



Australian Government

Department of Health and Ageing

Office of the Gene Technology Regulator

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

Licence No: DIR 057/2004

Licence Holder: Bayer CropScience Pty Ltd

Title: Field trial of genetically modified hybrid, herbicide tolerant Indian mustard (*Brassica juncea*)

Issued: 2 June 2005

Varied: 29 June 2005

Varied: 23 June 2006

More information about this licence is contained in the risk assessment and risk management plan prepared in connection with this 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

The *Gene Technology Act 2000* (Cth) and corresponding state and territory legislation form a substantial part of a range of integrated regulatory measures relevant to controlling genetically modified organisms (GMOs) and their use.

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.

Note in relation to the approval of genetically modified foods for human consumption

Food Standards Australia New Zealand (FSANZ), is responsible for human food safety assessment. Due to the early stage of this research, Bayer has not applied to FSANZ for evaluation of material from the GM Indian mustard for use in human food. FSANZ approval would need to be obtained before any parts of the GM Indian mustard could be used as human food. This licence contains a condition that prohibits this use.

Note in relation to herbicide usage and herbicide resistance management

The GMOs referred to in this licence have been modified to be tolerant to a herbicide. The APVMA has responsibility for setting registration conditions for the use of herbicides in Australia, including implementation of herbicide resistance management programs. Conditions of this licence do not relate to use of herbicides, and do not replace any conditions set by the APVMA. The licence holder must comply with any conditions imposed by the APVMA in relation to the use of herbicides in connection with these GMOs.

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 057/2004 Site Details'. This document can be viewed by accessing the document on the OGTR website at <http://www.ogtr.gov.au/ir/dir057.htm>.

SECTION 1 INTERPRETATION AND DEFINITIONS

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.

In this licence:

Words and phrases used in this licence have the same meaning as they do in the Act and the Regulations;

Words importing a gender include any other gender;

Words in the singular include the plural and words in the plural include the singular;

Words importing persons include a partnership and a body whether corporate or otherwise;

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;

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;

Specific conditions prevail over standard conditions to the extent of any inconsistency.

In this licence:

‘Act’ means the *Gene Technology Act 2000* (Cth) and equivalent provisions in corresponding State law;

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

‘Brassica Crops’ means any crop of *Brassica* plants or Canola (and includes commercial *Brassica* crops).

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

‘Indian mustard’ means plants of the species *Brassica juncea*.

‘Canola’ means plants of the species *Brassica napus*, the seed of which have oil containing less than 2% erucic acid and 30 µmol/g allyl glucosinolates.

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

- (a) in relation to a Location or other area, the Destruction of the GMOs, Material from the GMOs, Pollen Trap plants, Material from Pollen Trap plants, Reference *Brassicas* and Materials from Reference *Brassicas* in that Location or area, to the reasonable satisfaction of the Regulator; or
- (b) in relation to Equipment, the removal and Destruction of the GMOs, Material from the GMOs, Pollen Trap plants, Material from Pollen Trap plants, Reference *Brassicas* and Materials from Reference *Brassicas* from the 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 1 metre of soil; and
- (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 GMO, treatment of post harvest remains by herbicide would not be a sufficient mechanism.

‘Equipment’ includes harvesters, seeders, storage equipment, transport equipment (eg bags, containers, trucks), clothing and tools.

‘GM’ means genetically modified.

‘GMOs’ means the genetically modified organisms listed in Attachment B and authorised for release by this licence.

‘GMO Type 1’ means the GMOs described as Type 1 in Attachment B of this licence.

‘GMO Type 2’ means the GMOs described as Type 2 in Attachment B of this licence.

‘GMO Type 3’ means the GMOs described as Type 3 in Attachment B of this licence.

‘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 *Brassica* crops when the GMOs are planted at the Location.

Note: the size of the Isolation Zone is dependent on what measures to manage gene flow are employed by the licence holder.

‘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 50 mm.

‘Location’ means an area of land where the GMOs are planted and grown.

‘Material from Pollen Trap plants’ means seed, stubble, pollen or any GM material (including parts of a plant) that is derived from or produced by Indian mustard or Canola from a Pollen Trap.

‘Material from the GMOs’ means genetically modified material, including parts of GMOs that are derived from or produced by the GMOs.

‘Material from the Reference Brassicas’ means material, including parts of the Reference Brassicas, that are derived from or produced by the Reference Brassicas.

‘Monitoring Zone’ means an area extending outwards by 50 m 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.

‘Permitted Plants’ means grasses, cereals, clover, lucerne, vetch and chickpeas.

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

‘Pollen Trap Plant’ means non-GM Indian mustard (*B. juncea*) or non-GM Canola or male sterile GM Canola from a Pollen Trap.

‘Prohibited Plants’ means *Brassica* plants of any kind (including Indian mustard), beans, lupins, poppies, peas, potatoes, pumpkins and radish.

‘Reference Brassicas’ means non-GM Indian mustard (*B. juncea*) and non-GM Canola, planted in a Location for the purpose of assisting comparisons of agronomic performance.

‘Regulator’ means the Gene Technology Regulator.

‘Related Species’ means *Brassica rapa*, *Brassica nigra*, *Brassica oleracea*, *Brassica carinata*, *Brassica tournefortii*, *Hirschfeldia incana*, *Raphanus raphanistrum* and *Sinapis arvensis*.

‘Sign-off’ means a notice in writing from the Regulator, in respect of a place, that post harvest inspection conditions no longer apply in respect of that place.

‘Volunteer Plants’ means progeny of any GMOs, Pollen Trap Plants, *Brassica* Crops, or Reference Brassicas that emerge after cleaning of the Location or other area 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 identified at Attachment A.

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 GMOs except as authorised by this licence

5 Persons covered by this licence must not deal with the GMOs and Reference *Brassicas*, if any, 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 to undertake any activity in connection with GMOs grown in a Location pursuant to this 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 The licence holder must provide the Regulator, on the Regulator's written request, signed statements from persons covered by this licence that the licence holder has informed those people of the conditions of this licence that apply to them.

Licence holder to notify of circumstances that might affect suitability

9 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 his licence to meet the conditions in it.

Licence Holder must provide information on matters related to suitability

9 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

10 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.

11 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

12 If a person is authorised by this licence to deal with 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.

Remaining an Accredited organisation

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

SECTION 3 SPECIFIC LICENCE CONDITIONS

GMOs covered by this licence

1. The GMOs covered by this licence are those described at Attachment B.
2. For the purpose of dealings conducted under this licence, and only for that purpose, the conditions of this licence prevail over conditions in licences DIR 021/2002 or DIR 032/2002.

Permitted dealings

3. The permitted dealings with the GMOs are to plant, grow 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.
4. Reference *Brassic*as may be planted and grown at the Location but if planted must be handled and controlled as if they are the GMOs.
5. Any GMO Type 3 planted in the Location must either be Destroyed prior to setting seed or used for destructive analysis only.

Location, size of release and restrictions on when the GMOs may be planted

6. The GMOs must not be grown at any Location in more than one growing season i.e. a Location cannot be used in successive or multiple growing seasons.
7. The licence holder must be able to access and control a Location to the extent necessary to comply with this licence, for the duration of the life of the licence.
8. No GMOs may be planted after 31 January 2008.

Winter plantings

9. The GMOs may be planted between 1 March and 31 August ('the winter growing season') in 2005, 2006 and 2007, within the Shires set out in following table.

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

VIC	SA	NSW
Ararat	Naracoorte/Lucindale	Coolamon
Hindmarsh	Grant	Culcairn
Glenelg	Wattle Range	Lockhart
Horsham		Junee
Moyne		Wagga Wagga
Northern Grampians		Narrandera
Southern Grampians		
Yarriambiack		

10. For the winter growing seasons, the maximum number of Locations for those growing seasons (where permitted dealings may be conducted) are set out in Table 2 at Column 2. The maximum combined area of all Locations where permitted dealings may occur in those growing seasons is limited to the size set out in Table 2 at Column 3.

Table 2: Maximum numbers of Locations and combined areas

Winter growing season	Maximum number of Locations/season	Maximum combined area of all Locations/season (ha)
2005	4	16
2006	4	16
2007	4	16

11. In the winter growing seasons, the maximum size of any individual Location is 4 ha (no individual field trial site can be more than 4 ha).

Summer plantings

12. The GMOs may be planted between 1 September and 31 January ('the summer growing season') in 2005/2006, 2006/2007 and 2007/2008, within the Shires set out in following table.

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

VIC	SA
Glenelg	Naracoorte/Lucindale
Moyne	Grant
Northern Grampians	Wattle Range
Southern Grampians	

13. For the summer growing seasons, the maximum number of Locations for those growing seasons (where permitted dealings may be conducted) are set out in Table 4 at Column 2. The maximum combined area of all Locations where permitted dealings may occur in those growing seasons is limited to the size set out in Table 4 at Column 3.

Table 4: Maximum numbers of Locations and combined areas

Summer growing season	Maximum number of Locations/year	Maximum combined area of all Locations/season (ha)
2005/6	4	16
2006/7	4	16
2007/8	4	16

14. In the summer growing seasons, the maximum number of Locations permitted in any one season is four, and the maximum size of any individual Location is 4 ha (no individual field trial site can be more than 4 ha).

Notice of intention to plant and of planting

15. At least 7 days prior to planting of the GMOs at a Location, the Location's GPS coordinates and either a street address, or other directions to the Location must be provided to the Regulator by notice in writing.

16. The licence holder must provide a notice in writing to the Regulator each time the GMOs are planted at a Location.

17. The notice must set out:

- (a) The date on which planting commenced; and

- (b) Details of the Location including a street address and GPS coordinates for the Location; and
- (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; and
- (e) The period during which the licence holder considers the are likely to be harvested (or Destroyed at a Location in lieu of harvest).

18. The notice must be provided to the Regulator within 14 days of the date on which planting commenced.

Note: Any Reference Brassicas planted or intended to be planted are to be treated as GMOs requiring notice (see condition 4)

Measures to manage gene flow

19. For each Location, one of the following measures for managing gene flow must be adopted:

- (a) The GMOs at the Location must be genetically modified male sterile Indian mustard only. The Location must be surrounded by an Isolation Zone extending outwards by at least 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 1 km in all directions from the outer edge of the Location; or
- (c) The Location must be surrounded by a Pollen Trap. The Pollen Trap must be surrounded by an Isolation Zone extending outwards by 400 m 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 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 400 m in all directions from the outer edge of the Location; or
- (e) All GMOs at the Location must be covered by an insect proof cage or tent. The cage or tent must remain in place during flowering. The Location must be surrounded by an Isolation Zone extending outwards by at least 400 m in all directions from the outer edge of the Location. Any bees introduced for pollination must be located within tents or cages. The bees must be either killed or confined to the tents or cages until flowering has ceased.

20. 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 37.

Conditions relating to Pollen Traps

21. Each Pollen Trap must contain only Pollen Trap Plants grown in such a way as to reasonably promote a dense and vigorous growth 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.

22. If male sterile GM Canola is used as the Pollen Trap Plants, all Pollen Trap Plants must be destroyed as soon as practicable after flowering.

23. If *B. juncea* or non-GM Canola are used as Pollen Trap Plants, they must be handled and controlled as if they are the GMOs (ie subject to other conditions applicable to the GMO 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 GMO elsewhere in this licence).

24. A Pollen Trap must be able to be accessed and controlled by the licence holder to an extent that is commensurate with the licence holder's rights to access and control the Location within it.

Use of GMOs and Material from the GMOs

25. The licence holder must not allow the GMOs or Reference *Brassicas* or any Material from the GMOs or Reference *Brassicas* to be used as human food or for animal feed.

Inspections to be conducted for Related Species while GMOs are being grown

26. Fourteen days before the expected commencement of flowering of the GMOs at a Location, the following areas must be inspected for the presence of Related Species:

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

27. The areas must be reinspected at least once every 35 days until either all GMOs at the location have been harvested or the Location is Cleaned.

28. Any Related Species growing in the areas must be Destroyed before flowering.

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

29. Fourteen 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.

30. The Monitoring Zone must be reinspected at least once every 35 days until either all GMOs at the location have been harvested or the Location is Cleaned.

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

Inspections to be conducted for *Brassica* Crops in the Isolation Zone while GMOs are being grown

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

33. Fourteen days 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.

34. 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 *Brassic*as in the Location must be Destroyed prior to flowering. If GMOs or Reference *Brassic*as 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.

35. The Isolation Zone must be reinspected at least once every 35 days thereafter until the GMOs and Reference *Brassic*as at the Location have finished flowering and any *Brassic*a Crop destroyed.

36. An Isolation Zone must be able to be accessed and controlled by the licence holder to an extent that is commensurate with the licence holder's rights to access and control the Location within it.

Logbook to be kept of inspections conducted while GMOs are being grown

37. The results of inspection activities must be recorded in a logbook. The logbook must be available on request for examination or photocopying by the OGTR. The findings of the inspections as recorded in the logbook must be provided to the Regulator every month and included in the licence holder's Annual Report. The logbook must contain at least the following:

- (a) details of the area inspected;
- (b) details of the date of inspection;
- (c) 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, *Brassic*a Crops and Related Species;
- (d) the number of Volunteer plants, *Brassic*a Crops in the Isolation Zone and Related Species observed, if any;
- (e) details of where Volunteer plants, *Brassic*a Crops in the Isolation Zone and Related Species were observed and the development stages reached by them, if any; and
- (f) details of methods used to Destroy Volunteer plants, *Brassic*a Crops and Related Species and the dates on which Destruction took place, if any; and
- (g) details of any repairs to cages or tents required under Condition 20.

Harvest of different GMOs and Reference *Brassic*as when grown concurrently in plots within a Location

38. Subject to the exceptions contained in conditions 39, 40 and 41 all seed obtained from harvest at a Location must only be:

- (a) used for destructive analysis; or
- (b) Destroyed; or
- (c) exported.

39. Seed harvested from the GMOs at a Location in which GMO Type 3 is grown and permitted to flower must only be:

- (a) used for destructive analysis; or
- (b) Destroyed; or
- (c) exported.

(See Table 5, (iii) and (iv)).

40. If GMO Type 1 and GMO Type 2 are grown together at a Location in which no GMO Type 3 is permitted to flower, seed obtained from harvest of those GMOs may be used for future planting but only if the GMOs at the Location are caged or tented according to Condition 19(e). Unless another authority under the Act to deal with this seed is obtained, after 31 January 2008 all such seed remaining, including subsequent generations of seed produced using this seed, must be Destroyed. (See Table 5, (ii))

Note: This licence requires that there be no planting of GMOs after 31 January 2008.

41. When GMO Type 1 is grown at a Location in which no other GMO Type is grown, and if the Pollen Trap Plants, if any, are either *B. juncea* or male sterile GM canola, seed may be harvested from the GMOs for future planting (see Table 5, (i)).

42. 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.

Table 5 Use of seed from different GMOs with or without mixed field plantings (summarising Conditions 38 – 41)

Licence DIR 057/2004	
GMO Types in Location (permitted to flower) (see Attachment B for GMO details)	Is future planting of seed harvested from a GMO permitted?
(i) Type 1 only	Yes provided that the pollen trap plants, if any, are either <i>B. juncea</i> or male sterile GM canola
(ii) Type 1 and Type 2	Yes provided that the GMOs are caged or tented. Unless otherwise authorised, seed remaining after 31 January 2008 must be destroyed
(iii) Type 1 and Type 3	No – must be Destroyed
(iv) Type 1, Type 2 and Type 3	No – must be Destroyed

Legend: Type 1 - GM *B. juncea* authorised under licence DIR 057/2004
 Type 2 - GM *B. napus* also authorised under licence DIR 032/2002
 Type 3 - GM *B. napus* also authorised under licence DIR 021/2002 (*InVigor® Canola*)

Note: If all GMO Type 3 plants at the Location are destroyed before flowering, (iii) will revert to (i) and (iv) will revert to (ii).

Handling of harvested seed and plant material

43. If seed from the GMOs is harvested, it must be harvested and stored separately from any other Indian mustard or Canola seed.

44. All material 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.

For example: Licence DIR 057/2004 GMO Type 1 (B. juncea) from caged plants, site XX Hindmarsh 2005 winter planting, mixed planting with GMO Type 2 and non-GM canola.

45. Parts of GMOs (including leaf tissue, flower buds, seed, roots and stems) that are collected may only be transported off the Location to:

- (a) storage within a secure enclosed area that is signed so as to indicate GM Plant Material is stored within that area. GMOs must be stored in a sealed primary container capable of preventing dispersal of the GMO and/or Plant Material and which is enclosed by a locked outer container that is signed so as to indicate that it contains GM Indian mustard or Canola; or
- (b) a facility certified by the Regulator to physical containment level 2 (PC2); or
- (c) be exported.

Note: Transport of GMOs is subject to the Transport conditions found at Conditions 70 - 72

46. Parts of the GMOs (including leaf tissue, flower buds, seeds, roots and stems) may be collected from the GMOs at the Location for the purpose of conducting experiments.

47. After any experiments with the GMOs or parts of GMOs (including leaf tissue, flower buds, seeds, roots and stems) are completed, the GMOs, or parts of GMOs, must be Destroyed.

Notice of harvest and Cleaning following harvest, or Destruction of the GMOs

48. The licence holder must provide the Regulator with a notice of intention to harvest GMOs at the 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 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.

49. The licence holder must provide the actual date or dates of commencement of harvesting of GMOs at the Location. This notice must be provided within 7 days of commencement of harvesting of the GMOs at the Location.

Note: There are 2 relevant notices with respect to a forecast of harvest. One is a long-term forecast provided under Condition 16-18 and the other is a short term forecast under Condition 48.

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

51. 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 14 days of the date on which Cleaning of the Location concluded.

Cleaning of the Location after GMOs are grown

52. Equipment, Locations and Pollen Traps used pursuant to this licence must be Cleaned within 14 days of harvest of the GMOs.

Cleaning of all other places and Equipment

53. If:

- (a) an area or place other than the Location or Pollen Trap is used in connection with this licence; or
- (b) Equipment is used in connection with the GMOs, Pollen Trap Plants or Material from the GMOs or Pollen Trap Plants;

then that area, place or Equipment must also be Cleaned.

54. Cleaning must occur immediately or as soon as practicable after use and before it is used for any other purpose.

55. If Equipment is Cleaned, the area in which the Equipment is Cleaned must also be Cleaned immediately or within 14 days of Cleaning of Equipment. (It is not necessary for Equipment to be Cleaned only at a Location.)

56. 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

57. Subject to Condition 58, if Destruction occurs by burial the licence holder must:

- (a) 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
- (b) inspect the Burial site at least once every 3 months for a period of 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 69.

58. 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 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

59. Light Tillage may only be adopted as a method for Cleaning a Location or Pollen Trap in conditions where germination of the GMOs or Reference *Brassicas* 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).

60. Following Cleaning of a Location or Pollen Trap, the Location or Pollen Trap must be Lightly Tilled twice, unless the Location or Pollen Trap was Lightly Tilled in the course of Cleaning it, in which case the Location or Pollen Trap must be Lightly Tilled again.

61. The two light tillage events required by Condition 60 at a Location or Pollen Trap must be separated by at least 28 days.

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

62. Light Tillage activities must be recorded in a logbook. The logbook must be available on request for examination or photocopying by the OGTR. 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 Locations and Pollen Traps Lightly Tilled;
- (b) the Light Tillage methods used; and
- (c) the dates Light Tillage occurred.

Post harvest (or post-Destruction) inspections to be conducted

63. Following Cleaning at the Location or other area, the following places must be inspected for the existence of Volunteer plants:

- (a) the Location;
- (b) the Pollen Trap in respect of the Location;
- (c) the Monitoring Zone in respect of the Location; and
- (d) any areas used to Clean Equipment that has been used in connection with the GMOs, Pollen Trap plants and/or Reference *Brassicas* and Material from the GMOs, Pollen Trap plants and/or Reference *Brassicas* .

64. Inspection must be performed by a person who is able to recognise Volunteer plants.

65. Any Volunteer plant must be Destroyed prior to the plant flowering.

66. All the places required to be inspected must be inspected at least once every 35 days for a period of 24 months that commences on the last day of Cleaning of the Location.

67. If no Volunteer plants are identified during 6 consecutive inspections, inspections may take place at intervals of at least once every 3 months for the remainder of the period that inspections are required (instead of once every 35 days).

68. At the conclusion of the 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 12 months; and
- (b) the Regulator has issued a Sign-off.

69. The results of inspection activities must be recorded in a logbook. The logbook must be available on request for examination or photocopying by the OGTR. The findings of the inspections as recorded in the logbook must be provided to the Regulator every month and included in the licence holder's Annual Report. The logbook must contain at least the following:

- (a) details of the areas inspected;
- (b) details of the date of inspection;
- (c) the names of the person or persons who undertook the inspections and details of the experience, training and/or qualification that enabled them to recognise Volunteer plants;
- (d) the number of Volunteer plants observed and where those plants or weeds were found, if any;
- (e) details of the development stages reached by the Volunteer plants if any; and
- (f) details of methods used to Destroy Volunteer plants and dates on which Destruction occurred, if any.

Transportation of seed or plant material

70. Subject to Condition 71, the GMOs, Pollen Trap Plants and/or *Reference Brassicas* and Material from the GMOs, Pollen Trap Plants and/or *Reference Brassicas* must be transported in accordance with the OGTR Guidelines for the Transport of GMOs (June 2001) issued by the Regulator.

71. Notwithstanding anything to the contrary in the Transport Guidelines, every container used to transport the GMOs, Pollen Trap Plants, *Reference Brassicas* and Material from the GMOs, Pollen Trap Plants and *Reference Brassicas* must be labelled:

- (a) to indicate that it contains GM Indian mustard or Canola; and
- (b) with telephone contact numbers for the licence holder and instructions to contact the licence holder in the event that the container is broken or misdirected.

72. The licence holder must ensure that the same quantity of GMOs, Pollen Trap Plants, *Reference Brassicas*, and Material from the GMOs, Pollen Trap Plants and *Reference Brassicas* sent is delivered. Routes, methods and procedures used for this transportation in accordance with this licence must be documented.

Limits on use of Locations and other areas after the Location has been Cleaned

73. Following Cleaning at a Location or other area required to be inspected under Condition 63, Prohibited Plants must not be grown in that place until the Regulator has issued a Sign-off in respect of that place.

Contingency Plans

74. Within 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 Material from the GMOs, Pollen Trap plants and/or Reference *Brassicas* at a Location, outside an area that must be inspected.

75. 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 Material from the GMOs, Pollen Trap Plants and/or *Reference Brassicas* at the Location; and
- (c) inspect and Destroy any Volunteer plants that may exist as a result of the event.

76. The Contingency Plan must be implemented in the event that the unintended presence of the GMOs, Pollen Trap Plants and/or *Reference Brassicas* and Material from the GMOs, Pollen Trap Plants and/or *Reference Brassicas* at the Location is discovered outside an area that must be inspected.

Compliance Management Plan

77. 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 these conditions and document that compliance.

Reporting

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

Research requirements

79. The licence holder must, in consultation with the OGTR, develop an agreed research program to collect information regarding:

- (a) changes to agronomic characteristics that may affect the weediness potential of the GM Indian mustard at all trial sites where the GMO is grown; and
- (b) stability of the inserted genes in the GM Indian mustard over successive generations.

80. The licence holder must provide the Regulator with progress and results of the research program in the Annual Report.

Testing methodology

81. 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 (at Attachment B) in a recipient organism. The instrument must be provided within 30 days of the issuing of this licence.

Attachment A to the Licence for dealings involving an intentional release of GMOs into the environment

DIR No: 057/2004

Full Title: Field trial of genetically modified herbicide tolerant Indian mustard incorporating a hybrid breeding system

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

Attachment B to the Licence for dealings involving an intentional release of GMOs into the environment

GMOs Description

Note: Confidential commercial information (CCI) has been removed from this attachment.

Purpose of the Dealings with the GMOs:

Conduct early stage research to: evaluate the agronomic performance of up to 70 different GM Indian mustard (*Brassica juncea*) lines (GMO Type 1), including comparison with conventional Indian mustard, conventional canola (*B. napus*) and GM canola (GMO Type 2 and GMO Type 3); assess the effectiveness of the herbicide tolerance trait in the field; and produce seed from lines selected for ongoing evaluation trials planned for overseas and possibly also Australia (subject to further approvals).

The GMOs covered by this licence are as follows:

GMO Type 1:

***Parent Organism:**

Common Name: Indian mustard, and hybrids of Indian mustard with Canola

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

***Modified traits:**

Category: Herbicide tolerance
Hybrid breeding system

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

- tolerance to the herbicide [CCI removed] ; 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 removed]

Hybrid breeding system:

- (1) 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.
- (2) 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.

Details:

Indian mustard, and hybrids of Indian mustard with Canola, modified by insertion of genetic material from any one or more of the following gene constructs:

[CCI removed]

GMO Type 2:

***Parent Organism:**

Common Name: Canola

Scientific Name: *Brassica napus* L. ssp. *oleifera*

***Modified traits:**

Category: Herbicide tolerance
Hybrid breeding system

***Genes responsible for conferring the modified traits:**

Herbicide tolerance:

[CCI removed]

Hybrid breeding system:

- (1) 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.
- (2) 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.

Details:

GM canola plant lines developed using the same gene constructs, and expressing the same traits, as for GMO Type 1.

These GMOs are also licensed for intentional release (field trial) under licence **DIR 032/2002**.

Full details of these GMOs are also provided in licence **DIR 032/2002**.

[CCI removed]

GMO Type 3:***Parent Organism:**

Common Name: Canola

Scientific Name: *Brassica napus*

***Modified traits:**

Category: Herbicide tolerance
Hybrid breeding system
Antibiotic resistance

***Genes responsible for conferring the modified traits:**

Herbicide tolerance:

bar gene from the bacterium *Streptomyces hygroscopicus*; or
pat gene from the bacterium *Streptomyces viridichromogenes*

Hybrid breeding system:

- (3) 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.
- (4) 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.

Antibiotic resistance:

nptII gene from the bacterium *Escherichia coli*

Details:

Canola has been genetically modified to express tolerance to the herbicide glufosinate ammonium, and a hybrid breeding system based on male sterile (MS) and fertility restorer (RF) lines, and resistance to the antibiotics neomycin and kanamycin.

These GMOs are known as InVigor[®] Canola

These GMOs are also licensed for intentional release (commercial release) under licence **DIR 021/2002**.

Full details of these GMOs are also provided in licence **DIR 021/2002**.

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