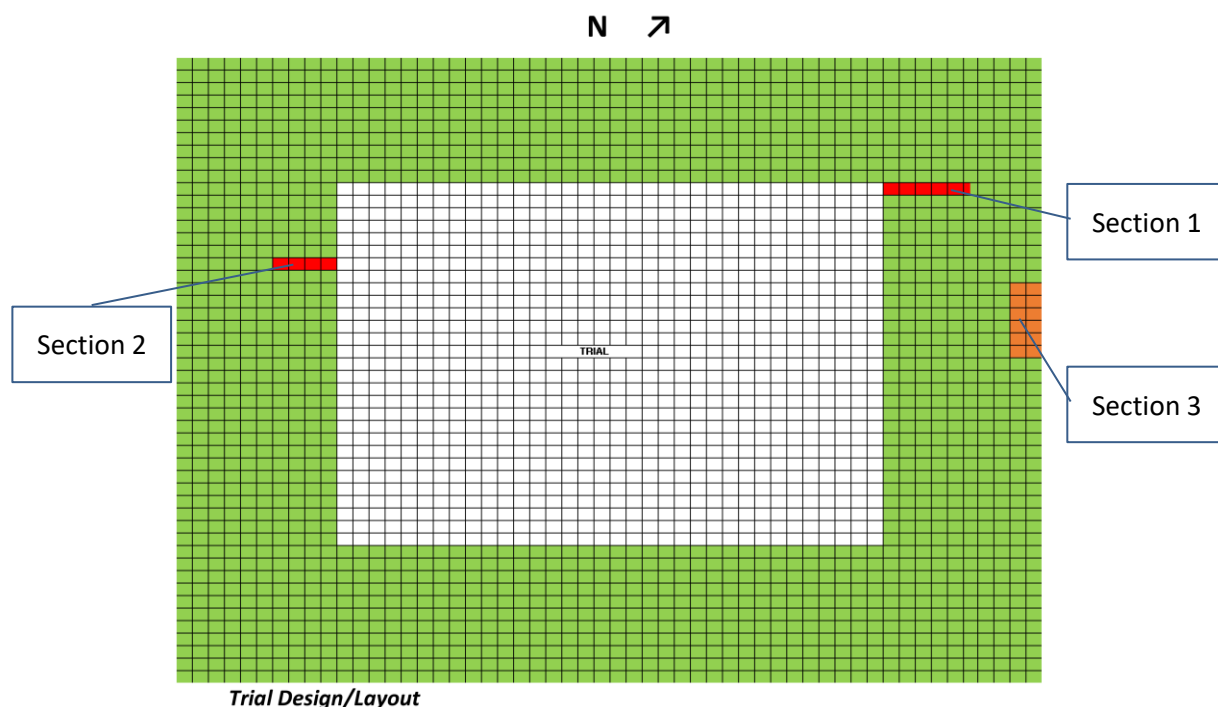
ATTACHMENT B

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	57a	At least 7 days prior to any planting
Planting	Planting	57(b)	Within 7 days of any planting
	Windrowing (if applicable)	57(c)	Within 7 days of commencement of windrowing
	Harvest	57(d)	Within 7 days of commencement
Post-Cleaning	Cleaning	57(e)	Within 7 days of completion
	Burial	57(f)i and ii 57(f)iii	Within 14 days of burial As soon as practicable
	Grazing (if applicable)	57(g)	Within 7 days of commencement and within 7 days of cessation of grazing in a Monitoring Zone
	Inspection	57(h)	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	35	As soon as practically and reasonably possible, if expected or occurs
	Methods and procedures for transport	44	If and when requested

ATTACHMENT C

The following diagram is the site-layout for Site 4 in 2022 only. White squares represent the Planting Area; green squares represent the Pollen Trap of at least 20 m. Each square is approximately 2 m².



Note: For the purposes of Condition 26(c), only the following gaps are permitted at Site 4 in 2022. Section 1 will either be no more than 12 m × 3 m in width or will be used as a path of up to 3 m in width in accordance with Condition 27(a)iii). Section 2 will be no more than 10 m × 3 m in width and Section 3 will be no more than 5 m × 12 m in width.

Note: Other than extending Section 1 to create a path of up to 3 m in width in accordance with Condition 27(a)iii), no other location within the Pollen Trap can be used as a path.