



Australian Government
Department of Health and Ageing
Office of the Gene Technology Regulator

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

Licence No.: DIR 105

Licence holder: Monsanto Australia Ltd

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

Issued: 22 December 2010
Varied: 21 March 2011

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 at <http://www.ogtr.gov.au>, 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 the development and use of 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, National Health and Medical Research Council and Australian Quarantine and Inspection Service. 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.

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 B of this licence.

Dealings permitted by this licence may also be subject to the operation of State legislation declaring areas to be GM, GM free, or both, for marketing purposes.

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 at

<http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/dir105>

Section 1 *Interpretations and Definitions*

1. In this licence:

- (a) unless defined otherwise in this licence, 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 any other gender;
- (c) words in the singular include the plural and words in the plural include the singular;
- (d) words importing persons include a partnership and a body whether corporate or otherwise;
- (e) references to any statute or other legislation (whether primary or subordinate) are a reference to a statute or other legislation of the Commonwealth of Australia as amended or replaced from time to time and equivalent provisions, if any, in corresponding State law, unless the contrary intention appears;
- (f) where any word or phrase is given a defined meaning, any other part of speech or other grammatical form in respect of that word has a corresponding meaning;
- (g) specific conditions prevail over standard conditions to the extent of any inconsistency.

2. In this licence:

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

'Approved Facility' means a facility approved in writing by the Regulator for experimentation, analysis and/or storage of the GMO, and which is signed so as to indicate that GM Plant Material is present within the facility.

'Burial site' means a place where the GMO or Plant Material is Destroyed by burial.

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

'Clean' as the case requires, means:

- (a) in relation to an area of land specified in this licence as requiring Cleaning, the Destruction of the GMO and Plant Material in that area, to the reasonable satisfaction of the Regulator; or
- (b) in relation to Equipment and Approved Facilities, the removal and Destruction of the GMO and Plant Material from the Equipment or Approved Facility, to the reasonable satisfaction of the Regulator.

'Destroy' means, as the case requires, killed by one or more of the following methods:

- (a) uprooting; or
- (b) cutting; or
- (c) shredding/mulching; or
- (d) burning/incineration; or
- (e) treatment with herbicide; or
- (f) autoclaving; or

- (g) burial, but only subject to the conditions of this licence; or
- (h) Tillage, but only subject to the conditions of this licence; 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 Plant Material remaining after harvest and additional treatment(s) may be required.

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

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

'GM' means genetically modified.

'GM InVigor[®] Canola' means GM Canola plants permitted for commercial release under licence DIR 021/2002.

'GMO' means the genetically modified organism that is the subject of the dealings authorised by this licence.

'GM Roundup Ready[®] Canola' means GM Canola plants permitted for commercial release under licence DIR 020/2002.

'Isolation Zone' means an area of land extending outwards from the outer edge of the Location, or the outer edge of the Pollen Trap with respect to a Location when a Pollen Trap is employed.

Note: The size of the Isolation Zone is dependent on additional measures to manage gene flow that are employed by the licence holder (see condition 34).

'Location' means an area of land where the GMO is planted and grown pursuant to this licence, but does not include the Pollen Trap.

'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 at least 50 metres in all directions from the outer edge of a Location, or the outer edge of a Pollen Trap with respect to a Location when a Pollen Trap is employed.

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

'Personal Information' means information or an opinion (including information forming part of a database), whether true or not, and whether recorded in a material form or not, about an individual whose identity is apparent, or can reasonably be ascertained, from the information or opinion.

'Place' means an area of land which will require Cleaning, or which has been Cleaned, pursuant to this licence.

‘Plant Material’ means any part of the GM or non-GM Canola plants grown at a Location or in the Pollen Trap with respect to a Location, whether viable or not, including, but not limited to, seed, stubble and pollen, whether from the plant itself or derived from or produced by the plant.

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

‘Pollen Trap Plants’ means non-GM Canola or GM Roundup Ready[®] Canola or InVigor[®] canola plants grown in a Pollen Trap.

‘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 a Site, that post harvest inspection conditions no longer apply in respect of that Site.

‘Site’ means the aggregate of all Places in respect of any one Location.

‘Tillage’ 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 permanent natural waterways.

Note: Irrigation channels, holding dams or storage ponds that do not flow into natural waterways are not considered Waterways for the purpose of this licence.

Section 2 *General conditions*

Duration of licence

3. This licence remains in force until it is suspended, cancelled or surrendered. No dealings with the GMO are authorised during any period of suspension.

Holder of licence

4. The holder of this licence ('the licence holder') is Monsanto Australia Ltd.

5. The licence holder must, at all times, remain an accredited organisation in accordance with the Act and comply with its instrument of accreditation.

Project supervisor

6. The project supervisor in respect of this licence is the person named in Attachment A of the final licence.

7. The licence holder must immediately notify the Regulator in writing if any of the contact details of the project supervisor change.

No dealings with the GMO except as authorised by this licence

8. Persons covered by this licence must not deal with the GMO except as expressly permitted by this licence.

Persons covered by this GMO licence

9. 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.

Informing people of their obligations

10. The licence holder must inform any person covered by this licence, to whom a particular condition of this licence applies, of the following:

- (a) the particular condition (including any variations of it);
- (b) the cancellation or suspension of the licence;
- (c) the surrender of the licence.

11. If a particular condition, including any variation of it, applies to a person with respect to a particular dealing, the licence holder must not permit a person covered by this licence to conduct that dealing unless:

- (a) the person has been informed of the condition, including any variation of it; 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 condition and, when applicable, its variation; and
 - ii) has understood and agreed to be bound by the condition, or its variation.

12. The licence holder must provide the Regulator, on the Regulator's request, with copies of the signed and dated statements referred to in the immediately preceding condition.

13. Prior to growing the GMO the licence holder must provide the Regulator with an explanation of how the licence holder has informed, or proposes to inform, each person intended to be covered by this licence of the conditions of the licence, including conditions related to the collection of Personal Information by the licence holder.

14. Where any of the details provided under the immediately preceding condition change, the Licence holder must notify the Regulator of the changes within 14 days of the change occurring.

15. The licence holder must notify the project supervisor and all persons covered by the licence that Personal Information collected by the licence holder which is relevant to the administration and/or enforcement of the licence may be released to the Regulator.

Additional information to be given to the Regulator

16. The licence holder must immediately, by notice in writing, inform the Regulator of:

- (a) any relevant conviction of the licence holder occurring after the commencement of this licence; and

- (b) 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
- (c) 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.

17. The licence holder must provide information related to the licence holder's ongoing suitability to hold a licence when requested to do so in writing by the Regulator and must provide the information within a time period stipulated by the Regulator.

18. The licence holder must inform the Regulator, as soon as practically and reasonably possible, if the licence holder:

- (a) becomes aware of 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) becomes aware of any contraventions of the licence by a person covered by the licence; or
- (c) becomes aware of 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 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, if he or she was reckless as to whether such contraventions had occurred, or such unintended effects existed.*

19. Prior to growing the GMO, the licence holder must provide to the Regulator:

- (a) a list of the names of all organisations or natural persons who will be persons covered by this licence. Where a name of a person is not known at the time of submitting the list, the function or position of the person to be covered must be provided, and
- (b) a description of the responsibilities of the licence holder and of each person covered by the licence in relation to the requirements of this licence.

Note: Examples of functions or positions are 'Site manager', 'Farm labourer' etc.

20. Where any of the details provided under the immediately preceding condition change, the Regulator must be notified of the changes within 14 days of the change occurring.

People dealing with the GMO must allow auditing and monitoring of the dealing

21. If a person is authorised by this licence to deal with the GMO 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.

22. The licence holder must be able to access all Isolation Zones and to access and control all Sites, Approved Facilities or other premises to the extent necessary to comply with this licence, for the duration of the life of the licence.

23. Prior to growing the GMO, the licence holder must provide to the Regulator a description of how any contracts or other enforceable arrangements will allow the licence holder to access and control a Site, Isolation Zone, Approved Facility or other premises to the extent necessary to comply with this licence, for the duration of the life of the licence.

24. Where any of the details provided under the immediately preceding condition change, the Licence holder must notify the Regulator of the changes within 14 days of the change occurring.

Section 3 Growing the GMO

GMO covered by this licence

25. The GMO covered by this licence is described in Attachment B of the licence.

Permitted dealings

26. The permitted dealings with the GMO are to conduct experiments with the GMO, breed, propagate, grow, culture, import, transport and dispose of the GMO, use the GMO in the course of manufacture of a thing that is not a GMO, and the possession, supply and use of the GMO in the course of any of these dealings.

Non-GM Plants and GM plants other than the GMO

27. Other than the GMO, only non-GM Canola, GM Roundup Ready[®] Canola and GM InVigor[®] Canola plants may be grown at a Location. Plant Material from these plants must be handled and controlled as if they were the GMO or Plant Material from the GMO.

28. Only Pollen Trap Plants may be grown in a Pollen Trap. Plant Material from these plants must be handled and controlled as if they were the GMO or Plant Material from the GMO.

29. To the extent that there is any inconsistency between the conditions of this licence and the conditions of licences DIR 020/2002 and DIR 021/2002, the conditions of this licence prevail.

Limits - locations, timing and size of trial

30. With respect to the permitted dealings described in condition 26, planting, propagating, growing, culturing and harvesting must only be undertaken between the date of issue of this licence and December 2014, inclusive, in the local government areas listed in the immediately following table.

Proposed Local Government Areas in which GM canola may be released

| New South Wales | Victoria | Western Australia |
|------------------------|--------------------|--------------------------|
| Berrigan | Ararat | Albany |
| Bland | Ballarat | Beverley |
| Blaney | Benalla | Boddington |
| Boorowa | Buloke | Boyup Brook |
| Cabonne | Bendigo | Bridgtown-Greenbushes |
| Conargo | Central Goldfields | Brookton |
| Coolamon | Glenelg | Broomehill |

| New South Wales | Victoria | Western Australia |
|------------------------|--------------------|--------------------------|
| Coonamble | Golden Plains | Carnamah |
| Cootamundra | Greater Geelong | Coorow |
| 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 | Manjimup |
| Moree Plains | Yarriambiack | Mingenew |
| Murray | | Moora |
| Muswellbrook | | Morawa |
| 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 |

31. Intentional planting of the GMO must occur at no more than two Locations in 2011, no more than 8 Locations in each of 2012 and 2013, and no more than 20 Locations in 2014.

32. The area of each Location must not exceed 4 ha in 2011, and 10 ha in 2012 - 2014.

Containment measures

33. The outer edge of a Location, or the outer edge of a Pollen Trap with respect to a Location when a Pollen Trap is employed, must not be within 50 metres of a Waterway.

34. Each Location, or Pollen Trap if employed, must be surrounded by a Monitoring Zone. In addition, one of the following measures to limit gene flow must be adopted:

- (a) the Location must be surrounded by an Isolation zone of at least one kilometre; or
- (b) the Location must be surrounded by a 15 metre Pollen Trap and an Isolation Zone of at least 400 metres.

35. Each Pollen Trap must be planted with only Pollen Trap Plants and maintained in such a way as to:

- (a) promote dense and vigorous growth of the Pollen Trap Plants; and
- (b) ensure that the Pollen Trap Plants Flower at the same time, and for the same period of time, as the GMOs in the Location; and
- (c) ensure that for the duration of Flowering of the GMOs there is a barrier of Pollen Trap Plants at least 15 metres deep in all directions from the outer edge of the Location, although allowance may be made for a path of approximately 2.5 metres in width in order to access the Location.

Note: If large irrigation equipment is moved into or out of a Location, wheel tracks may be left through the Pollen Trap in addition to the path permitted by condition 35(c). This is not considered to be a breach of condition 35(c).

36. The Monitoring Zone must be maintained in a manner appropriate to allow the identification and/or Destruction of Related Species whilst the GMO is growing in the Location.

Note: Measures to achieve this could include maintaining the area free of vegetation and/or keeping vegetation mown. Condition 78(d) of this licence requires details of current land use and recent land management practices to be recorded upon inspection of the Monitoring Zone.

37. The GMO must not be planted in a Location if Related Species are being intentionally grown in the Isolation Zone with respect to the Location.

Note: Other conditions of this licence require inspections for Related Species in the Location, Pollen Trap, Monitoring Zone and Isolation Zone whilst the GMO is growing in the Location (Section 7 – Inspections).

Section 4 Use of Plant Material

Plant Material not to be used in food or animal feed

38. Under this licence, Plant Material and GM plant products 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.

Experimentation and storage

39. Plant Material collected or harvested from a Location may be used for experimentation or analysis, subject to condition 38, provided the experimentation and analysis takes place:

- (a) within a Location, Pollen Trap or Monitoring Zone; or
- (b) in an Approved Facility.

40. Plant Material used for experimentation or analysis must be either stored according to the immediately following condition or Destroyed as soon as practicable after use.

41. Plant Material stored in an Approved Facility must be contained within a sealed, unbreakable container that is clearly labelled so as to identify the contained GMOs.

Note: This licence does not expressly authorise or prohibit any dealings or storage in certified physical containment facilities. Under the Act it is not an offence to deal with a GMO if the dealing is otherwise licensed or if it is an NLRD or an exempt dealing and it complies with all relevant statutory requirements.

Transportation of Plant Material

42. Plant Material may only be transported to the extent necessary to store it, Destroy it, export it, Clean it from Equipment, relocate it for dealings under another relevant authorisation under the Act, conduct experiments on it or transfer it to a Location.

43. Any Plant Material transported outside a Site must be transported in accordance with the Regulator's *Guidelines for the Transport of GMOs* as current at the time of transportation, and routes, methods and procedures used for this transportation in accordance with this licence must be documented and provided to the Regulator on request.

Use of Plant Material for future planting

44. Plant Material collected or harvested from a Location may be used for future planting in Australia pursuant to this licence, or used for dealings under another relevant authorisation under the Act.

Section 5 Harvest, Cleaning and Disposal

45. If the GMO, non-GM canola, GM Roundup Ready[®] Canola and GM InVigor[®] Canola plants grown at each Location or Pollen Trap are harvested, they must be harvested separately from any other crop.

46. If seed or other Plant Material is threshed, it must be threshed separately from any other crop.

Note: This licence does not expressly authorise or prohibit threshing in certified physical containment facilities. Under the Act it is not an offence to deal with a GMO if the dealing is otherwise licensed or if it is an NLRD or an exempt dealing and it complies with all relevant statutory requirements.

47. Cleaning of Equipment and Approved Facilities used in connection with the GMO must occur as soon as practicable after use and before it is used for any other purpose, so as to prevent dispersal of Plant Material.

48. The following Places must be Cleaned:

- (a) each Location, Pollen Trap and Monitoring Zone; and
- (b) any areas of land used to Clean Equipment used in connection with the GMO or Plant material; and
- (c) any areas of land onto which Plant Material was dispersed during harvest or threshing; and
- (d) any areas of land used to Destroy the GMO or Plant Material.

49. Places other than the Location, Pollen Trap and Monitoring Zone must be Cleaned as soon as practicable after use and before they are used for any other purpose.

50. Each Location, Pollen Trap and Monitoring Zone must be Cleaned within 60 days of harvest of the GMO and before the Location, Pollen Trap or Monitoring Zone is replanted to the GMO or becomes a Place associated with a new Location.

Note: Other conditions of this Licence require the licence holder to make records and give notices to the Regulator in relation to Cleaning of Places (Section 8 – Reporting and Documentation Requirements).

Note: If Tillage is adopted as a method of Destruction for the purpose of condition 50, it must comply with conditions 55 and 58 of this Licence.

Conditions relating to Destruction by burial

51. If Destruction of Plant Material occurs by burial, the licence holder must:

- (a) bury Plant Material in a pit dug into the ground in such a way that the Plant Material can be covered by a layer of soil at least 1 metre in depth, the top of which is no higher than the soil surface surrounding the Burial site; and

- (b) within 30 days of burial, provide the Regulator a written notice indicating the precise location of the Burial site (GPS coordinates and either a street address or other directions) and the date on which burial occurred; and
- (c) subject to condition 52, inspect the Burial site at least once every 3 months for a period of 2 years to identify any significant disturbance that may affect the emergence of Volunteers, and:
 - i) if disturbance is identified, take appropriate remedial action and notify the Regulator of the disturbance and the remedial action taken; and
 - ii) if Volunteers are identified, Clean the Burial site as soon as practicable.

Note: Results of inspection activities are required to be recorded in a Logbook and provided to the Regulator (see Section 8 – Reporting and Documentation Requirements).

52. Monitoring 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) not to disturb the Burial site for a period of at least 2 years from the date of burial; and
- (b) to notify both the licence holder and the Regulator in writing of any significant disturbance of the Burial site that may affect the emergence of Volunteers.

Section 6 Conditions on use of Locations and Pollen Traps after harvest and Places after Cleaning

General conditions on use of Location post - harvest

53. Following Cleaning, each Place must be maintained in a manner appropriate to allow the identification of Volunteers for as long as inspections are required for the Site.

Note: Condition 78(d) of this licence requires details of current land use to be recorded upon inspection of all Places with respect to a Site.

54. Unless permitted by this licence, no plants may be intentionally grown in a Place following its Cleaning unless:

- (a) the plants are the GMO, non-GM Canola, GM Roundup Ready[®] Canola or GM InVigor[®] Canola plants planted in accordance with the conditions of this licence; or
- (b) the plants are plants that are listed as permitted in the OGTR policy on post-harvest crops as current at the time of planting (refer to table that specifies the post-harvest crops permitted for GM *Brassica* field trial sites at <<http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/policies-1>>); or
- (c) the plants are plants agreed to in writing by the Regulator; or
- (d) the Regulator has issued a Sign-off for the Site.

Conditions related to Tillage

55. All Places in respect of a Location must be Tilled within 60 days of harvest of the GMO at a Location, unless otherwise approved in writing by the Regulator. Tillage must occur in conditions where germination of Volunteers is reasonably likely to ensue (e.g. immediately after rain or irrigation). Tillage must occur before the Location, Pollen Trap or Monitoring Zone is replanted with the GMO or becomes a Place associated with a new Location.

Note: Conditions 50 and 55 of this licence require that all Places in respect of a Location must be Cleaned and Tilled before the Location, Pollen Trap or Monitoring Zone is replanted with the GMO or becomes a Places associated with a new Location.

Note: Delaying Tillage until at least 28 days after harvest may result in reduced persistence of seed in the soil, but if conditions are conducive to germination Tillage may be carried out earlier.

56. All Places in respect of the Site must be Tilled at least once in conditions where germination of Volunteers is reasonably likely to ensue (e.g. immediately after rain or irrigation) within the 12 months prior to submission of a Sign-off application.

57. Additional Tillage of Places after harvest of the GMO at a Location is permitted only after the Tillage event required by condition 55 of this licence has been completed.

Note: Additional Tillage (other than that required by conditions 55 and 56) 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.

58. Tillage must not bury plant material to a depth of more than 5 cm.

Note: Condition 78(e) of this licence requires details of all Tillage events to be recorded upon inspection of all Places with respect to a Site.

Section 7 Inspections

59. Inspections must be performed by a person who is able to recognise Volunteers and Related Species. Details of the experience, training or qualification that enables them to recognise Volunteers and Related Species must be provided to the Regulator within 14 days of their first inspection.

Note: Results of inspection activities are required to be provided to the Regulator (see Section 8 – Reporting and Documentation Requirements). However, contraventions of licence conditions must be reported as soon as reasonably and practically possible according to condition 18.

Inspections to be conducted while the GMO is being grown

60. Inspections must be conducted at least once every 35 days, beginning 14 days before the expected commencement of flowering of the GMOs at a Location and continuing until the Location, Pollen Trap and Monitoring Zone have been Cleaned.

61. Each Location, Pollen Trap and Monitoring Zone must be inspected for the presence of Related Species, and any Related Species occurring in these areas must be either Destroyed before Flowering or prevented from Flowering.

62. Each Isolation Zone must be inspected for the presence of intentionally planted Related Species, and if any Related Species is found to be planted or grown within the Isolation Zone whilst the GMO is being grown in a Location, either the GMOs in the Location or the Related Species must be Destroyed prior to Flowering of the GMOs.

Note: If the GMOs 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.

Note: Results of inspection activities under both condition 61 and condition 62 of this licence must be reported to the Regulator (see Section 8 – Reporting and Documentation Requirements).

Post-Cleaning inspections

63. All Places must be inspected for the existence of Volunteers at least once every 35 days commencing on the day of Cleaning and continuing until:

- (a) the area is replanted to the GMO or becomes a Place associated with a new Location;
or
- (b) the Regulator has issued a Sign-off for the Site.

Note: Areas of land which become Places in respect of a new Location effectively cease to be considered Places in respect of the post-Cleaning Location. For example, a new Location may be established in a former Monitoring Zone post-Cleaning. Part of the post-Cleaning Monitoring Zone would then be within the Monitoring Zone of the new Location and would cease to be subject to post-Cleaning inspections whilst the GMO is growing in the new Location but would be subject to inspection under condition 61. Other parts of the post-Cleaning Monitoring Zone which have not become a Place associated with the new Location will continue to be subject to post-Cleaning inspection under condition 63.

Note: Results of inspection activities under condition 63 of this licence must be reported to the Regulator (see Section 8 – Reporting and Documentation Requirements).

64. Any Volunteers in a Place must be Destroyed prior to the Volunteers Flowering.

65. Inspection requirements do not apply in respect of a Place if the licence holder has received a Sign-off for the Site.

Sign off

66. The licence holder may make written application to the Regulator that inspection conditions no longer apply to a Site if inspections have been routinely completed for a period of at least 24 months and no Volunteers have been observed in the most recent 12 month inspection period.

Note: Licence conditions require two Tillage events for all Places prior to a Sign-off application (see Section 6 – Conditions on use of Locations and Pollen Traps after harvest and Places after Cleaning). The Regulator will take into account the management and inspection history for the Site, including Tillage and irrigation regimes, management of any post-harvest crops and occurrence of volunteers, in deciding whether or not he is satisfied that no further inspections are required to manage persistence of the GMO.

Section 8 Reporting and Documentation Requirements

Contingency Plan for unintended presence of Plant Material

67. Within 30 days of the date of issue of this licence, a written Contingency Plan must be submitted to the Regulator detailing measures to be taken in the event of the unintended presence of the GMO or Plant Material outside an area that must be inspected.

68. The Contingency Plan must include details of procedures to:

- (a) ensure the Regulator is notified immediately if the licence holder becomes aware of the event; and
- (b) Destroy any of the GMO or Plant Material; and
- (c) inspect for and Destroy any Volunteers that may exist as a result of the event.

69. The Contingency Plan must be implemented in the event that the unintended presence of the GMO or Plant Material is discovered outside an area that must be inspected.

Notice of intention to plant, planting and Flowering

70. At least 7 days prior to the date on which planting of the GMO is intended to commence, the licence holder must provide a notice in writing to the Regulator which contains:

- (a) the date(s) on which planting of the GMO and Pollen Trap Plants (if any) is intended to commence; and
- (b) details of each Location where the GMO will be planted, including if the Location was previously used as a Location, Pollen Trap or Monitoring Zone under this licence, the size of each Location, the local government area, GPS coordinates and street address for each Location; and
- (c) the identity of the GMO which is intended to be planted; and
- (d) whether or not the Location will be surrounded by a Pollen Trap; and
- (e) the size of the Isolation Zone employed with respect to each Location; and
- (f) the period during which the licence holder considers the GMO and Pollen Trap Plants are likely to flower; and
- (g) the period during which the licence holder considers the GMO is likely to be windrowed (if applicable) and harvested and the likely method of harvesting; and

- (h) the period during which the licence holder considers each Location and Pollen Trap with respect to each Location, if any, are likely to be Cleaned; and
- (i) if GMOs have previously been planted at a Location or within the Pollen Trap or Monitoring Zone with respect to that Location under a different authorisation under the Act, a history indicating how the Location, Pollen Trap or Monitoring Zone has been used in the preceding 2 years, including details of previous GMOs and post-harvest crops planted; and
- (j) a description of how the Location is intended to be used during the first 2 years following the harvest of the GMO.

71. Within 7 days of planting of the GMO, the licence holder must provide a notice in writing to the Regulator which indicates the actual date(s) on which planting of the GMO and any Pollen Trap Plants occurred and any changes in the details required to be provided under the immediately preceding condition.

72. Between 21 and 7 days before the expected commencement of each Flowering season of the GMO, the licence holder must provide a notice in writing to the Regulator indicating the period during which the licence holder considers the GMO and any Pollen Trap Plants are likely to remain Flowering and any changes in the details provided under the preceding two conditions.

73. Within 7 days of the commencement of each Flowering season of the GMO, the licence holder must provide a notice in writing to the Regulator which contains the actual date on which Flowering of the GMO and any Pollen Trap Plants commenced and indicating any changes in the details provided under the preceding three conditions.

Notice of windrowing, harvest and Cleaning

74. The licence holder must provide the Regulator with a notice of intention to harvest the GMO at each Location. This notice must be provided at least 7 days, and not more than 21 days, in advance of the intended date of windrowing or harvest set out in the relevant notice. The notice must indicate the proposed method of harvest and, if windrowing is proposed, indicate intended dates of both windrowing and harvest. Any change of intention prior to the intended harvest date must be notified to the Regulator as soon as is reasonably and practically possible.

75. Within 7 days of commencement of harvesting of the GMO at a Location, the licence holder must provide the actual date or dates of commencement of harvesting of the GMO at a Location.

76. Within 14 days of the date on which Cleaning of a Place is completed, the licence holder must provide a notice in writing to the Regulator indicating the date or dates on which Cleaning was undertaken.

77. On the request of the Regulator, the licence holder must provide written documentation of the procedures in place to ensure compliance with the Cleaning conditions in this licence.

Notices of inspection activities

78. The results of all inspection activities must be recorded in a Logbook and must contain at least the following:

- (a) the date(s) of inspection; and
- (b) the names of the person or persons who undertook the inspection; and
- (c) details of the areas inspected; and
- (d) details of current land use (eg type of crop being grown) and of recent land management practices (eg irrigation, spraying and any maintenance measures used to facilitate inspections for Volunteers/Related Species) applied in all areas inspected; and
- (e) details of all Tillage undertaken including date(s) that Tillage occurred, Places Tilled, technique(s) used and any relevant rainfall or irrigation data associated with the Tillage event; and
- (f) details of any rainfall events at the Location that occur after harvest of the GMOs, including measurements of any rainfall at or near the Location;
- (g) the number of Volunteers and/or Related Species observed in the Location, Pollen Trap and Monitoring Zone, if any; and
- (h) details of the development stages reached by the Volunteers and Related Species found in the Location, Pollen Trap and Monitoring Zone, if any; and
- (i) details of methods used to Destroy Volunteers and Related Species found in the Location, Pollen Trap and Monitoring Zone, if any, and the actual date(s) of Destruction, if different from the date of inspection; and
- (j) details of any Related Species planted or grown in the Isolation Zone and any relevant destruction activities as per condition 62.

79. The results of the inspections as recorded in the Logbook must be forwarded to the Regulator within 35 days of inspection taking place.

Extreme weather conditions

80. The licence holder must immediately, by notice in writing, inform the Regulator of any extreme weather conditions such as strong winds or flooding that have affected a Site whilst the GMO is growing at a Location and until the Site is Cleaned, noting any movement of GM material off site.

Note: The Contingency Plan must be implemented in the event that the GMO or Plant Material is moved off site, as per condition 69.

Other records to be kept

81. The licence holder must keep records of the area planted to the GM Canola line.

Testing methodology

82. The licence holder must provide a written instrument to the Regulator describing an experimental method that is capable of reliably detecting the presence of the GMO and the presence of the genetic modifications described in this licence in a recipient organism. The instrument must be provided within 30 days of the issuing of this licence.

DIR No: 105

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

Organisation Details

Postal address: Monsanto Australia Ltd
PO Box 6051
ST KILDA ROAD CENTRAL VIC 8008

Phone No: (03) 9522 7122

Project Supervisor Details

Surname: *[Personal information redacted]*

First Name: *[Personal information redacted]*

Title: *[Personal information redacted]*

Phone No: *[Personal information redacted]*

Fax: *[Personal information redacted]*

Email Address: *[Personal information redacted]*

Position: *[Personal information redacted]*

Organisation: Monsanto Australia Ltd

Postal Address: PO Box 6051
ST KILDA ROAD CENTRAL VIC 8008

IBC Details

IBC Name: Monsanto Australia Limited IBC

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

A line of *Brassica napus* L. genetically modified by introduction of only the gene and genetic elements listed below.

***Parent Organisms:**

Common Names: Canola
 Scientific Names: *Brassica napus* L.

***Modified traits:**

Categories: Herbicide tolerance
 Description: GM Canola line generated by *Agrobacterium*-mediated transformation, containing the gene described below.

***Genetic elements responsible for conferring the modified traits:**

Promoter: FMV/*Tsfl* (Figwort mosaic virus/*Arabidopsis thaliana*)
 Gene: *cp4 epsps* (*Agrobacterium tumefaciens*) – herbicide tolerance
 Terminator: 3' *E9* (*Pisum sativum*)
 Other regulatory elements: *Tsfl* leader and intron sequences (*Arabidopsis thaliana*), CTP2 chloroplast transit peptide (*Arabidopsis thaliana*)

Purpose of the dealings with the GMOs:

Monsanto Australia Ltd applied for a licence for dealings involving the intentional release of GM canola into the environment on a limited scale and under controlled conditions. The purpose of the release is to evaluate the agronomic performance of GM canola line under field conditions.

* Information that must be included in the Record of GM Products and GMO dealings.