



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 069/2006

Licence holder: Bayer CropScience Pty Ltd

Title: Limited and controlled release of GM herbicide tolerant hybrid *Brassica napus* and *Brassica juncea*

Issued: 28 March 2007

Varied: 8 October 2007

Varied: 8 October 2009

Varied: 24 March 2010

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).

The Gene Technology Regulator is required to consult with, and take into account advice from a range of key stakeholders, including 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 Pesticide and Veterinary Medicine 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.

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 found in a separate document entitled 'DIR 069/2006 Site Details'. This document can be viewed by accessing the OGTR website at <http://www.ogtr.gov.au/ir/dir069.htm>.

Section 1 Interpretation and Definitions

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.

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 ninety (90) days of each anniversary of this licence containing all the information required by this licence to be provided in the Annual report.

‘Bees’ means honeybees of the species *Apis mellifera*.

‘Brassica Crops’ means any crop of *Brassica* plants including Canola, Indian mustard and commercial *Brassica* crops.

‘Burial site’ means a place where the GMOs or Material from the GMOs is Destroyed by burial under at least one (1) metre of soil.

‘Canola’ means plants of the species *Brassica napus*, the seed of which have oil containing less than two (2) percent erucic acid and thirty (30) micromoles per gram allyl glucosinolates.

‘Clean’ (or **‘Cleaned’**), as the case requires, means:

- (a) in relation to a Place specified in this licence as requiring cleaning, the Destruction of Plant Material in that Place, to the reasonable satisfaction of the Regulator; or
- (b) in relation to Equipment, the removal and Destruction of Plant Material from Equipment, 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) treatment with herbicide(s);
- (b) slashing;
- (c) mowing;
- (d) hand weeding;
- (e) shredding/mulching mechanically;
- (f) burning;
- (g) cutting;
- (h) autoclaving;
- (i) incineration;
- (j) burial under at least one (1) metre of soil; or
- (k) light tillage but only subject to the conditions of this licence.

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, in the case of killing the remains of harvest of the GMOs, treatment of post harvest remains by herbicide would not be a sufficient mechanism.

'Equipment' includes cages, tents, harvesters, seeders, storage equipment, transport equipment (eg bags, containers, trucks), clothing and tools.

'Flies' means sheep blowflies (*Lucilia cuprina*) or eastern golden haired blowfly (*Calliphora stygia*).

'GM' means genetically modified.

'GMOs' means the genetically modified organisms the subject of the dealings authorised for release by this licence.

'Indian mustard' means plants of the species *Brassica juncea*.

'Isolation Zone' means, in respect of a Location, an area of land surrounding either the Location, or the Location's Pollen Trap (if the Location is surrounded by a Pollen Trap) that is known not to contain any flowering *Brassica* crops when the GMOs are growing at the Location.

Note: The size of the Isolation Zone is dependent on the measures to manage gene flow that are employed by the licence holder (see condition 32).

'Light tillage' or **'Lightly tilled'** means the use of a technique to disturb the soil in an area in order to promote the growth of any GMOs in that area and to reduce onset of secondary dormancy of GMO seed in that area, but so as not to bury plant material in the area to a depth of more than fifty (50) millimetres.

'Location' means an area of land where the GMOs are planted and grown pursuant to this licence.

'Monitoring Zone' means an area extending outwards by fifty (50) meters in all directions from the outer edge of a Location, or the Location's Pollen Trap (if the Location is surrounded by a Pollen Trap).

'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 required to be Cleaned and/or inspected in respect of each Location.

‘Plant Material’ means any part of the GM canola, GM Indian mustard, Pollen Trap Plants or Reference *Brassicas* grown at a Location, 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 fifteen (15) metres in all directions from the outside edge of a Location, planted with Pollen Trap Plants.

‘Pollen Trap Plant’ means plants of non-GM canola or Indian mustard, or male sterile GM canola or Indian mustard from a Pollen Trap.

‘Reference *Brassicas*’ means plants of non-GM canola or Indian mustard, or GM InVigor® canola, planted in a Location for the purpose of assisting comparisons of agronomic performance.

‘Regulator’ means the Gene Technology Regulator.

‘Related Species’ means plants of the species *Brassica rapa*, *Brassica nigra*, *Brassica oleracea*, *Brassica carinata*, *Brassica tournefortii*, *Hirschfeldia incana*, *Raphanus raphanistrum* or *Sinapis arvensis*.

‘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 a Location.

‘Volunteer Plants’ means progeny of any GMO, Pollen Trap Plants, *Brassica* Crops, or Reference *Brassicas* that emerge after cleaning of the Location or other Places required to be inspected.

Section 2 General conditions

Duration of Licence

1. 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

2. The holder of this licence ('the licence holder') is Bayer CropScience Pty Ltd.

Project Supervisor

3. The Project Supervisor in respect of this licence is the person named in Attachment A of the licence.

4. 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

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

Persons covered by this GMO licence

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 the licence.

Informing people of their obligations

7. 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.

8. Prior to a person covered by this licence conducting any dealings, the licence holder must obtain signed statements from those persons that the licence holder has informed those people of the conditions of this licence that apply to them and that they have understood the conditions and agree to be bound by them. The licence holder must provide the Regulator, on the Regulator's written request, with copies of these signed statements from persons covered by this licence.

9. The immediately preceding condition does not apply to conditions imposed by way of variation to the licence. Where a variation to a licence imposes a new condition, the licence holder must notify persons to whom the condition applies within the time period, and in the manner, stipulated by the Regulator at the time the licence is varied.

10. The licence holder must notify the project supervisor and all persons covered by a 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.

Applicant to notify of circumstances that might affect suitability

11. 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;
- (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;
- (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.

Licence holder must provide information on matters related to suitability

12. 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.

Additional information to be given to the Regulator

13. It is a condition of the licence that the licence holder informs 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 of a kind mentioned in subsection (1) if he or she was reckless as to whether such information existed; and*
- (b) *the licence holder will be taken to have become aware of contraventions, or unintended effects, of a kind mentioned in subsection (1) if he or she was reckless as to whether such contraventions had occurred, or such unintended effects existed.*

14. 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.

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

15. 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.

16. The licence holder must be able to access and control the Site to the extent necessary to comply with this licence, for the duration of the life of the licence.

Remaining an Accredited organisation

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

Notices

18. The licence holder must provide all notices to the Regulator required to be given by this licence and each notice must be provided in the manner required by this licence.

Section 3 Specific Licence Conditions

GMOs covered by this licence

19. The GMOs covered by this licence are those described at Attachment B.

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

Permitted dealings

21. The permitted dealings with the GMOs are to plant, grow, produce seed, and conduct experiments with the GMOs and the possession, supply, use, transport and disposal of the GMOs for the purpose of any of the permitted dealings or in the course of any of these dealings.

Locations, growing season and size of trial

22. The GMOs must not be grown at any Location in more than one growing season, a Location cannot be used in successive or multiple growing seasons.

23. The licence holder must be able to access and control a Site to the extent necessary to comply with this licence, for the duration of the life of the licence.

24. No GMOs may be planted after 31 January 2011.

Winter plantings

25. The GMOs may be planted between 1 March and 31 August ('the winter growing season') in 2007, 2008, 2009 and 2010 within the Shires set out in following table.

Table 1: Shires where winter planting of the GMOs is permitted

VIC	SA	NSW
Ararat	Grant	Coolamon
Corangamite	Kingston	Greater Hume
Glenelg	Mount Gambier	Junee
Hindmarsh	Naracoorte/Lucindale	Lockhart
Horsham	Robe	Narrandera
Moyne	Tatiara	Wagga Wagga
Northern Grampians	Wattle Range	
Pyrenees		

VIC	SA	NSW
Warrnambool		
Yarriambiack		
Colac-Otway		

26. In the winter growing seasons, the maximum number of Locations permitted in any one season is eight (8), and no individual location can be more than six (6) hectares.

Summer plantings

27. The GMOs may be planted between 1 September and 31 January ('the summer growing season') in 2007/2008, 2008/2009, 2009/2010 and 2010/2011 within the Shires set out in following table.

Table 3: Shires where summer planting of the GMOs is permitted

VIC	SA
Ararat	Grant
Glenelg	Kingston
Moyne	Mount Gambier
Northern Grampians	Naracoorte/Lucindale
Southern Grampians	Robe
Warrnambool	Tatiara
Corangamite	Wattle Range
Colac-Otway	

28. In the summer growing seasons, the maximum number of Locations permitted in any one season is six (6), and no individual location can be more than six (6) hectares.

Notice of intention to plant and of planting

29. The licence holder must, in the manner required by condition 90, give advance notice to the Regulator of an intention to plant the GMOs.

30. The licence holder must, in the manner required by condition 91, give notice to the Regulator of the actual date of planting the GMOs.

Measures to manage gene flow

31. Reference *Brassicas* may be planted and grown at the Location but if planted must be handled and controlled as if they are the GMOs.

32. For each Location, the Location must be surrounded by a fifty (50) metre Monitoring Zone and one of the following measures for managing gene flow must be adopted:

- (a) The GMOs at the Location must be genetically modified male sterile canola or Indian mustard only. The Location must be surrounded by an Isolation Zone extending outwards by at least four hundred (400) metres in all directions from the outer edge of the Location; or
- (b) The Location must be surrounded by an Isolation Zone extending outwards by one (1) kilometre in all directions from the outer edge of the Location; or

- (c) The Location must be surrounded by a fifteen (15) metre Pollen Trap, in the manner required by conditions 34 and 35. The Pollen Trap must be surrounded by an Isolation Zone extending outwards by four hundred (400) metres in all directions from the outer edge of the Pollen Trap; or
- (d) All flowering heads of the GMOs must be covered with selfing bags at least seven (7) days prior to flowering. The bags must remain on the GMOs during flowering. The Location must be surrounded by an Isolation Zone extending outwards by at least four hundred (400) metres in all directions from the outer edge of the Location; or
- (e) All the GMOs at the Location must be covered by insect proof cages and/or tents at least seven days prior to the flowering of the GMOs. The cages or tents must remain in place during flowering and Bees or Flies may be introduced into cages or tents to facilitate pollination, in the manner required by conditions 36-38. The Location must be surrounded by an Isolation Zone extending outwards by at least four hundred (400) metres in all directions from the outer edge of the Location.

33. If cages or tents are used, they must be inspected for damage at least fortnightly and if necessary, repaired immediately. Repairs must be recorded and reported as per condition 97.

Conditions relating to Pollen Traps

34. Each Pollen Trap must contain only Pollen Trap Plants grown in such a way as to reasonably promote a dense and vigorous growth that forms a continuous barrier of Pollen Trap Plants surrounding the Location and in such a way as to ensure that the Pollen Trap Plants flower at the same time and for the same period as the GMOs.

35. Pollen Trap Plants must be handled and controlled as if they are the GMOs (ie subject to other conditions applicable to the GMOs elsewhere in this licence), and Material from these Pollen Trap Plants must be handled and controlled as if it is Material from the GMOs (ie subject to other conditions applicable to the GMOs elsewhere in this licence).

Conditions relating to use of Bees or Flies

36. Bees or Flies may be introduced into cages for pollination and prior to removal of the cage, any surviving Bees or Flies must be killed using insecticidal spray.

37. Beehives along with Bees may be introduced into tents for pollination and must be confined to the tents until flowering of the GMOs within the tents has ceased and pollen from the GM plants is no longer viable.

38. Subject to the ensuing condition, beehives and Bees may be removed from a tent prior to cessation of flowering of the GMOs within the tent provided that:

- a) the Beehive and the Bees are confined in a second tent until such time as any pollen they may carry from the GMOs is non-viable, and
- b) any Bees remaining in the first tent are killed with insecticidal spray prior to removal of the first tent.

Section 4 Use and Disposal of Plant Material, Cleaning of Equipment and Places

Use of Plant Material

39. The licence holder must not allow the GMOs, Pollen Trap Plants or Reference *Brassicac*s plants or any Plant Material from these plants to be used as human food or for animal feed.

Transportation of Plant Material

40. Plant Material may only be transported to the extent necessary to store it, Destroy it, export it, Clean it from Equipment, relocate it to a facility approved by the Regulator or to a physical containment level 2 (PC2) facility, or relocate it to the Site from a facility approved by the Regulator or from a PC2 facility.

41. Plant Material must be transported according to the OGTR *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.

Collection or Harvest of Plant Material (including seed)

42. All Plant Material collected or harvested from a Location must only be:

- (a) used for destructive analysis; and/or
- (b) Destroyed; and/or
- (c) stored; and/or
- (d) used for future planting in Australia pursuant to this licence; and/or
- (e) exported.

43. All Plant Material collected or harvested must be clearly identified with details of:

- (a) the plants from which the material was harvested;
- (b) the Location from which it was harvested; and
- (c) all field plantings at the Location.

44. Any Plant Material that is collected or harvested may be transported off the Site to:

- (a) a facility certified by the Regulator to PC2; or
- (b) a facility approved in writing by the Regulator and signed so as to indicate that GM Plant Material is stored within the facility

and may be experimented on and stored in any one or more of these facilities in accordance with certification conditions or Regulator's conditions as appropriate.

Note: the above conditions do not permit experiments involving any genetically modified organisms other than that covered by this licence to be performed in these facilities.

45. Plant Material or waste derived from experimental analyses must be Destroyed as soon as practicable.

46. Unless another authority is obtained under the Act to deal with harvested seed, after 31 January 2011, all such seed remaining, including subsequent generations of seed produced using this seed, must be Destroyed.

Note: This licence requires that there be no planting of the GMOs after 31 January 2011.

47. If harvested seed is used for destructive analysis, the OGTR must be notified of the details of the premises used for analysis *prior* to the analysis being undertaken.

Notice of harvest

48. The licence holder must, in the manner required by condition 92, provide the regulator with a notice of intention to harvest the GMOs at each Site.

49. The licence holder must, in the manner required by condition 93, provide the actual date or dates of harvesting of the GMOs at each Site.

Harvest and post-harvest procedures

50. If Plant Materials are harvested, they must be harvested separately from any other crop.

51. The seed obtained from harvest is subject to condition 42.

52. Any Plant material obtained from harvest may only be transported to the extent necessary to undertake activities permitted under this licence.

Cleaning – post harvest and generally

53. Equipment and Places used pursuant to this licence must be Cleaned within fourteen (14) days of harvest of the GMOs.

54. Cleaning of Equipment must occur before it is used for any other purpose (it is not necessary for Equipment to be Cleaned only at a Location.).

55. The following Places must be Cleaned in accordance with all relevant licence conditions:

- (a) the Location, Pollen Trap and Monitoring Zone;
- (b) any areas used during harvest or threshing of seed;
- (c) any areas used to Clean Equipment used in connection with harvest of Plant Material at the Location, Pollen Trap and Monitoring zone or to Destroy Plant Material.

56. If the GMOs are not harvested, each Place must be Cleaned within fourteen (14) days of Destruction of the GMOs.

57. The licence holder must, in a manner required by condition 94, give notice to the Regulator of the date on which Cleaning of the Place concluded.

58. On the request of the Regulator, the Regulator must be provided with written documentation of the procedures in place to ensure continuing compliance with these Cleaning conditions.

Conditions relating to Destruction by burial

59. Subject to Condition 42, if Destruction occurs by burial the licence holder must:

- (a) within thirty (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

- (b) inspect the Burial site at least once every three (3) months for a period of three (3) years to identify:
 - (i) any significant disturbance that may effect the emergence of Volunteer Plants and if disturbance is identified, notify the Regulator of appropriate remedial action taken; and
 - (ii) any emergence of Volunteer Plants. If Volunteer Plants are identified, the Burial site must be Cleaned; and
- (c) report the findings according to condition 97.

60. 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 three (3) 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 Volunteer Plants.

Conditions in relation to Light Tillage

61. Light Tillage may only be adopted as a method for Cleaning a Place in conditions where germination of the GMOs, Pollen Trap Plants or Reference *Brassic* is reasonably likely to ensue (for example, immediately after rain or irrigation).

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

62. Following Cleaning of a Place, the Place must be Lightly Tilled twice, unless the Place was Lightly Tilled in the course of Cleaning it, in which case the Place must be Lightly Tilled again.

63. The two light tillage events required by condition 62 at a Place must be separated by at least twenty-eight (28) days.

Note: Additional Light Tillage within the twenty-eight (28) days between the first and second required Light Till of a Location or Pollen Trap are not prohibited.

64. Light Tillage activities must be recorded in a logbook. The logbook must be available on request for examination or photocopying by the Regulator or a person authorised by the Regulator. Records in the logbook must be included in the licence holder's Annual Report. The logbook must contain, at least, details of the following:

- (a) the Places Lightly Tilled;
- (b) the Light Tillage methods used; and
- (c) the dates Light Tillage occurred.

Section 5 Use of Site, inspections and Sign off

Inspections while GMOs are being grown

65. Fourteen (14) days before the expected commencement of flowering of the GMOs at a Location, the following Places must be inspected for the presence of Related Species:

- (a) The Location; and
- (b) The Location's Pollen Trap, if any.

66. The above Places must be reinspected at least once every thirty-five (35) days until either all GMOs at the Location have been harvested or the Location is Cleaned and any Related Species growing in these Places must be Destroyed before flowering.

Inspections to be conducted in the Monitoring Zone while GMOs are being grown

67. Fourteen (14) days before the expected commencement of flowering of the GMOs at a Location, the Monitoring Zone must be inspected for the presence of GMOs, Reference *Brassicas*, any other Volunteer Plants and Related Species.

68. The Monitoring Zone must be reinspected at least once every thirty-five (35) days until either all GMOs at the location have been harvested or the Location is Cleaned.

69. Any GMOs, Reference *Brassicas*, other Volunteer Plants or Related Species growing in the Monitoring Zone during inspections must be Destroyed before flowering.

Inspections to be conducted in the Isolation Zone while GMOs are being grown

70. No *Brassica* Crops may be grown in an Isolation Zone while GMOs are being grown at the Location within it.

71. Fourteen days (14) before the expected commencement of flowering of the GMOs at a Location, the Location's Isolation Zone must be inspected for the presence of *Brassica* Crops.

72. If any *Brassica* Crop is planted or occurs in an Isolation Zone while the GMOs are being grown at the Location within it, either the *Brassica* Crop or the GMOs and Reference *Brassicas* in the Location must be Destroyed prior to flowering. If GMOs or Reference *Brassicas* are Destroyed pursuant to this Condition, 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.

73. The Isolation Zone must be reinspected at least once every thirty-five (35) days thereafter until the GMOs and Reference *Brassicas* at the Location have finished flowering and any *Brassica* Crop destroyed.

General conditions on use of Locations post-harvest

74. Subject to the immediately ensuing condition, no plants may be grown in a Place following its Cleaning unless the Regulator has issued a Sign Off for the Site.

75. The previous condition does not apply if the proposed planting is of a plant permitted by the Regulator's Guidelines for Post Harvest Crops as current at the proposed time of planting or agreed to in writing by the Regulator.

Post harvest (or post-Destruction) inspections

76. Following Cleaning, all Places Cleaned must be inspected for the existence of Volunteer Plants.
77. Inspection must be performed by a person who is able to recognise Volunteer Plants.
78. Any Volunteer Plant must be Destroyed prior to the plant flowering.
79. All the Places required to be inspected must be inspected at least once every thirty-five (35) days for a period of twenty-four (24) months that commences on the last day of Cleaning of the Location.
80. If no Volunteer Plants are identified during six (6) consecutive inspections, inspections may take place at intervals of at least once every three (3) months for the remainder of the period that inspections are required (instead of once every thirty-five (35) days).
81. At the conclusion of the twenty-four (24) month period of inspections, the Places required to be inspected must be inspected for the existence of Volunteer Plants until:
- (a) no Volunteer Plants are identified at those Places for twelve (12) continuous months; and
 - (b) the Regulator has issued a Sign-off.
82. The results of inspection activities must be recorded in a logbook as described in condition 97.
83. Inspection conditions do not apply in respect of a Place if the licence holder has received a Sign-off.

Sign off of Site

84. For each Site,
- (a) if inspections have been routinely completed for a period of at least twenty-four (24) months, and
 - (b) if after completion of the twenty-four (24) month inspection period, no Volunteer Plants are identified at those places for an additional, continuous, twelve (12) month period

the licence holder may make written application to the Regulator that these inspection conditions no longer apply to the Site.

Section 6 Reporting and Documentation Requirements

Compliance Management Plan

85. Prior to growing the GMOs, a written Compliance Management Plan must be provided to the Regulator. The Compliance Management Plan must describe in detail how the licence holder intends to ensure compliance with each of these conditions and document that compliance and must include,
- (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 Compliance Management Plan the function or position of the person to be covered must be provided.

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

- (b) An explanation of how the licence holder has informed, or proposes to inform, each person intended to be covered by the licence of the conditions of this licence including conditions related to the collection of Personal Information by the licence holder from the person intended to be covered by the licence.
 - (c) 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
 - (d) A description of how any contracts, agreements, or other enforceable arrangements between the licence holder and persons covered by the licence will allow the licence holder to access and control a Site to the extent necessary to comply with this licence, for the duration of the life of the licence.
 - (e) A description of the licence holder's plans for post harvest use of a Site during the life of this licence.
86. Where any of the details of the compliance management plan change, the Regulator must be notified of the changes within fourteen (14) days of the change occurring.

Contingency Plans

87. Within thirty (30) days of the date of the commencement 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, Pollen Trap Plants and/or Reference *Brassicas* and Plant Material from these plants outside an area that must be inspected.
88. 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;
 - (b) destroy any of the GMOs, Pollen Trap Plants and/or Reference *Brassicas* and Plant Material from these plants; and
 - (c) inspect and Destroy any Volunteer Plants that may exist as a result of the event.
89. The Contingency Plan must be implemented in the event that the unintended presence of the GMOs, Pollen Trap Plants and/or Reference *Brassicas* and Plant Material from these plants at the Location is discovered outside an area that must be inspected.

Notice of intention to plant and of planting

90. At least seven (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 on which planting of the GMOs is intended to commence;
 - (b) details of the Site where the GMOs will be planted, including the size of the Site, a street address and GPS coordinates for the Site;

- (c) the identity of the GMOs which are planted; and
- (d) the period during which the licence holder considers the GMOs are likely to flower;
- (e) the period during which the licence holder considers the GMOs are likely to be harvested (or Destroyed at a Location in lieu of harvest)
- (f) a description of how the Site is intended to be used during the first two years following harvest of the GMOs.

91. Within seven (7) days of planting of the GMOs, the licence holder must provide a notice in writing to the Regulator which contains:

- (a) the actual date on which planting of the GMOs occurred;
- (b) details of the Site where the GMOs were planted, including the size of the Site, a street address and GPS coordinates for the Site;
- (c) the identity of the GMOs which were planted; and
- (d) the period during which the licence holder considers the GMOs are likely to flower;
- (e) the period during which the licence holder considers the GMOs are likely to be harvested (or Destroyed at a Location in lieu of harvest)
- (f) a description of how the Site is intended to be used during the first two years following harvest of the GMOs.

Notice of harvest and Cleaning following harvest

92. The licence holder must provide the Regulator with a notice of intention to harvest the GMOs at the Location. This notice must be provided at least seven (7) days, and not more than twenty-one (21) days, in advance of the intended date of harvest set out in the 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.

93. The licence holder must provide the actual date or dates of commencement of harvesting of the GMOs at the Locations. This notice must be provided within seven (7) days of commencement of harvesting of the GMOs at the Locations.

Note: There are 2 relevant notices with respect to a forecast of harvest. One is a long-term forecast provided under conditions 90 and 91 and the other is a short term forecast under condition 92.

94. The licence holder must provide a notice in writing to the Regulator when a Location is Cleaned following harvest. The notice must be provided to the Regulator within fourteen (14) days of the date on which Cleaning of the Location concluded.

95. On the request of the Regulator, the Regulator must be provided with written documentation of the procedures in place to ensure continuing compliance with the Cleaning conditions in this licence.

96. The licence holder must provide a notice in writing to the Regulator when GMOs or plants required to be treated as GMOs are destroyed.

Results of inspection activities

97. The results of inspection activities must be recorded in a logbook or paper file. The findings of the inspections as recorded in the logbook or paper file must be

forwarded to the Regulator within fourteen (14) days of inspection taking place and must also be included in the licence holder's Annual Report to the Regulator. The logbook or paper file must contain at least the following:

- (a) details of the areas inspected;
- (b) details of current land use (eg type of crop being grown) and of recent land management practices (eg cultivation or spraying) applied in the areas inspected;
- (c) details of the date of inspection;
- (d) the names of the person or persons who undertook the inspections and details of the experience, training or qualification that enabled them to recognise Volunteer Plants, *Brassica* Crops and Related Species;
- (e) the means of inspection used;
- (f) the number of Volunteer Plants, *Brassica* Crops or Related Species observed, if any;
- (g) details of where Volunteer Plants, *Brassica* Crops or Related Species were observed and the development stages reached by them, if any;
- (h) details of methods used to Destroy Volunteer Plants, *Brassica* Crops or Related Species, if any
- (i) details of any repairs to cages or tents required under condition (e).

98. The licence holder must keep records of the number and type of GMOs, Pollen Trap Plants, and Reference *Brassic*as grown at the Site as part of the trial, and the Plant Material, including seed, from the Site stored, at the end of the trial.

Annual Report

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

Testing methodology

100. 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 (for details see Attachment B of the licence) in a recipient organism. The instrument must be provided within thirty (30) days of the issuing of this licence.

ATTACHMENT A

DIR No: 069/2006

***Full Title:** Limited and controlled release of GM herbicide tolerant hybrid *Brassica napus* and hybrid *Brassica juncea*

Organisation Details

Organisation: Bayer CropScience Pty Ltd

Postal address: 391-393 Tooronga Road
EAST HAWTHORN
VIC 3123

Phone No: (03) 9248 6833

Fax No: (03) 9248 6605

Project Supervisors 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: Bayer CropScience Pty Ltd

Postal Address: 391-393 Tooronga Road
EAST HAWTHORN
VIC 3123

IBC Details

IBC Name: Bayer CropScience Biosafety Committee

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

ATTACHMENT B

GMOs Description

* The GMOs covered by this licence:

Brassica napus and *Brassica juncea* genetically modified by introduction of only the genetic elements which have been declared CCI and as listed in Attachment B of the non-redacted licence.

*Parent Organisms:

Common Name: Canola and Indian mustard

Scientific Name: *Brassica napus* L. ssp. *oleifera* (Canola) and *B. juncea* (L.) Czern and Coss.

*Modified traits:

Category: *Herbicide tolerance*
Hybrid breeding system

Description: GM canola and Indian mustard lines have been developed by introduction of genes conferring:

- tolerance to herbicide [CCI]¹; and
- a hybrid breeding system, which facilitates the production of hybrid seed.

The genes conferring these traits were initially introduced into canola by *Agrobacterium*-mediated transformation and then transferred to Indian mustard by conventional breeding.

*Genes responsible for conferring the modified traits:

Herbicide tolerance: [CCI]

Hybrid breeding system:

Male sterile (MS) lines contain the *barnase* gene derived from *Bacillus amyloliquefaciens*, encoding the ribonuclease inhibitor protein BARNASE, under the control of an anther specific promoter. Expression in the anther confers male sterility in the absence of the ribonuclease inhibitor BARSTAR.

Fertility restorer (Rf) lines contain the *barstar* gene derived from *Bacillus amyloliquefaciens*, encoding the ribonuclease inhibitor protein BARSTAR, under the control of an anther specific promoter. Expression in the anther overcomes male sterility produced by BARNASE.

¹ Bayer has received approval to have details of the herbicide tolerance trait as Confidential Commercial Information (CCI) under section 185 of the Act.

Details:

The GMOs covered by this licence are as follows:

Canola and Indian mustard, modified by insertion of genetic material from any one of gene constructs [CCI], intraspecific and interspecific hybrids comprising conventional crosses between male sterile (MS) and fertility restorer (Rf) lines or crosses between Rf lines from the constructs [CCI], or crosses between any of the Rf or MS lines and [CCI].

Purpose of the Dealings with the GMOs:

Conduct research to evaluate the agronomic performance of GM canola and Indian mustard lines, including comparison with conventional canola and Indian mustard, and GM canola; to assess the effectiveness of the herbicide tolerance trait in the field; and to produce seed from lines selected for ongoing evaluation trials planned for overseas and possibly also Australia (subject to further approvals).

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