



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 086/2008

Licence holder: CSIRO

Title: Limited and controlled release of maize genetically modified to investigate gene function

Issued: 3 December 2008

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 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.

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.

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 with respect to 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) and equivalent provisions in corresponding State law.

‘Annual Report’ means a written report provided to the Regulator within ninety (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.

‘Birdcage’ means a structure surrounding the Location that is fully enclosed, ie above and on all sides, by chicken wire mesh.

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

- (a) in relation to a Place specified in this licence as requiring Cleaning, the Destruction of the 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 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) stalk pulling; or
- (b) uprooting; or

- (c) ploughing; or
- (d) burning; or
- (e) treatment with herbicide; or
- (f) hand weeding; or
- (g) autoclaving.

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 harvesters, seeders, storage equipment, transport equipment (eg bags, containers, tractors), clothing and tools.

'GM' means genetically modified.

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

'Location' means the area of land within the Birdcage where the GMOs may be intentionally planted and grown pursuant to this licence.

'Maize' means plants of the species *Zea mays* L. ssp. *mays*.

'Monitoring Zone' means an area of land extending outwards at least ten (10) metres in all directions from the outer edge of the Birdcage.

'Natural Waterway' 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 required to be Cleaned and/or inspected under the conditions of this licence.

'Plant Material' means the whole, or any part of, the GMOs or non-GM Maize plants grown at the 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.

'Related Plants' means any plant of a species or subspecies that is sexually compatible with Maize, including plants of the subspecies *Zea mays* L. ssp. *mexicana*.

'Sign-off' means a notice in writing from the Regulator, with respect to a Site, that post harvest inspection conditions no longer apply with respect to that Site.

'Site' for each Location means the aggregate of all Places with respect to that Location.

'Volunteer Plants' means

- (a) for the Location, any progeny or regrowth of the GMOs or non-GM Maize Plants, and/or

- (b) for any other Place, GMOs, non-GM Maize plants, that are not intentionally grown at the Site, or progeny or regrowth of previous GMOs or non-GM Maize plants.

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 CSIRO.

Project Supervisor

- 6. The project supervisor with respect to this licence is the person identified in Attachment A of the licence.
- 7. The licence holder must immediately notify the Regulator in writing if any of the contact details of the project supervisor change.

No dealings with the GMOs except as authorised by this licence

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

Persons covered by this GMO licence

- 9. The persons covered by this licence are the licence holder and employees, agents or contractors of the licence holder and other persons who are, or have been, engaged or otherwise authorised by the licence holder to undertake any activity in connection with the dealings authorised by this licence.

Informing people of their obligations

- 10. The licence holder must inform any person covered by this licence, to whom a particular condition of this licence applies, of the following:
 - (a) the particular condition (including any variations of it);
 - (b) the cancellation or suspension of the licence;
 - (c) the surrender of the licence.
- 11. If a particular condition, including any variation of it, applies to a person with respect to a particular dealing, the licence holder must not permit a person covered by this licence to conduct that dealing unless,
 - (a) the person has been informed of the condition, including any variation of it, and
 - (b) the licence holder has obtained from the person a signed and dated statement that the person,
 - i) has been informed by the licence holder of the condition and, when applicable, its variation, and
 - ii) has understood and agreed to be bound by the condition, or its variation, and
 - iii) has not conducted the dealing without being informed of the condition, or its variation.

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

13. 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

14. 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

15. 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

16. It is a condition of this 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 the above condition 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 the above condition if he or she was reckless as to whether such contraventions had occurred, or such unintended effects existed.*

17. 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

18. 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.

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

Remaining an Accredited organisation

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

Notices

21. 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 Section 7 of this licence.

Section 3 Dealings with the GMOs – general conditions

GMOs covered by this licence

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

Permitted dealings

23. The permitted dealings with the GMOs are to

- (a) conduct experiments with the GMOs,
- (b) breed the GMOs,
- (c) propagate the GMOs,
- (d) grow, raise or culture the GMOs,
- (e) transport the GMOs, and
- (f) dispose of the GMOs

and includes the possession, supply or use of the GMO for the purposes of, or in the course of the above permitted dealings.

24. Limits – scope, scale, location and duration of the trial

25. The GMOs may only be grown at the CSIRO Black Mountain Site in the Australian Capital Territory.

26. The Location must be within a Birdcage that is covered above and on all sides by wire mesh with a mesh diameter of no more than two (2) centimetres and have lockable gates, which must be kept locked except when the Location is accessed by persons covered by this licence.

27. No more than 0.075 hectares may be used to grow GMOs within the Birdcage and the GMOs may be replanted in each growing season.

28. Only the GMOs, non-GM Maize or oats (*Avena sativa* L.) may be grown at the Location.

29. Non-GM plants other than Maize or oats may be grown in the area within the Birdcage, but outside the Location, if their morphological characteristics permit successful inspection for Volunteer Plants and Related Plants, and their destruction.

30. Of the permitted dealings described in condition 23, breeding, propagating, growing, raising and culturing may only be undertaken between December 2008 and May 2013, inclusive.

31. *Non-GM Plants*

32. Planting of variegated oil yellow non-GM Maize is permitted within the Location but must occur at seedling stage or at a later stage of development of the non-GM Maize plants.

33. Variegated oil yellow non-GM Maize plants that are planted intentionally must be clearly identifiable and capable of being distinguished from GMOs, Volunteer Plants and Related Plants.

34. Variegated oil yellow non-GM Maize plants that are clearly identifiable are permitted to flower and shed pollen but must otherwise be handled and controlled as if it were the GMO (ie subject to other applicable conditions elsewhere in this licence)

35. Pollen obtained from variegated oil yellow non-GM Maize plants that are clearly identifiable may be used in controlled crosses at the Location but all other Plant Material from variegated oil yellow non-GM Maize grown at a Location must be handled and controlled as if it were Plant Material from the GMO (ie subject to other conditions elsewhere in this licence).

Section 4 *Breeding, propagating, growing, raising and culturing the GMOs*

Notice of intention to plant and of planting

36. The licence holder must, in the manner required by paragraph 80, give advance notice to the Regulator of an intention to plant the GMOs.

37. The licence holder must, in the manner required by paragraph 81, give notice to the Regulator of the actual date of planting the GMOs.

Controls – planting and growing the GMOs

38. The Location must be located on land that is not subject to flooding and the edge of the location in which the GMOs are grown (the ‘outer edge of the Location’) must not be within fifty (50) metres of a Natural Waterway.

39. Access to the Birdcage must be restricted to persons covered by this licence.

40. The base of the cage must be in contact with the ground around its entire perimeter.

41. The birdcage must be surrounded by a Monitoring Zone.

42. The licence holder must monitor every two days during the likely and actual flowering period for the emergence of tassels on any of the GMOs. During the remainder of the growing season, monitoring for the emergence of tassels must occur weekly.

43. The licence holder must, in the manner required by paragraph 82, give notice to the Regulator of the date on which emergence of tassels is first observed.
44. All male flowers must be removed completely from the GMOs before pollen is mature. Male flowers need not be removed from variegated oil yellow non-GM Maize Plants that are clearly identifiable.

Section 5 Use of Plant Material

Controls - Experimenting and storing the GMOs and/or GM plant materials

45. Experiments and/or analysis of Plant Material is only permitted to be conducted within the Birdcage if it is in accordance with this licence.
46. Experiments and/or analysis of Plant Material may be conducted outside the Birdcage if:
- (a) the experiment and/or analysis is a notifiable low risk dealing; and
 - (b) the experiment and/or analysis does not involve the feeding of the Plant Material to humans or animals.

Note: A dealing will only be a notifiable low risk dealing if:

- (a) *an Institutional Biosafety Committee has been asked to assess whether the proposed dealing is a notifiable low risk dealing; and*
- (b) *the Committee has assessed the proposed dealing to be a notifiable low risk dealing; and*
- (c) *the person who proposes to undertake the proposed dealing and the project supervisor for the proposed dealing have been notified that the Committee;*
 - i) *has assessed the proposed dealing to be a notifiable low risk dealing; and*
 - ii) *considers that the personnel to be involved in the proposed dealing have appropriate training and experience.*

47. Any Plant Material may be collected from the Site for the purpose of conducting experiments and/or analysis on it or any other dealings permitted by this licence.

48. Any Plant Material that is collected for experiments and/or analysis may be transported off the Site for the purpose of conducting experiments on it.

49. Any Plant Material that is collected for experiments and/or analysis may be transported off the Site to:

- (a) a facility certified by the Regulator to Physical Containment Level 2 (PC2); or
- (b) a facility approved in writing by the Regulator and signed so as to indicate that GM Plant Material is experimented with or stored within the facility

and may be experimented on, analysed and stored in any one or more of these facilities.

Plant Material not to be used in food

50. The GMOs and Plant Material must not be used, sold or otherwise disposed of for in any way which would involve or result in their use as food for animals or humans or in the manufacture of a thing that is not the GMO.

Section 6 Transport, Cleaning and Disposal

51. If 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.

Notice of harvest and Cleaning following harvest

52. The licence holder must, in the manner required by paragraph 83, provide the Regulator with a notice of intention to harvest the GMOs at the Location.

53. The licence holder must, in the manner required by paragraph 84, provide the actual date or dates of harvesting of the GMOs at the Location.

54. The licence holder must, in a manner required by paragraph 85, give notice to the Regulator of the date on which Cleaning of each Place concluded.

Harvest and post harvest procedures

55. The GMOs or non-GM plants grown at the Location must be harvested separately from any other crop and be kept separate after harvest.

56. Seed from the GMOs and non-GM plants grown at the Location must only be:

- (a) stored in a sealed container, within a locked facility (PC2 or approved in writing by the Regulator) that is signed so as to indicate that GM Maize seed is stored within the facility; or
- (b) experimented on within a facility as specified in conditions 45 – 49; or
- (c) exported; or
- (d) replanted subject to the conditions of this licence or other relevant authorisation under the Act; or
- (e) Destroyed.

Transportation of Plant Material

57. Any Plant Material transported must be transported in accordance with the guidelines for the transportation of GM Plant Material found in 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.

58. In addition to the requirements of the above condition, every container used to transport Plant Material must be labelled:

- (a) to indicate that it contains GM Maize; 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.

Cleaning of Equipment and Places

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

60. The following Places must be Cleaned in accordance with these licence conditions:

- (a) the entire area within the Birdcage;

- (b) the Monitoring Zone; and
- (c) any areas used to Clean Equipment used in connection with the GMOs or Plant Material at the Location or to Destroy the GMOs or Plant Material.

61. Each Place must be Cleaned either within fourteen (14) days of any harvest of the GMOs or within eight (8) months of planting of the GMOs to be harvested, whichever occurs first.

Section 7 Inspection, Use of Site and Sign-off

62. Inspection must be performed by a person who is able to recognise Volunteer Plants and Related Plants.

Inspections

63. The licence holder must, in accordance with this licence:

- (a) inspect the Birdcage surrounding the Location and repair any damage as soon as reasonably possible; and
- (b) inspect the base of the Birdcage for the presence of plants and other material capable of attracting and/or harbouring rodents and as soon as reasonably possible remove these materials, if any. Measures to achieve this may include, but are not limited to, hand pulling and/or application of herbicide; and
- (c) inspect the Monitoring Zone and maintain it in a manner that does not attract or harbour rodents. Measures to achieve this could include keeping land free of any vegetation and/or vegetation kept mown to a height of less than ten (10) centimetres; and
- (d) inspect the Birdcage area for rodent activity and implement whatever additional measures that are reasonably necessary to monitor for and control rodents within the birdcage as appropriate. These may include, but are not limited to trapping and baiting; and
- (e) inspect the following areas for the presence of any Volunteer Plants and Related Plants, and destroy any such plants before they initiate flowering:
 - i. the entire area within the Birdcage;
 - ii. the Monitoring Zone; and
 - iii. any areas used to Clean Equipment used in connection with the GMOs or Plant Material at the Location or to Destroy the GMOs or Plant Material.

64. All inspections specified in the immediately preceding condition are to be carried out weekly between 1 October and 31 May, and monthly between 1 June and 30 September.

65. After the final harvest, all Places which must be inspected for the existence of Volunteer Plants and Related Plants must be maintained so as to allow the identification of any Volunteer Plants and Related Plants.

Note: The continued use of method(s) used to maintain the Monitoring Zone in a manner required under condition 63, may not be appropriate following Cleaning as these methods could interfere with the identification of Volunteer plants. For example,

mowing to a height of less than 10 cm or herbicide treatment of weeds may inhibit identification of Volunteer plants or Related Plants.

66. The licence holder must, in the manner required by paragraph 87, provide the Regulator with the findings of the inspections and any measures taken.

67. All the Places required to be inspected must be inspected until the Regulator has issued a Sign-off for the relevant Site.

68. Inspection conditions do not apply with respect to a Place within a Site if the licence holder has received a Sign-off for that Site.

Maize seed bank reduction

69. In the first spring or summer season following the final harvest of the GMOs – once temperatures are conducive to the germination and growth of Maize, the licence holder must cultivate the Location so as to promote the germination of Volunteer Plants. Shallow cultivation must be employed so as to prevent the induction of dormancy in any Maize seed.

70. If, in cultivating the Location, the soil does not contain sufficient moisture through accumulated rainfall or irrigation to cause the germination of Volunteer Plants, the licence holder must ensure that the Location is irrigated sufficiently to enable the germination of Volunteer Plants.

General conditions on use of the Location between re-plantings – oats

71. The licence holder may grow oats (*Avena sativa* L.) at the Location as a green manure crop between re-plantings of the GMOs. If the soil at the Location is cultivated for this purpose it must be cultivation which is sufficiently shallow to avoid inducing dormancy in any Maize seed at the Location.

General conditions on use of the Location after the final harvest of the GMOs

72. If the GMOs are grown at the Location, no plants may be planted at the Location after the final harvest of the GMOs until inspection obligations are completed unless:

- (a) the plants are the GMOs or non-GM Maize planted in accordance with the conditions of this licence as they apply to GMOs and non-GM Maize plants; or
- (b) the plants are plants agreed to in writing by the Regulator.

Sign-off

73. For each Site,

- (a) if, after the final harvest of the GMOs, inspections have been routinely completed for a period of at least twelve (12) months, and,
- (b) if inspection records for that Site show that no Volunteer Plants have been observed in the most recent six (6) month inspection period,

the licence holder may make written application to the Regulator that these inspection conditions no longer apply to the Site and that the site receive ‘Sign-off’.

Section 8 Reporting and Documentation Requirements

Compliance Management Plan

74. 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.

75. 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 Plan

76. Within thirty (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 GMOs and Plant Material outside the Site relevant to the Location.

77. 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 and Plant Material found outside of the Site;
- (c) inspect for and Destroy any Volunteer Plants that may exist as a result of the event.

78. 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.

79. If for any reason the licence holder cannot implement the Contingency Plan when required to do so, the licence holder must notify the Regulator as soon as is reasonably practicable.

Notice of intention to plant, of planting and development of male flowers

80. 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(s) on which planting of the GMOs is intended to commence;
- (b) the date(s) on which planting of any non-GM Maize on the Location is intended to commence;
- (c) details of the Location where the GMOs will be planted, including the size of the Location, a street address and GPS coordinates for the Location;
- (d) the period during which the licence holder considers the emergence of tassels is likely to occur on the GMOs and during which removal of the male flowers is likely to occur;
- (e) the period during which the licence holder considers the GMOs and other plants authorised by this licence are likely to be harvested (or Destroyed in lieu of harvest);
- (f) if GMOs have previously been planted at the Location, a history indicating how the Location has been used in the preceding two years, including details of previous GMOs and post harvest crops planted at the Location; and
- (g) a description of how the Location is intended to be used during the first two years following the final harvest of the GMOs.

81. 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(s) on which planting of the GMOs occurred;
- (b) the actual date(s) on which planting of any non-GM Maize plants on the Location occurred;
- (c) details of the Location where the GMOs were planted, including the size of the Location, a street address and GPS coordinates for the Location;
- (d) the period during which the licence holder considers the emergence of tassels is likely to occur on the GMOs and during which removal of the male flowers is likely to occur;
- (e) the period during which the licence holder considers the GMOs and other plants authorised by this licence are likely to be harvested (or Destroyed in lieu of harvest); and
- (f) a description of how the Location are intended to be used during the first two years following the final harvest of the GMOs.

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

- (a) the actual date on which the first tassels emerged on the GMOs;
- (b) the period during which the licence holder considers the emergence of tassels is likely to occur on the GMOs and during which removal of the male flowers is likely to occur;

- (c) the period during which the licence holder considers the GMOs are likely to be harvested;
- (d) the period during which the licence holder considers the GMOs are likely to be Destroyed.

Notice of harvest and Cleaning following harvest

83. 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.

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

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

86. 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.

Results of inspection activities

87. 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 any rainfall events at the location including measurements of any rainfall;
- (d) details of the date of inspection;
- (e) the names of the person or persons who undertook the monitoring and details of the experience, training or qualification that enabled them to recognise Volunteer Plants and Related Plants;
- (f) the means of inspection used;
- (g) the number of Volunteer Plants and/or Related Plants observed, if any;
- (h) details of the development stages reached by the Volunteer Plants and/or Related Plants, if any;
- (i) details of methods used to Destroy Volunteer Plants and/or Related Plants, if any;

- (j) if Volunteer Plants and/or Related Plants were found, the actual date(s) of Destruction, which must be confirmed to the Regulator within fourteen (14) days of Destruction;
- (k) details of any damage and/or repair to the Birdcage, if any; and
- (l) details of any rodent activity, if any and any measures taken to control rodents.

88. The licence holder must keep records of the type of GM Maize lines grown at the Site as part of the trial, and the area planted to each type.

Annual Report

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

Testing methodology

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

ATTACHMENT A

DIR No: 086/2008

***Full Title:** Limited and controlled release of maize genetically modified to investigate gene function

Organisation Details

Organisation: *CSIRO
Postal address: CSIRO Plant Industry
GPO Box 1600
CANBERRA ACT 2601

Phone No: 1300 363 400

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: CSIRO
Postal Address: CSIRO Plant Industry
GPO Box 1600
CANBERRA ACT 2601

IBC Details

IBC Name: IBC 103 (CSIRO Plant Industry)

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

GMO Description***Parent Organism(s):**

Common Name: Maize (corn)
 Scientific Name: *Zea mays* L. ssp. *mays*

***Modified trait(s):**

Category: Any maize characteristics may be affected by the introduced genetic modification.

Antibiotic resistance

Herbicide tolerance

β -glucuronidase (GUS = β -D glucuronide glucuronosohydrolase, EC 3.2.1.31) activity

Description: The GM maize lines contain a modified version of a maize transposable genetic element. Under certain conditions, it can move within the maize genome. If the introduced transposable element moves into a region controlling the expression of a particular gene, that gene may be over-expressed. The over-expression of the gene is used as a tag or marker, which helps to identify that gene for further investigation of its function. The offspring of the GM maize lines would be assessed for traits not observed in the parent plants.

The GM maize lines also contain an antibiotic resistance selectable marker gene and a reporter gene, both derived from *Escherichia coli*, and a herbicide tolerance selectable marker gene derived from *Streptomyces hygroscopicus*.

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

UbiDs transposable element (Partial) sequences derived from *Zea mays* ssp *mays*: *Ac wx-m9* and *Ubi* sequences. The transposable element also includes the *uidA* gene from *Escherichia coli* (see below).

Selectable marker genes *hph* gene from *E. coli*;
uidA gene from *E. coli*;
bar gene from *S. hygroscopicus*.

Purpose of the Dealings with the GMOs:

CSIRO applied for a licence to release up to eleven genetically modified (GM) maize lines into the environment on a limited scale and under controlled conditions. The purpose of the trial is to conduct basic research to investigate gene function in maize in order to improve characteristics that may be of agronomic importance. None of the GM plant material from the trial will be used in human food, animal feed or the manufacture of any maize product.

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