



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 103

Licence holder: The Victorian Department of Primary Industries

Title: Limited and controlled release of canola genetically modified for enhanced yield and delayed leaf senescence

Issued: 6 August 2010
Varied: 26 August 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/dir103>

Section 1 Interpretations and Definitions

1. This licence does not authorise dealings with GMOs that are otherwise prohibited as a result of the operation of State legislation declaring areas to be GM, GM free, or both, for marketing purposes.
2. 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.
3. In this licence:

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

'Annual Report' means a written report provided to the Regulator within 90 days of each anniversary of issue of this licence containing all the information required by this licence to be provided in the Annual Report.

'Burial site' means a place where GMOs or Plant Material from the GMOs are Destroyed by burial.

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

'Clean', as the case requires, means:

- (a) in relation to an area specified in this licence as requiring Cleaning, the Destruction of the GMOs and Plant Material in that area, to the reasonable satisfaction of the Regulator; or
- (b) in relation to Equipment, the removal and Destruction of the GMOs and Plant Material from the Equipment, 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) mowing; or
- (d) slashing; or
- (e) shredding/mulching; or
- (f) burning/incineration; or
- (g) treatment with herbicide; or
- (h) autoclaving; or
- (i) burial, but only subject to the conditions of this licence; or
- (j) tillage, but only subject to the conditions of this licence; or
- (k) 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 and tools.

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

'GM' means genetically modified.

'GMOs' means the genetically modified organisms that are the subject of the dealings authorised by this licence.

'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 the additional measures to manage gene flow that are employed by the licence holder (see Condition 32).

'Location' means an area of land where the GMOs are 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.

'Natural Waterways' means waterways other than irrigation channels, holding dams or storage ponds used to collect water runoff from irrigated areas.

'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 plants grown in a Pollen Trap.

‘Related Species’ means plants of the species *Brassica napus*, *Brassica rapa*, *Brassica juncea*, *Brassica oleracea*, *Hirschfeldia incana*, *Raphanus raphanistrum* or *Sinapis arvensis*, but does not include the GMOs 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 obligations no longer apply in respect of that Site.

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

‘Volunteers’ means GM or non-GM Canola plants which have not been intentionally grown.

Section 2 General conditions

Duration of licence

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

Holder of licence

5. The holder of this licence ('the licence holder') is the Victorian Department of Primary Industries.

6. 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

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

8. 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 GMOs except as authorised by this licence

9. Persons covered by this licence must not deal with the GMOs except as expressly permitted by this licence.

Persons covered by this GMO licence

10. 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

11. 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.
12. 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.
13. 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.
14. Prior to growing the GMOs 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.
15. 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.
16. 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

17. 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.
18. 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.
19. The licence holder must inform the Regulator 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.*

20. The licence holder must provide the information required by paragraphs (a), (b) and (c) of the immediately preceding condition to the Regulator as soon as practically and reasonably possible, and must also include the information in the Annual Report.

21. Prior to growing the GMOs, 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.

22. 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 GMOs must allow auditing and monitoring of the dealing

23. 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.

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

25. Where the licence holder does not have legal access and control of a Site, Monitoring Zone, Isolation Zone, approved facility or other premise to the extent necessary to comply with this licence, for the duration of the life of the licence, then prior to growing the GMOs, 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, Monitoring Zone, Isolation Zone, approved facility or other premise to the extent necessary to comply with this licence, for the duration of the life of the licence.

26. 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 GMOs

GMOs covered by this licence

27. The GMOs covered by this licence are described in Attachment B.

Permitted dealings

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

Non-GM Plants

29. Other than the GMOs, only non-GM Canola plants may be grown at a Location or Pollen Trap with respect to a Location, and Plant Material from these plants must be handled and controlled as if they were the GMOs or Plant Material from the GMOs.

Limits - locations, timing and size of trial

30. With respect to the permitted dealings described in condition 28, planting, propagating, growing, culturing and harvesting must only be undertaken between the date of issue of this licence and May 2012, inclusive, at Victorian Government research stations within the local government areas of Horsham and Southern Grampians, Victoria.

31. Intentional planting of the GMOs must occur at no more than one Location per growing season in each of the local government areas listed in the immediately preceding condition, and the area of each Location must not exceed 0.4 hectares.

Containment measures

32. Each Location must be surrounded by either:

- (a) a Pollen Trap, a Monitoring Zone and an Isolation Zone of at least 400 m from the outer edge of the Location; or
- (b) a Monitoring Zone and an Isolation Zone of at least 1 km from the outer edge of the Location

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

- (a) promote a 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; and
- (c) ensure that for the duration of Flowering of the GMOs there is a continuous barrier of plants at least 15 metres deep in all directions around the Location, although allowance may be made for a path of approximately 2.5 metres in width in order to access the location.

35. If the immediately preceding condition cannot be satisfied, one of the following measures to limit gene flow must be adopted:

- (a) all flower buds of the GMOs must be covered with insect-proof selfing bags at least seven days prior to Flowering and must remain in place until completion of Flowering; or
- (b) GMOs must be prevented from Flowering by removal of flower buds; or
- (c) the Location must be surrounded by an Isolation Zone of at least one kilometre.

Note: Other conditions of this Licence require the licence holder to give notices to the Regulator in relation to containment measures employed (Section 8 – Reporting and documentation).

36. A Monitoring Zone may only consist of an area of land:

- (a) free of vegetation; or
- (b) kept mown such that all vegetation is at a height of 10 cm or less; or
- (c) planted with a plant species agreed to in writing by the Regulator.

37. GMOs 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, and control of, Related Species in the Location, Pollen Trap, Monitoring Zone and Isolation Zone while the GMOs are 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 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 or soil from a Location or Pollen Trap may be collected or harvested and used for experimentation or analysis provided the experimentation and analysis takes place:

- (a) within a Location or Pollen Trap; or
- (b) at the CSBP Ltd., 2 Altona Street, Bibra lake, WA 6163; or
- (c) in a facility approved in writing by the Regulator and signed so as to indicate that GM Plant Material is present within the facility.

Note: Soil collected from a Location or Pollen Trap may contain Plant Material

40. Plant Material and soil containing Plant Material must either be stored or Destroyed as soon as practicable after use.

41. Plant Material may be stored off Site in a facility approved in writing by the Regulator and signed so as to indicate that GM Plant Material is stored within the facility. Stored Plant Material 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 or soil containing Plant Material may only be transported to the extent necessary to store it, Destroy it, export it, Clean it from Equipment, conduct experiments or analysis on it, transfer it to a Location or relocate it for the purpose of conducting dealings pursuant to another relevant authorisation under the Act.

43. Any Plant Material or soil containing Plant Material transported outside a Site must be transported in accordance with the Regulator's *Guidelines for the Transport, Storage and Dispersal 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.

Section 5 Harvest, Cleaning and Disposal

44. If the GMOs or non-GM plants grown at a Location or Pollen Trap are harvested, they must be harvested separately from any other crop.

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

46. If a thresher is used, threshing must take place within the Location or Pollen Trap.

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 used in connection with the GMOs 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 and Pollen Trap; and
- (b) any areas used to Clean Equipment used in connection with the GMOs or Plant Material; and
- (c) any areas onto which Plant Material was dispersed during harvest or threshing of the GMOs; and
- (d) any areas used to Destroy the GMOs or Plant Material; and
- (e) any areas used to store or experiment on Plant Material.

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

50. Each Location and associated Pollen Trap must be Cleaned within 60 days of harvest of the GMOs or before the Location is replanted to the GMOs, whichever occurs first.

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).

51. Each Location and associated Pollen Trap must not be tilled for at least 28 days after the GMOs at the Location are harvested, but must be tilled within 60 days after harvest of the GMOs and before the Location is replanted to the GMOs.

Note: If tillage is adopted as a method of Cleaning for the purpose of Condition 50, this can count as the tillage event required in Condition 51.

Note: All tillage events must comply with Conditions 57 and 58 of this Licence.

Conditions relating to Destruction by burial

52. 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 notice in writing of the precise location of the Burial site (GPS coordinates and either a street address or other directions to the Location) and the date on which burial occurred; and
- (c) 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).

53. 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 other Places after harvest

General conditions on use of Places post-harvest

54. 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.

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

- (a) the plants are the GMOs or non-GM 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 relevant Site.

56. Prior to an application for Sign-off in respect of a Site, all Places in respect of the Site must be tilled at least twice. The first tillage event must occur as specified in Condition 51. The last tillage must occur within 12 months prior to submission of a Sign-off application.

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

58. Tillage must occur in conditions where germination of Volunteers is reasonably likely to ensue (for example, immediately after rain or irrigation).

Note: Condition 59 prohibits tillage at times when germination of the GMOs is not likely to ensue as a result (eg during drought).

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).

Inspections to be conducted while the GMOs are 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, and associated Pollen Trap have been Cleaned.

61. Each Location and Pollen Trap must be inspected for

- (a) the presence of Related Species, and any Related Species occurring in these areas must be either Destroyed before Flowering or prevented from Flowering; and
- (b) growth and Flowering of GMOs and Pollen Trap Plants, in order to determine if condition 35 should apply; and
- (c) GM flower buds, and if Condition 35(a) or (b) applies, any GM flower buds must be bagged or removed prior to Flowering.

62. The Monitoring Zone must be inspected for the presence of Volunteers and Related Species, and any Volunteers or Related Species occurring in these areas must be either Destroyed before Flowering or prevented from Flowering.

63. 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 GMOs are 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.

Post-Cleaning inspections

64. 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 GMOs; or
- (b) the Regulator has issued a Sign-off for the Site.

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

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

Sign off

67. 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 GMOs.

Section 8 Reporting and Documentation Requirements

Contingency Plan for unintended presence of Plant Material

68. 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 GMOs or Plant Material outside an area that must be inspected.

69. 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 GMOs or Plant Material; and
- (c) inspect for and Destroy any Volunteers that may exist as a result of the event.

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

Notice of intention to plant, planting, Flowering and containment measures

71. At least 7 days prior to the date on which planting of the GMOs 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 GMOs and Pollen Trap Plants is intended to commence; and
- (b) details of each Location where the GMOs will be planted, including the size of each Location, the local government area and GPS coordinates for each Location; and
- (c) the identity of the GMOs which are intended to be planted; and

- (d) the period during which the licence holder considers the GMOs and Pollen Trap Plants are likely to flower; and
- (e) the period during which the licence holder considers the GMOs are likely to be harvested (or Destroyed in lieu of harvest); and
- (f) the period during which the licence holder considers each Location and Pollen Trap with respect to each Location are likely to be Cleaned; and
- (g) if GMOs have previously been planted at a Location, a history indicating how the Location and the Pollen Trap with respect to that Location has been used in the preceding 2 years, including details of previous GMOs and post-harvest crops planted at the Location and the Pollen Trap with respect to that Location; and
- (h) a description of how the Location is intended to be used during the first 2 years following the harvest of the GMOs.
- (i) containment measures employed to limit gene flow according to Condition 32.

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

73. Between 21 and 7 days before the expected commencement of each Flowering season of the GMOs, the licence holder must provide a notice in writing to the Regulator which contains

- (a) the changes in Flowering date, if Flowering is expected to begin or end more than 7 days outside the previously notified Flowering period; or
- (b) the containment measure to be employed to limit gene flow if the growth and Flowering of Pollen Trap Plants does not satisfy Condition 34; or
- (c) the changes if any other details provided under the preceding two conditions have changed.

74. Within 7 days of the commencement of each Flowering season of the GMOs, the licence holder must provide a notice in writing to the Regulator which contains

- (a) the actual date on which Flowering of the GMOs commenced; and
- (b) if applicable, the containment measure selected to limit gene flow under Condition 35; and
- (c) the actual date on which removal of flower buds commenced and how long bud removal is expected to continue, if the GMOs are prevented from Flowering; and
- (d) the actual date on which bagging of flower buds commenced and how long bagging is expected to continue, if the GM flower buds are bagged; and
- (e) the size of the Isolation Zone employed with respect to each location; and
- (f) any changes in the details provided under the preceding three conditions.

Notice of harvest and Cleaning

75. The licence holder must provide the Regulator with a notice of intention to harvest the GMOs 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 harvest set out in the relevant notice. Any change of

intention prior to the intended harvest date must be notified to the Regulator as soon as is reasonably and practically possible.

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

77. 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.

78. 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

79. 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, cultivation or spraying) applied in the areas inspected; and
- (e) details of any rainfall events at the Location including measurements of any rainfall at or near the Location;
- (f) the number of Volunteers and/or Related Species observed, if any; and
- (g) details of the development stages reached by the Volunteers and Related Species, if any; and
- (h) details of methods used to Destroy Volunteers and Related Species, if any, and the actual date(s) of Destruction, if different from the date of inspection.
- (i) details of removal of flowers or bagging, if used.

80. The results of the inspections as recorded in the Logbook must be forwarded to the Regulator within 35 days of inspection taking place and must also be included in the licence holder's Annual Report to the Regulator.

Other records to be kept

81. The licence holder must keep records of the type of GM Canola lines grown at each Location as part of the trial, and the area planted to each GM Canola line.

Annual Report

82. The licence holder must provide an Annual Report to the Regulator.

Note: Conditions 20 and 80 specify information to be included in an Annual Report.

Testing methodology

83. 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 GMOs 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: 103

***Full Title:** Limited and controlled release of canola genetically modified for enhanced yield and delayed leaf senescence

Organisation Details

Postal address: The Victorian Department of Primary Industries
Victorian Agribiosciences Centre
1 Park Drive
BUNDOORA VIC 3083

Phone No: (03) 9032 7000

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: The Victorian Department of Primary Industries

Postal Address: Victorian Agribiosciences Centre
1 Park Drive
BUNDOORA VIC 3083

IBC Details

IBC Name: Department of Primary Industries - Victoria

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

Up to 10 lines of *Brassica napus* L. genetically modified by introduction of only the genes and genetic elements listed below.

***Parent Organism:**

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

***Modified traits:**

Categories: Enhanced yield
 Delayed leaf senescence
 Antibiotic resistance

Description: Canola plants have been genetically modified for enhanced yield and delayed leaf senescence. The plants also contain an antibiotic resistance marker.

Genetic elements responsible for conferring the modified traits:*Enhanced yield and delayed leaf senescence:**

ipt gene from *Agrobacterium tumefaciens*
 modified *AtMYB32* promoter from *Arabidopsis thaliana*

Antibiotic resistance:

hph gene from *Escherichia coli*

Purpose of the dealings with the GMOs:

The Victorian Department of Primary Industries 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 conduct experiments to evaluate agronomic performance, including seed yield, of the GM canola lines under field conditions. Some seed would be collected and retained for analysis and possible future trials, subject to further approval(s).

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