Australian Government
Department of Health, Disability and Ageing
Office of the Gene Technology Regulator

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

Licence No.: DIR 165

Licence holder: The University of Melbourne

Title: Limited and controlled release of wheat genetically modified for altered iron uptake, transport and bioavailability, and enhanced yield

Issued: 17 April 2019

Varied: 20 February 2023

Varied: 12 March 2024

Varied: 22 May 2024

Varied: 2 March 2025

Varied: 5 January 2026

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 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, Australian Industrial Chemicals Introduction Scheme and the Department of Agriculture, Fisheries and Forestry. 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 recognising areas as designated for the purpose of preserving the identity of GM crops, non-GM crops, or both GM crops and non-GM crops, for marketing purposes.

Licence DIR 165

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.

Information about where the GMOs have been planted pursuant to this licence can be accessed on the OGTR website.

Section 1 Interpretations and Definitions

1. In this licence:

    a. unless defined otherwise, words and phrases used in this licence have the same meaning as they do in the Act and the Regulations;

    b. words importing a gender include any other gender;

    c. words in the singular include the plural and words in the plural include the singular;

    d. words importing persons include a partnership and a body whether corporate or otherwise;

    e. references to any statute or other legislation (whether primary or subordinate) are a reference to a statute or other legislation of the Commonwealth of Australia as amended or replaced from time to time and equivalent provisions, if any, in corresponding State law, unless the contrary intention appears;

    f. where any word or phrase is given a defined meaning, any other part of speech or other grammatical form in respect of that word has a corresponding meaning;

    g. specific conditions prevail over general conditions to the extent of any inconsistency.

2. In this licence:

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

'Burial Site' means a place where the GMOs are Destroyed by burial.

'Clean' means, as the case requires:

    a. in relation to Equipment or a Facility, remove and/or Destroy the GMOs; or

    b. in relation to an area of land specified in this licence as requiring Cleaning:

        i. Destroy GM plants, if present, to the reasonable satisfaction of the Regulator, and

        ii. Remove most of the GM seeds from the soil surface.

Note: One method of removing most GM seeds from the soil surface is Tillage, which moves seeds to under the soil.

'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 to the reasonable satisfaction of the Regulator; and

    c. inspect for and Destroy any Volunteers that may exist as a result of the event to the reasonable satisfaction of the Regulator.

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

    a. uprooting;

    b. Tillage, but only subject to the conditions of this licence;

    c. root cutting and shredding/mulching

    d. treatment with herbicide;

    e. burning/incineration;

f. autoclaving;

g. milling;

h. grinding/crushing;

i. burial, but only subject to the conditions of this licence; or

j. 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, Tillage would not be appropriate due to the possible introduction of large numbers of viable seeds into the seedbank.

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

'Extreme Weather' includes, but is not limited to, flooding, cyclones or torrential rain, that could disperse GMOs or affect the licence holder's ability to comply with licence conditions.

'Facility' means a facility approved in writing by the Regulator.

'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 and viable seed.

'Inspection Zone' means an area of land extending at least 50 m in all directions from the outer edge of a Monitoring Zone, as shown in Figure 1.

'Isolation Zone' means an area of land extending at least 140 metres in all directions from the outer edge of an Inspection Zone, as shown 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 Regulator on request.

'Monitoring Zone' means an area of land extending outwards at least 10 m from the outer edge of a Planting Area, as shown in Figure 1. If multiple Planting Areas are present in a Site, the Monitoring Zone also includes the areas of land, of any size, between Planting Areas, as shown in Figure 1.

'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.

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

'Planting Area' means an area of land where the GMOs and non-GM Wheat are planted and grown pursuant to this licence.

'Regulations' means the Gene Technology Regulations 2001.

'Regulator' means the Gene Technology Regulator.

'Related Species' means durum wheat, rye or triticale plants.

'Sign off' means a notice in writing from the Regulator, in respect of an area, that post-Cleaning obligations no longer apply in respect of that area.

'Site' means an area of land containing one or more Planting Areas and their joint Monitoring Zone, as shown in Figure 1.

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

'Volunteers' means GM or non-GM Wheat plants which have not been intentionally grown.

'Waterways' means all permanent natural waterways and man-made waterways that flow into natural waterways.

Wheat means plants of the species *Triticum aestivum* L. (bread wheat).

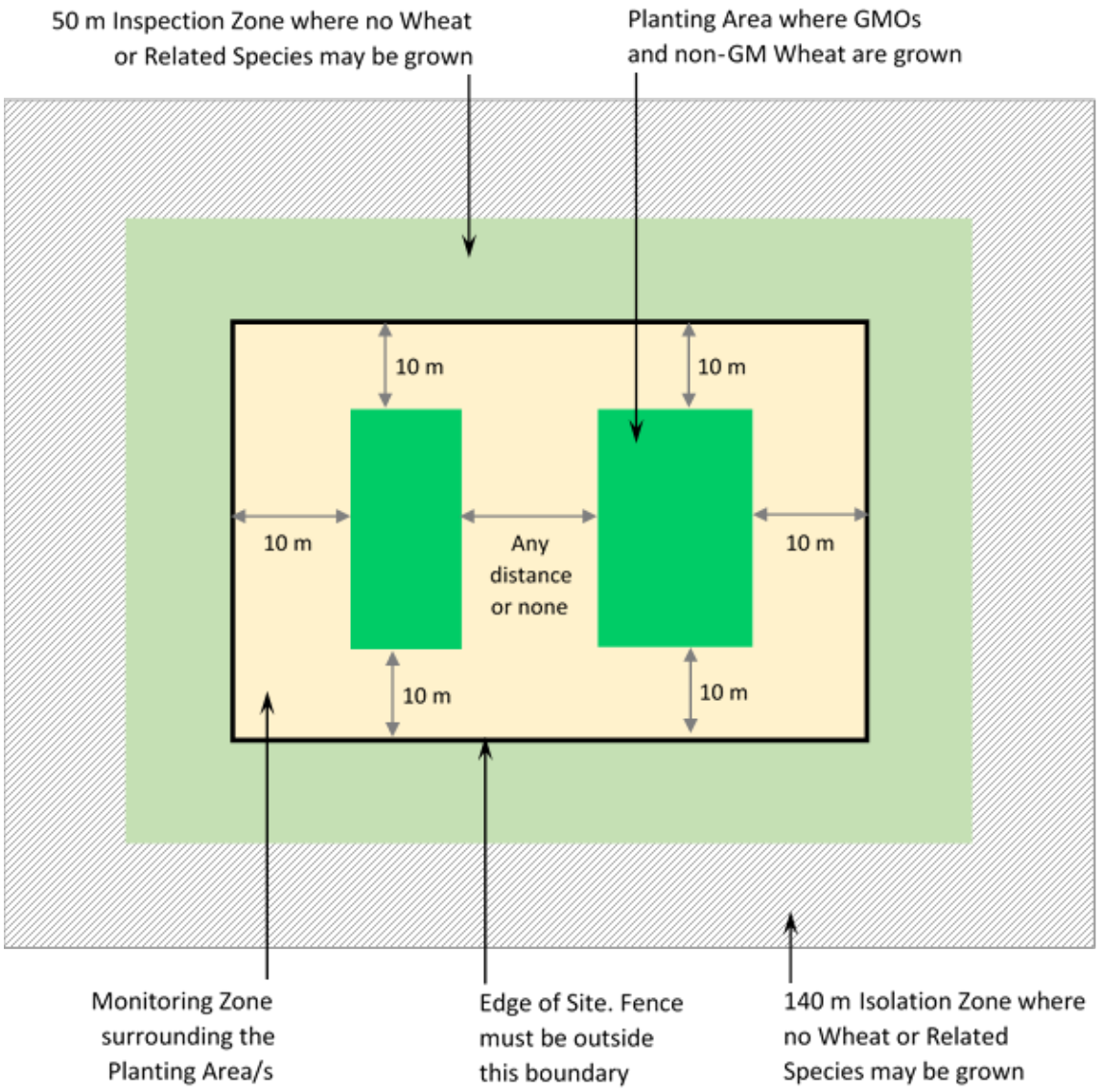

Figure 1. Diagram (not to scale) showing the relationship between Planting Area, Monitoring Zone, Site, Inspection Zone and Isolation Zone.

Section 2 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 recognising an area as designated for the purpose of preserving the identity of GM crops, non-GM crops, or both GM crops and non-GM crops, for marketing purposes.

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

5. The licence holder is The University of Melbourne.
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, breed, propagate, grow, import, transport and dispose of the GMOs, use the GMOs in the course of manufacture of a thing that is not a GMO, 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 send all correspondence related to the licence to OGTR.M&C@health.gov.au.

Prior to issuing a licence, the Regulator considers suitability of the applicant to hold a licence. The following two 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 by the Regulator, within the stipulated timeframe.
11. The licence holder must be able to access and control the Planting Areas, Monitoring Zones, Inspection Zones, Isolation Zones, Burial Sites and approved Facilities to the extent necessary to comply with this licence, for the duration of the licence.
12. At least 14 days 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 Areas, Monitoring Zones, Inspection Zones, Isolation Zones, Burial Sites and approved Facilities, 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. The detection method must be capable of identifying each GM wheat line planted under this licence; 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.

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.

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 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 conditions require 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 Condition 17 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 Condition 17, 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 has 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. 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 Condition 17 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.

Note: Under the Act, the definition of premises includes a building, area of land or vehicle.

Section 3 Limits and Control Measures

3.1 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 which persons are permitted to deal with the GMOs.

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 Wheat plants; and

    c. plants approved in writing by the Regulator.

23. Non-GM Wheat plants grown in a Planting Area must be handled as if they were the GMOs.

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

Area and duration

Year	Maximum number of Sites	Maximum combined area of Planting Areas in each Site
2019	2	2 ha
2020 – 2023	10 per calendar year	2 ha
2024	4	5 ha
2025 autumn/winter planting	4	5 ha
2025-26 spring/summer planting	4	5 ha
2026 autumn/winter planting	4	5 ha

Local government areas in which Sites may be located

New South Wales	Victoria	Western Australia
Berrigan	Ararat	Albany
Bland	Ballarat	Beverley
Blayney	Benalla	Boddington
Cabonne	Buloke	Boyup Brook
Coolamon	Greater Bendigo	Bridgetown-Greenbushes
Coonamble	Campaspe	Brookton
Cootamundra-Gundagai	Central Goldfields	Broomehill-Tambellup
Cowra	Colac Otway	Carnamah
Dubbo	Corangamite	City of Greater Geraldton
Edward River Council	Gannawarra	Coorow
Forbes	Glenelg	Corrigin
Federation Council	Golden Plains	Cranbrook
Gilgandra	Greater Geelong	Cuballing
Greater Hume	Greater Shepparton	Cunderdin
Griffith	Hepburn	Dalwallinu
Gunnedah	Hindmarsh	Denmark
Gwydir	Horsham	Donnybrook-Balingup
Hay	Indigo	Dowerin
Hilltops Council	Loddon	Dumbleyung
Inverell	Macedon Ranges	Esperance
Junee	Mildura	Gnowangerup
Leeton	Mitchell	Goomalling
Liverpool Plains	Moira	Jerramungup
Lockhart	Moorabool	Katanning
Mid-Western	Mount Alexander	Kent
Moree Plains	Moyne	Kojonup
Murray River Council	Northern Grampians	Manjimup
Murrumbidgee Council	Pyrenees	Merredin
Muswellbrook	Southern Grampians	Mingenew
Narrabri	Strathbogie	Moora
Narrandera	Swan Hill	Morawa
Narromine	Wangaratta	Narrogin
Orange	West Wimmera	Nannup
Parkes	Wodonga	Northam
Snowy Valleys Council	Wyndham	Perenjori
Tamworth	Yarriambiack	Pingelly
Temora		Plantagenet
Upper Hunter		Quairading
Wagga Wagga		Ravensthorpe
Walgett		Tammin
Warren		Three Springs
Warrumbungle		Toodyay
Weddin		Victoria Plains
		Wagin

New South Wales	Victoria	Western Australia
		Wandering West Arthur Wickepin Williams Wongan-Ballidu Woodanilling Wyalkatchem York

25. The licence holder must not permit a person covered by this licence to conduct any dealing which may expose the person to inhalation of Plant Material from GM Wheat overexpressing a Class 5 gene (as defined in Attachment A) unless the licence holder has determined that the person does not have a known respiratory allergy to Wheat or Related Species.

Note: This condition applies to dealings with Plant Material grown under this licence, regardless of whether the dealings are conducted under this licence or under an NLRD authorisation.

Note: The licence holder should document compliance with this condition.

3.2 Control measures

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

Restrictions on GMOs and Plant Material in food or feed

26. Subject to condition 26A, 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.

26A. Non-viable products derived from the GMOs may be fed to poultry or pigs for experimental purposes, subject to those experiments being approved by an Animal Ethics Committee operating under the Australian Code for the Care and Use of Animals for Scientific Purposes.

Control measures regarding pollen flow

27. A Planting Area must be surrounded by a Monitoring Zone. Multiple Planting Areas may be contained within a single Monitoring Zone. No Planting Area may be less than 10 m from the outer edge of the Monitoring Zone (as indicated in Figure 1).

28. The Monitoring Zone must be maintained in a manner appropriate to allow the identification and/or Destruction of Volunteers and Related Species while the GMOs are growing in the Planting Area(s) and until the Planting Area(s) is Cleaned.

Note: Acceptable measures to achieve this include keeping land free of vegetation or keeping vegetation mown to a height of less than 10 cm. Condition 56(d) requires details of current land use and recent land management practices to be recorded upon inspection of the Monitoring Zone.

29. The Monitoring Zone must be surrounded by an Inspection Zone (as indicated in Figure 1).

30. The Inspection Zone must be surrounded by an Isolation Zone (as indicated in Figure 1).

31. The GMOs must not be grown in a Planting Area if any crop of Wheat or a Related Species is present in the Monitoring Zone, Inspection Zone or Isolation Zone.

32. While the GMOs are growing in a Planting Area, associated areas must be inspected by people trained to recognise Wheat and Related Species, and actions taken as follows:

Area	Period of inspection	Inspection frequency	Inspect for	Action
a. Monitoring Zone b. Inspection Zone	**From** 14 days prior to the expected commencement of Flowering of any GMOs* **until** 14 days after all GMOs in the Planting Area have finished Flowering	At least once every 14 days	Volunteers & Related Species	Destroy before Flowering or prevent from Flowering

**Condition 57(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 (Condition 56) and reported to the Regulator (Condition 57(f)).

Control measures regarding seed dispersal

33. Any Equipment used in connection with the GMOs must be Cleaned as soon as practicable after use and before use for any other purpose.

34. Each Site must be inside a fence that is capable of excluding livestock and other large animals, such as kangaroos, while GMOs are being grown on the Planting Area(s) and until the Planting Area(s) is Cleaned.

35. While a fence is required under the preceding condition, the fence must be inspected for damage at least once every 35 days, and if damage is found, must be repaired as soon as practicable.

Note: Details of any inspection activity must be recorded in a Logbook (Condition 56) and reported to the Regulator (Condition 57(f)).

36. Measures must be implemented to control rodents within a Planting Area while GMOs are being grown and until the Planting Area is Cleaned.

Note: Measures for rodent control may include, but are not limited to, traps and/or poison baits within and/or surrounding the Planting Area.

37. The Monitoring Zone must be maintained in a manner that does not attract or harbour rodents while the GMOs are being grown at a Planting Area(s) and until the Planting Area(s) is Cleaned.

Note: Acceptable measures to achieve this include keeping land free of vegetation or keeping vegetation mown to a height of less than 10 cm.

38. The outer edge of each Planting Area must be at least 50 m away from Waterways.

39. The licence holder must notify the Regulator in writing as soon as reasonably practicable of any Extreme Weather event that could cause or has led to the dispersal of GMOs from a Planting Area while the GMOs are growing or from any area subject to Cleaning and post-Cleaning inspection requirements.

Note: The Contingency Plan must be implemented if the GMOs are detected outside areas under inspection (Condition 54).

Processing or experimentation with GMOs

40. If seed harvested from the GMOs is threshed other than in accordance with Notifiable Low Risk Dealings (NLRD) requirements, it must be threshed separately from any other crop, and threshing must take place on a Planting Area or Monitoring Zone before Cleaning or in 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 processing of GM seed or 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 Monitoring Zone before Cleaning; or
    c. a Facility approved in writing by the Regulator.
42. Within a Facility approved under the preceding conditions, any area that is used for threshing, processing, experimentation or analysis of the GMOs must be Cleaned as soon as practicable and before use for any other purpose.

Note: Cleaning of a Facility must be reported to the Regulator (Condition 57(d)).

43. GMOs that are not required for further experimentation or future planting must be Destroyed as soon as practicable.

Transport or storage of the GMOs

44. GM seed may be stored in field bins at trial sites until the end of January 2027. Any other storage or transport of the GMOs that is not conducted in accordance with NLRD requirements 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.

45. 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 54).

Destruction by burial

46. Burial must be conducted in a manner expected to prevent dispersal of GMOs on or near the surface of the Burial Site or surrounding areas.
47. If Destruction of GMOs occurs by burial:
    a. the GMOs must be buried in a pit and covered by a layer of soil at least 1 metre in depth, the top of which is no higher than the soil surface surrounding the Burial Site; and
    b. seeds must be sufficiently irrigated at time of burial to encourage decomposition; and
    c. within 14 days of burial, the licence holder must provide the Regulator a written notice indicating the precise location of the burial site (GPS coordinates and either a street address or other directions), the date on which burial occurred and a broad description of the GMOs buried (Planting Area and year the GMOs were planted); and
    d. the Burial Site must not be intentionally disturbed for a period of at least 12 months from the date of burial; and
    e. the Burial Site must be inspected at least every 70 days during this period to identify any significant disturbance. If disturbance is identified, the licence holder must take

appropriate remedial action and notify the Regulator of the disturbance and the remedial action taken.

Note: If Volunteers are observed on a Burial Site, the Burial Site becomes an area of land that requires Cleaning under Condition 50(d), and is subject to post-Cleaning requirements.

Note: Details of any inspection activity must be recorded in a Logbook (Condition 56) and reported to the Regulator (Condition 57(f)).

Note: The licence cannot be surrendered until Burial Site conditions have been satisfied.

Cleaning of Sites

48. GMOs must be harvested or Destroyed within 8 months after planting.

49. If all GMOs in a Planting Area have been Destroyed, then for the purposes of this licence:

    a. the GMOs are taken to have been harvested; and

    b. the Planting Area is taken to have been Cleaned.

Note: Cleaning activities must be reported to the Regulator (Condition 57(d)).

50. Areas of land used in connection with the GMOs must be Cleaned as follows:

Areas to be Cleaned	When
a. Planting Area b. Monitoring Zone	Within 35 days after harvest of the GMOs
c. any area of land, outside a Planting Area or Monitoring Zone, used to Clean any Equipment used in connection with the GMOs d. any area of land, outside a Planting Area or Monitoring Zone, where GMOs have dispersed during planting, growing, harvest or burial.	As soon as practicable
e. Land where a field bin is located	Immediately after removal of any GM seed from the field bin

Note: Cleaning activities must be reported to the Regulator (Condition 57(d)). Areas of land that have been Cleaned are subject to inspections (Condition 52).

51. If Tillage is used as a method of Cleaning, the Tillage must be to a depth no greater than 5 cm.

Post-Cleaning requirements

52. Areas of land that were Cleaned must be inspected by people trained to recognise Wheat. Inspections must cover the entirety of the areas to be inspected. Actions must be taken as follows:

Area of land	Period of inspection	Inspection frequency	Inspect for	Action
a. Planting Area b. Monitoring Zone c. other areas that were Cleaned	From the day of Cleaning, until: i. the area is replanted with the GMOs; or ii. the Regulator has issued a Sign off for the area.	At least once every 35 days	Volunteers	Destroy before Flowering

Note: Details of any inspection activity must be recorded in a Logbook (Condition 56) and reported to the Regulator (Condition 57(f)).

53. While post-Cleaning inspection requirements apply to an area:

    a. the area must be maintained in a manner appropriate to allow identification of Volunteers; and

    b. no plants may intentionally be grown in the area unless the plants are:

i. the GMOs or non-GM Wheat planted in accordance with the conditions of this licence; or

ii. agreed to in writing by the Regulator; and

c. the area must not be used for grazing livestock; and

d. any Tillage of the area must be to a depth no greater than 5 cm; and

e. prior to an application for Sign off, the area must be Tilled, at a time that would promote the germination of Volunteers within the volunteer-free period immediately prior to the Sign off application; and

f. prior to an application for Sign off, the area must receive at least three irrigations, at intervals of at least 28 days, with the last required irrigation occurring at a time that would promote the germination of Volunteers within the volunteer-free period immediately prior to the Sign off application.

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

Contingency plan

54. If any unintentional presence of the GMOs is detected outside the areas requiring Cleaning, the Contingency Plan must be implemented.

Section 4 Sign off

55. The licence holder may make written application to the Regulator that planting restrictions and inspection requirements no longer apply to the Planting Area and other areas requiring Cleaning if:

a. post-Cleaning inspection activities have been conducted for at least 24 months on the area;

b. conditions have been conducive for germination and detection of Volunteers; and

c. no Volunteers have been detected on this area for at least six consecutive months of the inspection period immediately prior to the Sign off request.

Note: An area requires Tillage and three irrigations prior to a Sign off application (Condition 53).

Note: The Regulator will take into account the management and inspection history for the Planting Area and other areas requiring Cleaning, including post-harvest crops planted (if any), Tillage, irrigation, rainfall, application of herbicide, removal of seeds from field bins and occurrence of Volunteers, in deciding whether or not further inspections are required to manage persistence of the GMOs.

Section 5 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.

56. 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 Wheat and/or Related Species, if not already recorded in the logbook;

d. details of areas inspected including current land use and recent management practices applied;

Note: management practices include Tillage events, spraying or maintenance measures used to facilitate inspections.

e. details of the developmental stage of the GMOs while they are being grown;

f. details of any post-Cleaning rainfall events including measurements at or near the area, or any irrigation events;

g. details of any Volunteers observed during inspections or during land-management activities, including number, developmental stage and approximate position of the Volunteers within each area inspected[†];

h. date(s) and method(s) of Destruction of or preventing Flowering of any Volunteers and/or Related Species, including destruction of Volunteers and/or Related Species during land-management activities;

i. details of any damage and any repairs to the fence surrounding the Site, while the fence is required; and

j. details of rodent control methods used and any evidence of rodent activity, while rodent control methods are required.

[†] 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 a corresponding map/sketch

Note: Details of inspection activities must be provided to the Regulator (Condition 57(f)). The Regulator has developed a standardised proforma for recording inspection activities. This can be made available on request.

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

Notice	Content of notice	Timeframe
a. Intention to Plant	i. Details of the Planting Area including size, the local government area, GPS coordinates, a street address, a diagrammatical representation of the Site (e.g. Google Maps) and any other descriptions ii. Identity of the GMOs to be planted at the Planting Area (e.g. which classes of introduced genes, as defined in Attachment A, are present) iii. Date on which the GMOs will be planted iv. Period when the GMOs are expected to Flower v. Period when harvesting is expected to commence vi. How all areas requiring post-Cleaning inspections are intended to be used until Sign off, including the proposed post-harvest crop(s) (if any) vii. Details of how inspection activities will be managed, including strategies for the detection and Destruction of Volunteers viii. History of how the Site has been used for the previous two years	At least 7 days prior to each planting (to be updated immediately if the notified details change)
b. Planting	i. Actual date(s) of planting the GMOs ii. Any changes to the details provided under part (a) of this condition	Within 7 days of any planting
c. Harvest	i. Actual date(s) of harvesting the GMOs	Within 7 days of commencement of any harvesting

Notice	Content of notice	Timeframe
d. Cleaning	i. Actual date(s) on which any areas of land or Facilities needing Cleaning were Cleaned ii. Method(s) of Cleaning	Within 7 days of completion of any Cleaning
e. Burial	i. Actual date and precise location of burial and broad description of the GMOs buried (Planting Area and year the GMOs were planted) ii. Details of any disturbance to the Burial Site, if disturbance occurs, and remedial actions taken iii. Details of any Volunteers observed at the Burial Site	Within 14 days of any burial As soon as practicable As soon as practicable
f. Inspection activities	i. Information recorded in a Logbook as per the inspection requirements (Conditions 32, 35, 47, 52 and 56).	Within 35 days of inspection

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

ATTACHMENT A

DIR No: 165

Full Title: Limited and controlled release of wheat genetically modified for altered iron uptake, transport and bioavailability, and enhanced yield

Organisation Details

Postal address: The University of Melbourne
161 Barry St
Parkville, VIC 3010

Phone No: (03) 9035 5511

IBC Details

IBC Name: The University of Melbourne Institutional Biosafety Committee

GMO Description

GMOs covered by this licence:

Triticum aestivum genetically modified by introduction of only the genes or genetic elements listed below.

Parent Organism:

Common Name: Wheat

Scientific Name: *Triticum aestivum*

Modified traits:

Category: Composition – food (human nutrition)
Enhanced yield
Selectable marker – antibiotic
Selectable marker – herbicide
Selectable marker – visual marker

Description: The licence holder is authorised to release up to 100 lines of wheat genetically modified for altered iron uptake, transport and bioavailability and enhanced yield.

The introduced iron-related or yield-related genes are divided into twelve classes (Table 1). Each GM wheat line may contain up to three introduced genes from classes 1-12 and up to one introduced selectable marker gene. The introduced genes permitted in the GM wheat are listed in Table 2. The introduced regulatory sequences permitted in the GM wheat are listed in Table 3.

GM wheat lines may be crossed. No GM wheat may contain more than 10 introduced iron-related or yield-related genes.

Purpose of the dealings with the GMOs:

The purpose of the release is to gather research and regulatory data under field conditions. The GM wheat grown in this field trial is not permitted to be used for human food or animal feed, except for poultry feeding trials.

Confidential commercial information (CCI)

The names and source organisms of some genes and the names of some regulatory sequences were declared CCI under Section 185 of the *Gene Technology Act 2000*.

Table 1. Classes of introduced iron-related and yield-related genes in the GM wheat

Gene class	Gene family	Altered trait	Type of promoter used
1	Nicotianamine synthase (NAS)	Iron uptake and transport	Constitutive
2	CCI	Iron bioavailability	Constitutive
3	Nicotianamine aminotransferase (NAAT)	Iron uptake	Seed/tissue specific
4	Deoxymugineic acid synthase (DMAS)	Iron uptake	Seed/tissue specific
5	Iron-related transcription factor (IRO)	Iron uptake and transport	Constitutive
6	Vacuolar iron transporter (VIT)	Iron transport and storage	Seed/tissue specific
7	Ferritin (Fer)	Iron storage	Seed/tissue specific
8	Yellow stripe-like transporter (YSL)	Iron transport	Seed/tissue specific
9	Arabidopsis vacuolar H^+-pyrophosphatase (AVP)	Enhanced yield	Constitutive
10	Phosphorous starvation tolerance (PSTOL)	Enhanced yield	Constitutive
11	MUTE transcription factor	Enhanced yield	Constitutive
12	YDA protein kinase	Enhanced yield	Constitutive

Table 2. List of introduced genes in the GM wheat

Gene class	Gene name	Source organism	Gene class	Gene name	Source organism
1	*OsNAS1*	*Oryza sativa*	8	*TaYSL6-5-B*	*Triticum aestivum*
	OsNAS2	"		*TaYSL6-5-D*	"
	OsNAS3	"		*TaYSL8-A*	"
	54 genes that are CCI	Plant species that are CCI		*TaYSL8-D*	"
2	7 genes that are CCI	Plant species that are CCI		*TaYSL9-A*	"
3	*TaNAAT1-A*	*Triticum aestivum*		*TaYSL9-D*	"
	TaNAAT1-B	"		*TaYSL9-LIKE-A*	"
	TaNAAT1-D	"		*TaYSL9-LIKE-B*	"
	TaNAAT2-A	"		*TaYSL9-LIKE-D*	"
	TaNAAT2-B	"		*TaYSL10-A*	"
	TaNAAT2-D	"		*TaYSL10-B*	"
4	*TaDMAS-A*	*Triticum aestivum*		*TaYSL11-A*	"
	TaDMAS-B	"		*TaYSL11-B*	"
	TaDMAS-D	"		*TaYSL12-A*	"
5	*TaIRO2-A*	*Triticum aestivum*		*TaYSL12-B*	"
	TaIRO2-B	"		*TaYSL12-D*	"
	TaIRO2-D	"		*TaYSL13-B*	"
	TaIRO2-like-A	"		*TaYSL13-D*	"
	TaIRO2-like-B	"		*TaYSL13-like-A*	"
	TaIRO2-like-D	"		*TaYSL13-like-B*	"
6	*TaVIT1-A*	*Triticum aestivum*		*TaYSL13-like-D*	"
	TaVIT1-B	"		*TaYSL14-A*	"
	TaVIT1-D	"		*TaYSL14-B*	"

Gene class	Gene name	Source organism
6	*TaVIT2-A*	*Triticum aestivum*
	TaVIT2-B	"
	TaVIT2-D	"
7	*TaFer1-A*	*Triticum aestivum*
	TaFer1-B	"
	TaFer1-D	"
	TaFer2-A	"
	TaFer2-B	"
	TaFer2-D	"
8	*TaYSL1-A*	*Triticum aestivum*
	TaYSL1-B	"
	TaYSL1-D	"
	TaYSL2-A	"
	TaYSL2-B	"
	TaYSL2-D	"
	TaYSL5-A	"
	TaYSL5-B	"
	TaYSL5-D	"
	TaYSL6-1-B	"
	TaYSL6-1-D	"
	TaYSL6-2-A	"
	TaYSL6-2-B	"
	TaYSL11-D	"
	TaYSL6-2-D	"
	TaYSL6-3-A	"
	TaYSL6-3-B	"
	TaYSL6-3-D	"
	TaYSL6-4-A	"
	TaYSL6-4-B	"
	TaYSL6-4-D	"
8	*TaYSL14-D*	*Triticum aestivum*
	TaYSL15-A	"
	TaYSL15-B	"
	TaYSL15-D	"
	TaYSL15-LIKE-A	"
	TaYSL15-LIKE-B	"
	TaYSL15-LIKE-D	"
	TaYSL16	"
	TaYSL17-A	"
	TaYSL17-D	"
	TaYSL18	"
9	*AVP1*	*Arabidopsis thaliana*
10	*PSTOL1*	*Oryza sativa*
11	*TaMUTE-A*	*Triticum aestivum*
	TaMUTE-B	"
	TaMUTE-D	"
12	*TaYDA1-A*	*Triticum aestivum*
	TaYDA1-B	"
	TaYDA1-D	"
	TaYDA2-A	"
	TaYDA2-B	"
	TaYDA2-D	"
Marker	*hptII*	*Escherichia coli*
	pat	*Streptomyces viridochromogenes*
	nptII	*Escherichia coli*
	bar	*Streptomyces hygroscopicus*
	pporRFP	*Porites porites*

Table 3. Introduced regulatory sequences in the GM wheat

Element function	Genetic element	Source organism
Constitutive promoter	*CaMV35S*	Cauliflower mosaic virus
	Ubi1	*Zea mays*
	Actin1	*Oryza sativa*
	Actin2	*Oryza sativa*
	PvUbi1+3	*Panicum virgatum*
	Promoters that are CCI	*Triticum aestivum*
Seed/tissue specific promoter	Promoters that are CCI	*Triticum aestivum*
	Promoters that are CCI	*Hordeum vulgare*
Amplification promoting sequence	*Ubi1* intron	*Zea mays*
	Ubi1 5'UTR	*Zea mays*

Element function	Genetic element	Source organism
Termination sequence	*nos* *ocs* *CaMV35S* Terminators that are CCI Terminators that are CCI	*Agrobacterium tumefaciens* *Agrobacterium tumefaciens* *Cauliflower mosaic virus* *Triticum aestivum* *Hordeum vulgare*

ATTACHMENT B

Checklist of documents that must be sent to the Regulator:

When	What	Condition	Timeframe
Prior to conducting any dealings	Details of persons covered	12(a)	At least 14 days prior to conducting any dealings with the GMOs
	Plan to inform people covered by the licence	12(b)	
	Plan to ensure control and access to all trial sites	12(c)	
	Detection methodology	12(d)	
	Contingency plan	12(e)	
Prior to planting	Intention to plant	57(a)	At least 7 days prior to any planting
While growing	Planting	57(b)	Within 7 days after planting
	Inspection activities	57(f)	Within 35 days after each inspection
	Harvest	57(c)	Within 7 days after commencement of harvesting
Post-harvest	Cleaning	57(d)	Within 7 days after completion of cleaning
	Burial, if occurs	57(e)(i) 57(e)(ii)	Within 14 days after burial As soon as practicable, if disturbance occurs
	Inspection activities	57(f)	Within 35 days after 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; revocation, suspension or cancellation of any relevant permit; or 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 by the licence	16(b)	If and when requested
	Any additional information regarding risks to 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, if become aware
	Extreme weather conditions	39	As soon as practicable, if expected or occurs
	Methods and procedures for transport	45	If and when requested