



**Australian Government**

**Department of Health**

Office of the Gene Technology Regulator

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

**Licence No.: DIR 160**

**Licence holder: Department of Economic Development, Jobs, Transport and Resources (DEDJTR)**

**Title: Limited and controlled release of perennial ryegrass genetically modified for fructan biosynthesis**

Issued: 6 March 2018

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](#) 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 activities involving genetically modified organisms (GMOs).

This licence is issued by the Gene Technology Regulator in accordance with the *Gene Technology Act 2000* and, as applicable, Corresponding State Law.

The Gene Technology Regulator is required to consult with, and take into account advice from, a range of key stakeholders, including other regulatory authorities, on risks to human health and safety and to the environment in assessing applications for dealings involving the intentional release of GMOs into the Australian environment.

Other agencies that also regulate GMOs or GM products include Food Standards Australia New Zealand, Australian Pesticides and Veterinary Medicines Authority, Therapeutic Goods Administration, National Industrial Chemicals Notification and Assessment Scheme and the Department of Agriculture and Water Resources. 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.

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 A of this licence.

### **Note about where dealings with GMOs are being undertaken pursuant to this licence**

Information about where the GMOs have been planted pursuant to this licence can be accessed on the [OGTR website](#).

## Interpretations and definitions

1. In this licence:

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

2. In this licence:

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

**'Adjacent Area'** means land other than the Planting Area which is inside the Polyhouse Enclosure, as indicated in Figure 1. Land defined as an Adjacent Area while a Polyhouse Enclosure is in place continues to be defined as an Adjacent Area if the Polyhouse Enclosure is removed after harvest of the GMOs.

**'Bare Fallow'** means land where no plants are intentionally grown, and where plant growth is controlled as reasonably practicable to permit identification of plants as required by this licence.

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

- (a) in relation to an area specified in this licence as requiring Cleaning, the Destruction of the GMOs in that area, to the reasonable satisfaction of the Regulator; or
- (b) in relation to Equipment, clothing and footwear, the removal and/or Destruction of the GMOs, to the reasonable satisfaction of the Regulator.

**'Contingency Plan'** means a written plan detailing measures to be taken in the event of the unintended presence of the GMOs outside an area that must be inspected. A Contingency Plan must include procedures to:

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

**'Destroy'**, (or **'Destroyed'** or **'Destruction'**) means, as the case requires, killed by one or more of the following methods:

- (a) manual uprooting;
- (b) treatment with herbicide;
- (c) burning/incineration;
- (d) crushing or grinding of seed;

- (e) autoclaving; or
- (f) a method approved in writing by the Regulator.

*Note: 'As the case requires' has the effect that, depending on the circumstances, one or more of these techniques may not be appropriate. For example, in the case of plants with mature seed heads still attached, treatment with herbicide would not be appropriate as it would not destroy viable seeds.*

**'Equipment'** includes, but is not limited to, seeders, harvesters, transport equipment (e.g. bags, containers, trucks) and tools.

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

**'GM'** means genetically modified.

**'GMOs'** means the genetically modified organisms that are the subject of the dealings authorised by this licence. GMOs include live plants, tillers and root stock that are able to grow into live plants, and viable seed.

**'Isolation Zone'** means an area of land extending outwards at least 100 m in all directions from the outer edge of the Monitoring Zone, as indicated in Figure 1.

**'Logbook'** means a written or electronic record containing information required to be collected and maintained by this licence and which is able to be presented to the OGTR on request.

**'Monitoring Zone'** means an area of land extending outwards at least 40 m from the edge of the Polyhouse Enclosure, as indicated in Figure 1. Land defined as a Monitoring Zone while a Polyhouse Enclosure is in place continues to be defined as a Monitoring Zone if the Polyhouse Enclosure is removed after harvest of the GMOs.

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

**'Personal Information'** means information or an opinion about an identified individual, or an individual who is reasonably identifiable:

- (a) whether the information or opinion is true or not; and
- (b) whether the information or opinion is recorded in a material form or not.

**'Perennial Ryegrass'** means plants of the species *Lolium perenne*.

**'Planting Area'** means an area of land where the GMOs and non-GM Perennial Ryegrass may be planted and grown pursuant to this licence.

**'Plant Material'** means any part of the GM or non-GM Perennial Ryegrass plants grown at a Planting Area, whether viable or not, or any product of these plants.

**'Polyhouse Enclosure'** means a structure having walls, anteroom and vent boxes composed of steel mesh with a maximum aperture size of 154 microns and the roof and outer ends of the structure covered with greenhouse film.

**'Regulations'** means the Gene Technology Regulations 2001(Commonwealth) or the corresponding State law under which this licence is issued.

**'Regulator'** means the Gene Technology Regulator.

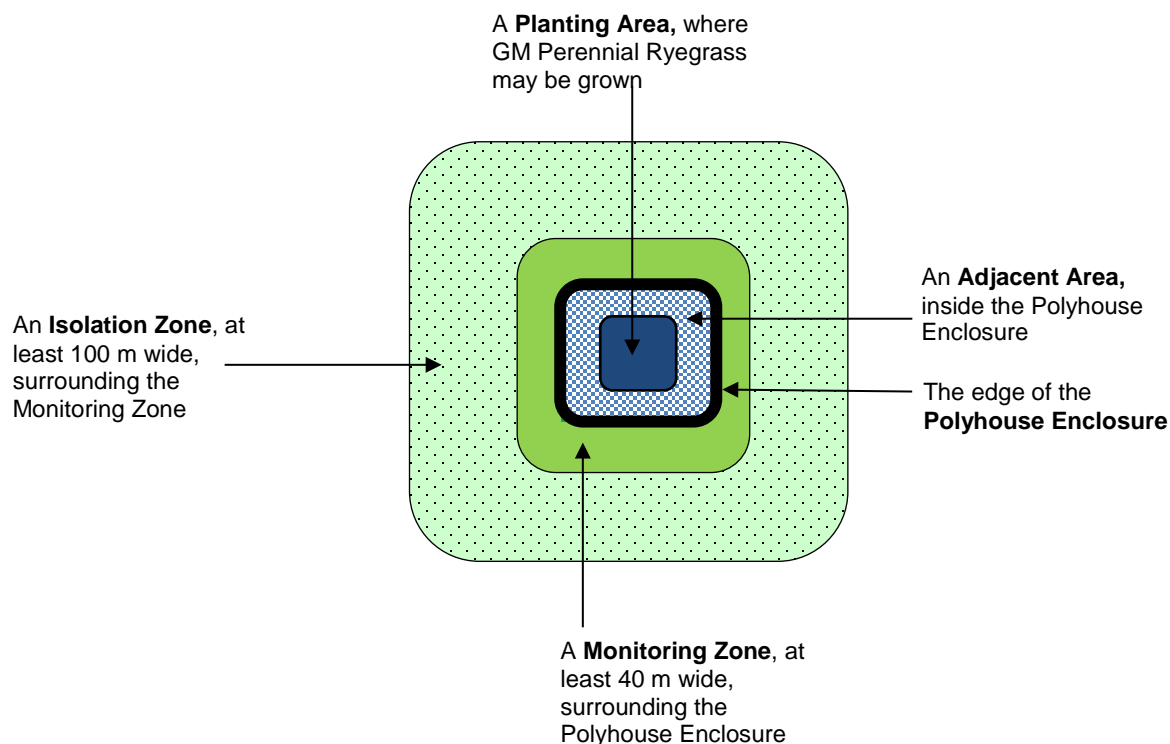
**'Related Species'** means plants of the species *Lolium multiflorum* Lam. (Italian ryegrass), *L. rigidum* Gaud. (annual ryegrass), *L. loliaceum* (rigid ryegrass), *L. remotum* (hardy ryegrass), *Festuca pratensis* (meadow fescue), *F. rubra* L. (red fescue) and *F. arundinaceum* (tall fescue).

**'Sign-off'** means a notice in writing from the Regulator, in respect of an area, that post-harvest obligations no longer apply in respect of that planting area and associated areas.

**'Tillage'** means the use of any technique to disturb the soil.

**‘Volunteers’** means GM or non-GM Perennial Ryegrass plants, or hybrid plants of Perennial Ryegrass and a Related Species, that have not been intentionally grown.

**‘Waterways’** means all permanent natural waterways and man-made waterways that flow into natural waterways.



**Figure 1. Diagram (not to scale) showing the relationships between the Planting Area, Adjacent Area, Polyhouse Enclosure, Monitoring Zone and Isolation Zone.**

## General conditions and obligations

3. 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.
4. This licence remains in force until it is suspended, cancelled or surrendered. No dealings with GMOs are authorised during any period of suspension.
5. The holder of this licence ('the licence holder') is the Department of Economic Development, Jobs, Transport and Resources (DEDJTR; Victoria).
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 this licence.
7. The dealings authorised by this licence are to conduct experiments with the GMOs, propagate and grow the GMOs, transport and dispose of the GMOs, and possession, supply or use of the GMOs in the course of any of these dealings.

### ***Obligations of the Licence Holder***

8. The licence holder must notify the Regulator in writing as soon as practically possible if any of the contact details of the project supervisor change from those notified in the licence application or subsequently.

*Note: please address correspondence to [ogtr.applications@health.gov.au](mailto:ogtr.applications@health.gov.au).*

*Prior to issuing a licence, the Regulator considers suitability of the applicant to hold a licence. The following conditions address ongoing suitability of the licence holder.*

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

10. The licence holder must:

- (a) inform the Regulator immediately in writing, of:
  - i. any relevant conviction of the licence holder occurring after the commencement of this licence; and
  - ii. any revocation or suspension of a licence or permit held by the licence holder under a law of the Australian Government, a State or a foreign country, being a law relating to the health and safety of people or the environment; and
  - iii. 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; and
- (b) provide any information related to the licence holder's ongoing suitability to hold a licence, if requested, within the stipulated timeframe.

11. The licence holder must be able to access and control the Planting Area, Adjacent Area, Monitoring Zone, Isolation Zone and approved facilities (if any) to the extent necessary to comply with this licence, for the duration of the licence.

*The following conditions seek to ensure that persons conducting the dealings are aware of the licence conditions and appropriate processes are in place to inform people of their obligations.*

12. Prior to conducting any dealings with the GMOs, the licence holder must provide to the Regulator:

- (a) names of all organisations and persons or functions or positions of the persons who will be covered by the licence, with a description of their responsibilities; and  
*Note: Examples of functions or positions are 'project supervisor', 'site manager', 'farm labourer' etc.*
- (b) detail of how the persons covered by the licence will be informed of licence conditions; and
- (c) detail of how the licence holder will access and control the Planting Area, Adjacent Area, Monitoring Zone, Isolation Zone and approved facilities (if any) for the duration of the licence; and  
*Note: this may include a description of any contracts, agreements, or other enforceable arrangements.*
- (d) written methodology to reliably detect the GMOs or the presence of the genetic modifications in a recipient organism, and to distinguish between categories of GMOs approved for release; and
- (e) a Contingency Plan to respond to inadvertent presence of the GMOs outside an area that must be inspected.

13. Any changes to the information provided under the immediately preceding condition must be communicated in writing to the Regulator within 14 days of the changes occurring.

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

- (a) the particular condition (including any variations of it); and

- (b) the cancellation or suspension of the licence; and
- (c) the surrender of the licence.

15. The licence holder must not permit a person covered by this licence to conduct any dealing with the GMOs unless:

- (a) the person has been informed of any applicable licence conditions, including any variation of them; 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 licence conditions including any variation of them; and
  - ii. has understood and agreed to be bound by the licence conditions, or variation.

16. The licence holder must:

- (a) inform the persons covered by this licence that any Personal Information relevant to the administration and/or enforcement of the licence may be released to the Regulator; and
- (b) provide the Regulator, if requested, with copies of the signed and dated statements referred to in the immediately preceding condition.

#### ***Provision of new information to the Regulator***

*Licence conditions are based on the Risk Assessment and Risk Management Plan developed in relation to the application using information available at the time of assessment. The following condition requires that any new information that may affect the risk assessment is communicated to the Regulator.*

17. The licence holder must inform the Regulator if the licence holder becomes aware of:

- (a) 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) any contraventions of the licence by a person covered by the licence; or
- (c) 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 paragraph 17(a) 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 paragraph 17(b) or 17(c) if he or she was reckless as to whether such contraventions had occurred, or such unintended effects existed.*

*Note: Contraventions of the licence may occur through the action or inaction of a person. For example if it is a condition of the licence that Volunteers are destroyed prior to Flowering and a Volunteer flowers, then the person responsible for controlling Volunteers will have contravened that licence condition.*

18. If the licence holder is required to inform the Regulator under the immediately preceding condition, the Regulator must be informed without delay.

*Note: An example of informing without delay is contact made within a day of the incident via the OGTR free call phone number 1800 181 030, which provides emergency numbers for incidents that occur out of business hours. Notification without delay will allow the OGTR to conduct a risk assessment on the incident and attend the location if required.*

19. If the licence holder informs the Regulator under the immediately preceding condition and the Regulator requests further information, such information must be provided in a manner, and within the time period, stipulated by the Regulator.

#### ***Obligations of persons covered by the licence***

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

21. 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.

### **Limits and control measures**

#### ***Limits on the release***

*The following licence conditions maintain the risk assessment context within which the application was assessed, by imposing limits on where and when the GMOs may be grown, and on other activities that can be undertaken.*

22. The only plants that may be intentionally grown at a Planting Area are:

- (a) the GMOs covered by this licence as described in Attachment A of the licence;
- (b) non-GM Perennial Ryegrass plants; and
- (c) plants approved in writing by the Regulator.

23. Planting and growing of the GMOs may only occur within the following limits:

| <b>Period</b>        | <b>Maximum number of Planting Areas per year</b> | <b>Maximum size of Planting Area</b> | <b>Local Government Area in which Planting Area may be located</b> |
|----------------------|--------------------------------------------------|--------------------------------------|--------------------------------------------------------------------|
| May 2018 – June 2020 | 1                                                | 160 m <sup>2</sup>                   | Southern Grampians Shire                                           |

24. Plant Material must not be used, sold or otherwise disposed of for any purpose which would involve or result in its use as food for humans or feed for animals.

#### ***Containment measures***

*The following licence conditions maintain the risk assessment context within which the application was assessed by restricting spread and persistence of the GMOs.*

#### **Pollen and seed dispersal during cultivation**

25. The outer edge of any Planting Area must be at least 100 m away from Waterways.

26. Any extreme weather event that is expected to affect or has already affected a Planting Area or associated areas, while the GMOs are growing or while the Planting Area is subject to inspection requirements, must be notified in writing to the Regulator as soon as practically and reasonably possible.

*Note: The Contingency Plan must be implemented if the GMOs are detected outside areas under inspection (Condition 48).*

27. Non-GM Perennial Ryegrass plants grown in a Planting Area must be handled as if they were the GMOs.



28. Rodents within the Planting Area and Adjacent Area must be controlled by trapping and/or baiting from planting the GMOs until at least 60 days after the GMOs are harvested or Destroyed.
29. The Planting Area must be enclosed within a Polyhouse Enclosure from planting the GMOs until at least 60 days after the GMOs are harvested or Destroyed.
30. Entry and exit to the Polyhouse Enclosure must be through an anteroom with an inner and an outer door.
31. People entering the Polyhouse Enclosure must wear dedicated outer clothing and footwear, and must remove this clothing and footwear in the anteroom when exiting the Polyhouse Enclosure. The used clothing and footwear must be Cleaned before use for any other purpose.
- Note: Clothing and footwear may be transported for Cleaning in accordance with the conditions of this licence.*
32. Equipment used in connection with the GMOs must be Cleaned as soon as practicable and before use for any other purpose.
33. The Polyhouse Enclosure must be enclosed within a fence capable of excluding livestock and rabbits from planting the GMOs until at least 60 days after the GMOs are harvested or Destroyed.
34. The Adjacent Area must be maintained as Bare Fallow from planting the GMOs until the GMOs are harvested or Destroyed.
35. The Polyhouse Enclosure must be surrounded by a Monitoring Zone that is maintained as Bare Fallow from planting the GMOs until the GMOs are harvested or Destroyed.
36. The Monitoring Zone must be surrounded by an Isolation Zone that is maintained in a manner that does not permit Flowering of Perennial Ryegrass or Related Species, from 14 days prior to the expected Flowering of any GMOs until all GMOs in the Planting Area have finished Flowering.
- Note: Examples of methods to prevent Flowering of Perennial Ryegrass or Related Species include mowing, heavy grazing, or application of herbicide effective in killing these grass species.*
37. Inspections must be conducted by people trained to recognise Perennial Ryegrass and Related Species, and actions taken as follows:

| Area                                  | Period of inspection                                                                                                                                                                                 | Inspection frequency        | Inspect for                            | Action                                                                          |
|---------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------|----------------------------------------|---------------------------------------------------------------------------------|
| (a) Planting Area                     | First inspection must occur at least 14 days prior to the expected commencement of Flowering of any GMOs*, and inspections must continue until all GMOs in the Planting Area have finished Flowering | At least once every 14 days | Related Species                        | Destroy before Flowering or prevent from Flowering simultaneously with the GMOs |
| (b) Adjacent Area and Monitoring Zone | First inspection must occur at least 14 days prior to the expected commencement of Flowering of any GMOs*, and inspections must continue until all GMOs in the Planting Area have finished Flowering | At least once every 14 days | Perennial Ryegrass and Related Species | Destroy before Flowering or prevent from Flowering simultaneously with the GMOs |

| Area                    | Period of inspection                                                                                                                                                                                                                  | Inspection frequency                                                      | Inspect for                             | Action                                   |
|-------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------|-----------------------------------------|------------------------------------------|
| (c) Polyhouse Enclosure | i. From 14 days prior to the expected commencement of Flowering of any GMOs*, and until all GMOs in the Planting Area have finished Flowering<br><br>ii. At all other times while Polyhouse Enclosure is required under Condition 29. | i. At least once every three days<br><br>ii. At least once every 14 days. | Damage that may reduce containment      | Repair and notify as soon as practicable |
| (d) Fence               | From planting the GMOs until at least 60 days after the GMOs are harvested or Destroyed..                                                                                                                                             | At least once every 14 days                                               | Damage that may permit animals to enter | Repair as soon as practicable            |

*\*Condition 51(a) requires the licence holder to provide information to the Regulator on the expected Flowering period, however the inspection period should be based on the observed development of the GMOs, so that inspections commence prior to Flowering of any GMOs.*

*Note: Details of any inspection activity must be recorded in a Logbook as detailed in Condition 51(e).*

38. GMOs planted in the Planting Area must be harvested or Destroyed within 10 months of planting.

39. If the GMOs planted in the Planting Area 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.

#### **Processing or experimentation with GMOs**

40. If processing of GM seed is not conducted under a Notifiable Low Risk Dealings (NLRD) authorisation, such activities may only be undertaken within:

- (a) a Planting Area before Cleaning; or
- (b) a facility approved in writing by the Regulator.

*Note: Dealings conducted under a NLRD authorisation must be assessed by an Institutional Biosafety Committee before commencement, must comply with the requirements of the Regulations, and are not subject to the conditions of this licence.*

41. If experimentation or analysis with the GMOs is not conducted under a NLRD authorisation, such activities may only be undertaken within:

- (a) a Planting Area before Cleaning; or
- (b) a facility approved in writing by the Regulator.

42. Within a facility approved under either of the two immediately preceding conditions, any area that is used for processing, experimentation or analysis of the GMOs must be Cleaned as soon as practicable and before use for any other purpose.

#### **Transport or storage of the GMOs**

43. If transport or storage of the GMOs is not conducted under a NLRD authorisation, such activities must:

- (a) only occur to the extent necessary to conduct the dealings permitted by this licence or other valid authorisation; and
- (b) be in accordance with the Regulator's *Guidelines for the Transport, Storage and Disposal of GMOs* for PC2 GM plants as current at the time of transportation or storage; and

- (c) comply with all other conditions of this licence.

*Note: Condition 15 requires signed statements for persons transporting or disposing of the GMOs.*

44. Methods and procedures used to transport GMOs must be recorded, and must be provided to the Regulator, if requested.

*Note: The Contingency Plan must be implemented if the GMOs are detected outside areas under inspection (Condition 49).*

#### **Persistence of the GMOs**

45. The Planting Area and Adjacent Area must be Cleaned within 14 days after completion of harvest of the GMOs.

46. After Cleaning, the Planting Area and associated areas of land must be inspected by people trained to recognise Perennial Ryegrass. Inspections must cover the entirety of areas to be inspected. Actions must be taken as follows:

| Area of land                                                                                                                                                                                                                                                                   | Period of inspection                                                                                                                                                                                             | Inspection frequency        | Inspect for | Action                   |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------|-------------|--------------------------|
| (a) Planting Area<br>(b) Adjacent Area<br>(c) Monitoring Zone<br>(d) Any other area where GMOs have dispersed during planting, growing or harvesting<br>(e) Any other area used to Clean Equipment used in connection with the GMOs<br>(f) Any other area used to Destroy GMOs | From the day of completion of Cleaning of the Planting Area and Adjacent Area, until:<br>i. an area becomes a new Planting Area under this licence*; or<br>ii. the Regulator has issued a Sign-off for the area. | At least once every 35 days | Volunteers  | Destroy before Flowering |

*\* If an area subject to post-harvest inspection requirements under Condition 46 is replanted with GMOs, the new Planting Area no longer requires post-harvest inspections, but surrounding areas do still require post-harvest inspections. In this case, some areas would be subject to inspection requirements under both Condition 46 and Condition 37.*

47. Details of any inspection activity must be recorded in a Logbook and must include:

- (a) date of the inspections;
- (b) name of the person(s) conducting the inspections;
- (c) details of the experience, training or qualification that enables the person(s) to recognise Perennial Ryegrass and/or Related Species, if not already recorded in the Logbook;
- (d) details of areas inspected including current land use;
- (e) details of the developmental stage of the GMOs while they are being grown;
- (f) details of any post-harvest rainfall events, including measurements at or near the area, or any irrigation events including the amount of water applied;
- (g) for post-harvest areas, details of any post-harvest crops and any recent management practices applied (including Tillage events)

*Note: this may include spraying or maintenance measures used to facilitate inspections for Volunteers*

- (h) details of any Volunteers observed during post-harvest inspections or land-management activities, including number, developmental stage and approximate position of the Volunteers within each area inspected <sup>⌘</sup>;
- (i) date(s) and method(s) of Destruction or of preventing Flowering simultaneously with the GMOs of any Perennial Ryegrass, Related Species or Volunteers;
- (j) details of any damage and any repairs to the Polyhouse Enclosure surrounding the Planting Area, while the Polyhouse Enclosure is required;
- (k) details of any damage and any repairs to the fence surrounding the Polyhouse Enclosure, while the fence is required; and
- (l) details of rodent control methods used and any evidence of rodent activity, while rodent control methods are required.

<sup>⌘</sup> *Examples of acceptable ways to record the positional information for Volunteers in the Logbook include:*

- *descriptive text*
- *marking on a diagram*
- *indicating grid references on corresponding map/sketch*

*Note: Details of Inspection activities must be provided to the Regulator (Condition 51(e)).*

48. While post-harvest inspection requirements apply to the Planting Area, Adjacent Area, Monitoring Zone and any associated areas:

- (a) the area must be maintained in a manner appropriate to allow identification of Volunteers;
- (b) the area may not be grazed by livestock; and
- (c) no plants may intentionally be grown in the area unless the plants are:
  - i. the GMOs or non-GM Perennial Ryegrass, planted in accordance with the conditions of this licence; or
  - ii. agreed to in writing by the Regulator.

### **Contingency plan**

49. If any unintentional presence of the GMOs is detected outside the areas requiring inspection, the contingency plan must be implemented.

### **Sign off**

50. The licence holder may make written application to the Regulator that planting restrictions and inspection requirements no longer apply to a Planting Area and associated areas if:

- (a) all post-harvest inspection activities have been conducted for at least 12 months on these areas;
- (b) conditions have been conducive for germination and detection;
- (c) the Planting Area, Adjacent Area and any area where seed may have been dispersed have undergone at least one Tillage and irrigation event, where Tillage and irrigation both occur within a period of 14 days;
- (d) no Volunteers that are GMOs have occurred after the most recent Tillage and irrigation event, as described in the previous clause; and

- (e) no Volunteers that are GMOs have occurred in the most recent 6 month period.

*Note: A period of natural rainfall may be taken as irrigation only with the agreement of the Regulator. Evidence (such as rainfall measurements, photos etc.) that the rainfall has been sufficient to promote germination should be provided.*

*Note: The Regulator will take into account the management and inspection history for the Planting Area and associated areas, including post-harvest Tillage, irrigation, rainfall, application of herbicide and occurrence of Volunteers, in deciding whether or not further inspections are required to manage persistence of the GMOs.*

## Reporting and documentation

*The following licence conditions are imposed to demonstrate compliance with other conditions, facilitate monitoring of compliance by staff of the OGTR, and emphasise appropriate selection of the planting area.*

51. Notifications must be sent to the Regulator as follows:

| Notice                    | Content of notice                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | Reporting Timeframe                                                                               |
|---------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------|
| (a) Intention to Plant    | <ul style="list-style-type: none"> <li>i. Details of the Planting Area including size, the Local Government Area, GPS coordinates, a street address or other directions and a diagrammatical representation of the site (e.g. Google Maps)</li> <li>ii. Identity of the GMOs to be planted at the Planting Area (e.g. lines or construct details)</li> <li>iii. Date on which the GMOs will be planted</li> <li>iv. Dates on which the rodent control, Polyhouse Enclosure, Fence, Adjacent Area and Monitoring Zone will be put in place</li> <li>v. Period when the GMOs are expected to Flower</li> <li>vi. Period when harvesting is expected to commence</li> <li>vii. How all areas requiring post-harvest inspections are intended to be used until Sign-off, including the proposed post-harvest crop(s), if any</li> <li>viii. Details on how inspection activities will be managed, including strategies for the detection and Destruction of Volunteers, Perennial Ryegrass or Related Species</li> <li>ix. History of how the site has been used for the previous two years</li> </ul> | At least 7 days prior to each planting (to be updated immediately if the notified details change) |
| (b) Planting              | <ul style="list-style-type: none"> <li>i. Actual date(s) of planting the GMOs</li> <li>ii. Any changes to the details provided under part (a) of this condition.</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | Within 7 days of any planting                                                                     |
| (c) Harvest               | Actual date(s) of harvesting or Destroying the GMOs.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | Within 7 days of commencement of any harvesting.                                                  |
| (d) Cleaning              | <ul style="list-style-type: none"> <li>i. Actual date(s) on which any areas needing Cleaning were Cleaned.</li> <li>ii. Method of Cleaning</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Within 7 days of completion of any Cleaning                                                       |
| (e) Inspection activities | Information recorded in a Logbook as per the inspection requirements (Conditions 37, 46 and 47).                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Within 35 days of inspection                                                                      |

*Note: Other reports and documents that may need to be sent to the Regulator are listed in Attachment B.*

**DIR No: 160**

**Full Title:** Limited and controlled release of perennial ryegrass genetically modified for fructan biosynthesis

**Organisation Details**

Postal address: Department of Economic Development, Jobs, Transport and Resources  
5 Ring Rd  
Bundoora  
Victoria 3083

Phone No: (03) 9032 7000

**IBC Details**

IBC Name: Biosciences Research Institutional Biosafety Committee

**GMO Description**

**GMOs covered by this licence:**

Perennial ryegrass plants genetically modified by introduction of only the genetic elements listed below.

**Parent Organism:**

Common Name: Perennial ryegrass

Scientific Name: *Lolium perenne*

**Modified traits:**

Categories: Composition – animal nutrition  
Yield  
Selectable marker – antibiotic resistance

Description: Perennial ryegrass plants have been genetically modified for altered fructan biosynthesis.  
The GM perennial ryegrass line contains the introduced genetic elements relating to fructan biosynthesis that are listed in Table 1 and also the antibiotic resistance marker gene listed in Table 2. The introduced regulatory sequences are listed in Table 3.

**Purpose of the dealings with the GMOs:**

The purpose of the release is to assess the agronomic characteristics of the GM perennial ryegrass plants under field conditions and to multiply seed for possible future trials.

The GM perennial ryegrass is not permitted to be used for human food or animal feed.

**Table 1. Introduced genetic elements relating to fructan biosynthesis in GM perennial ryegrass**

| Genetic element | Full name of gene                       | Source of gene        |
|-----------------|-----------------------------------------|-----------------------|
| <i>Lp1-SST</i>  | sucrose:sucrose 1-fructosyltransferase  | <i>Lolium perenne</i> |
| <i>Lp6G-FFT</i> | fructan:fructan 6G-fructosyltransferase | <i>Lolium perenne</i> |

**Table 2. Introduced antibiotic resistance marker gene in GM perennial ryegrass**

| Genetic element | Full name of gene                         | Source of gene          |
|-----------------|-------------------------------------------|-------------------------|
| <i>hph</i> gene | <i>Hygromycin phosphotransferase</i> gene | <i>Escherichia coli</i> |

**Table 3. Introduced regulatory sequences in GM perennial ryegrass**

| Regulatory sequence     | Source                   |
|-------------------------|--------------------------|
| <i>LpRbcS</i> promoter  | <i>Lolium perenne</i>    |
| <i>Actin 1</i> promoter | <i>Oryza sativa</i>      |
| 35S terminator          | Cauliflower Mosaic Virus |
| <i>LpFT4</i> terminator | <i>Lolium perenne</i>    |



## ATTACHMENT B

### Checklist of documents that must be sent to the Regulator:

| When                                | What                                                                                                                                                                                     | Condition | Timeframe of reporting                        |
|-------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------|-----------------------------------------------|
| Prior to conducting any dealings    | Details of persons covered                                                                                                                                                               | 12 (a)    |                                               |
|                                     | Plan to inform people covered by the licence                                                                                                                                             | 12 (b)    |                                               |
|                                     | Plan to ensure control and access to the Site                                                                                                                                            | 12 (c)    |                                               |
|                                     | Detection methodology                                                                                                                                                                    | 12 (d)    |                                               |
|                                     | Contingency plan                                                                                                                                                                         | 12 (e)    |                                               |
| Prior to planting                   | Intention to plant and put in place rodent control, Polyhouse Enclosure, Fence, Adjacent Area and Monitoring Zone                                                                        | 51 (a)    | At least 7 days prior to any planting         |
| Planting                            | Planting at a Planting Area                                                                                                                                                              | 51 (b)    | Within 7 days of any planting                 |
| While growing                       | Inspections of Polyhouse Enclosure and fence                                                                                                                                             | 37        | Within 35 days of each inspection             |
|                                     | Inspections of Planting Area, Adjacent Area and Monitoring Zone                                                                                                                          | 37        | Within 35 days of each inspection             |
| After harvest                       | Harvesting at a Planting Area                                                                                                                                                            | 51 (c)    | Within 7 days of harvesting                   |
|                                     | Post-harvest inspections                                                                                                                                                                 | 46        | Within 35 days of each inspection             |
| Any time after issue of the licence | Any changes of the project supervisor contact details                                                                                                                                    | 8         | As soon as practicable                        |
|                                     | Any relevant conviction, any revocation, suspension or cancellation of a relevant permit or any circumstances that may affect compliance with licence conditions                         | 10 (a)    | Immediately, if occurs                        |
|                                     | Any information relevant to on-going suitability                                                                                                                                         | 10 (b)    | If and when requested                         |
|                                     | Any changes to details provided under conditions 12(a) - 12(e)                                                                                                                           | 13        | Within 14 days of the changes                 |
|                                     | Signed statements from persons covered under the licence                                                                                                                                 | 16 (b)    | If and when requested                         |
|                                     | Any additional information regarding health and safety of people and the environment, contraventions of this licence or any unintended effects of the dealings authorized by the licence | 17        | Without delay, after becoming aware           |
|                                     | Extreme weather conditions                                                                                                                                                               | 26        | As soon as practicable, if expected or occurs |
|                                     | Methods and procedures for transport                                                                                                                                                     | 44        | If and when requested                         |
|                                     |                                                                                                                                                                                          |           |                                               |