



8 January 2010

**APPLICATION FOR LICENCE FOR INTENTIONAL RELEASE OF GMOs INTO THE ENVIRONMENT: Application No. DIR 100**

**SUMMARY INFORMATION**

Project Title:	Limited and controlled release of wheat genetically modified for enhanced carbon assimilation in drought and heat prone environments <sup>1</sup>
Applicant:	CSIRO
Common name of the parent organism:	Wheat
Scientific name of the parent organism:	<i>Triticum aestivum</i> L.
Modified trait(s):	Improved drought/heat tolerance, marker gene (antibiotic resistance and herbicide tolerance) expression
Identity of the gene(s) responsible for the modified trait(s):	<ul style="list-style-type: none"><li>• 26 genes<sup>2</sup> for enhanced carbon assimilation, grain weight, heat tolerance and/or water use efficiency from wheat (<i>Triticum aestivum</i> L.) or barley (<i>Hordeum vulgare</i> L.)</li><li>• <i>nptII</i> gene from the bacterium <i>Escherichia coli</i> (antibiotic resistance)</li><li>• <i>bar</i> gene from the bacterium <i>Streptomyces hygroscopicus</i> (herbicide tolerance)</li></ul>
Proposed Location(s):	One site in the Redland City LGA (Qld)
Proposed Release Size:	Up to 0.1 hectare per year
Proposed Release Dates:	May 2010 - December 2013

**Introduction**

The *Gene Technology Act 2000* (the Act) in conjunction with the *Gene Technology Regulations 2001*, an inter-governmental agreement and corresponding legislation that is being enacted in each State and Territory, comprise Australia's nationally consistent regulatory system for gene technology. Its objective is to protect the health and safety of people and the environment, by identifying risks posed by or as a result of gene technology, and managing those risks by regulating certain dealings with genetically modified organisms (GMOs).

The Act establishes a statutory officer, the Gene Technology Regulator (the Regulator), to administer and make decisions under the legislation. The Regulator is supported by the Office of the Gene Technology Regulator (OGTR), an Australian Government regulatory agency located within the Health and Ageing portfolio.

The legislation sets out requirements for considering applications for licences for dealings with GMOs, including matters that the Regulator must take into account before deciding whether or not

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<sup>1</sup> The title of the licence application submitted by CSIRO is 'Field trial of genetically modified wheat (*Triticum aestivum* L.) with enhanced carbon assimilation in drought and heat prone environments'.

<sup>2</sup> CSIRO has sought to have the sequence of some genes declared as Confidential Commercial Information.

to issue a licence. The Regulator's *Risk Analysis Framework*<sup>3</sup> outlines the assessment process that will be followed.

## **The application and the proposed dealings**

The Regulator has received an application from CSIRO for a licence for dealings involving the intentional release of genetically modified (GM) wheat (*Triticum aestivum* L.) into the Australian environment on a limited scale under controlled conditions.

One hundred and fifty lines<sup>4</sup> of GM wheat are proposed for release. The GM wheat will contain genes derived from wheat and barley. Expression of the genes is expected to show improved grain weight and yield of the GM wheat in heat and drought prone environments through enhanced water use efficiency, photosynthesis and carbon assimilation.

The purpose of the trial is to assess the agronomic performance, including biomass production, grain weight and yield of the GM wheat lines under rain-fed and drought/heat prone conditions.

The applicant proposes to limit the release to one site in the Redland City LGA (Qld) on a maximum area of 0.1 ha per year between May 2010 and December 2013.

The applicant has proposed a number of control measures to restrict the dissemination and persistence of the GM plants and their introduced genetic material, which will be considered in the assessment of this application, including:

- locating the trial site at least 100 m away from natural waterways
- restricting animal access by surrounding the trial with a fence and mouse baiting inside the fence perimeter
- locating the trial site at least 200 m from all other wheat plantings and at least 500 m from other wheat breeding lines
- surrounding the GM wheat with a 2 m wide buffer of non-GM wheat and a 10 m isolation zone in which growth of related species is controlled
- promoting the germination of any residual seed following harvest through two six weekly irrigation cycles and destroying any volunteer wheat
- post harvest monitoring of the trial site for 12 months or until the site has been clear of volunteers for one growing season and destroying any volunteer wheat
- destroying all plant material from the trial not required for testing or future trials
- transporting and storing of the GMOs in accordance with the Regulator's guidelines
- not allowing the GM plant material or products to be used for human food or animal feed.

## **Confidential Commercial Information**

The sequences of some of the genes are the subject of an application for declaration of Confidential Commercial Information (CCI) under section 185 of the Act, which is currently under consideration. The confidential information will be made available to the prescribed experts and agencies that will be consulted on the Risk Assessment and Risk Management Plan (RARMP) for this application.

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<sup>3</sup> The *Risk Analysis Framework* guides the risk assessment and risk management process. This document and further information on the assessment of licence applications is available from the Office of the Gene Technology Regulator (OGTR). Free call 1800 181 030 or at <<http://www.ogtr.gov.au>>.

<sup>4</sup> The term 'line' is used to denote plants derived from a single plant containing a specific genetic modification(s) made by one transformation event.

## Parent organism

The parent organism is the wheat (*Triticum aestivum* L.) cultivar 'Bob White', which is exotic to Australia. The wheat cultivar 'Bobwhite' is not grown commercially in Australia but is commonly used in genetic modification work. Commercial wheat cultivation occurs in the wheat belt from south eastern Queensland through New South Wales, Victoria, southern South Australia and southern Western Australia.

## The genetic modifications and their effect

The applicant proposes to release up to 150 GM wheat lines containing genes that will enhance survival and grain quality production in heat and drought prone environments.

Each line will contain one of 26 genes encoding proteins expected to enhance photosynthesis, biomass accumulation, carbon assimilation, grain yield, grain quality, water use efficiency, drought and/or heat tolerance. Some GM wheat lines may be generated to contain more than one of the candidate genes. The applicant also intends to cross some of the lines using conventional breeding to produce GM wheat which contain a combination of these traits. These genes which have been introduced into the GM plants are derived from either wheat or barley and include:

- Eighteen genes from wheat which encode transcription factors (proteins that control expression of genes through binding to specific DNA sequences) which are expected to provide improved water use efficiency, drought and heat tolerance, improved photosynthesis, and/or carbon assimilation and grain weight
- One gene from barley which encodes a transcription factor which is expected to provide improved drought tolerance/water use efficiency
- One gene from barley and four genes from wheat encoding proteins involved in enhancing growth and/or carbon assimilation and grain weight
- Two genes from wheat encoding proteins associated with grain weight and yield.

Expression of each of these genes will be under control of either a constitutive promoter, a developmental specific promoter or a drought inducible promoter derived from barley or maize.

The GM wheat lines also contain two selectable marker genes, *nptII* and *bar*. The *nptII* gene encodes neomycin phosphotransferase type II which provides resistance to antibiotics such as kanamycin. The *bar* gene encodes phosphinothricin acetyl transferase which provides resistance to herbicides containing glufosinate ammonium. These were used as selectable markers during early stages of development of the GM plants in the laboratory.

Other short regulatory sequences that contribute to control of expression of the introduced genes are also present in the GM wheat. These are derived from maize, rice, Cauliflower mosaic virus (CaMV) and *Agrobacterium tumefaciens* (a common soil bacterium). Although some of these sequences are derived from a plant pathogen (*A. tumefaciens* and CaMV), the regulatory sequences comprise only a small part of the pathogen's total genome, and in themselves have no pathogenic properties.

## Method of genetic modification

The genes were introduced into wheat by biolistic transformation, also known as particle bombardment. This technique involves coating very small gold particles with the gene constructs and 'shooting' these into wheat embryos. Biolistic transformation has been widely used in Australia and overseas for introducing new genes into plants and is not known to cause any adverse effects for people or the environment.

## **Previous releases of the same or similar GMOs**

There has been no previous release of these GM wheat lines in Australia. Other GM wheats with related traits have been grown in field trials in Australia on a limited scale under controlled conditions, including GM wheat modified for drought tolerance (DIR 71/2006 and DIR 080/2007) and abiotic stress tolerance (DIR 077/2007).

## **Suitability of Applicant**

Section 43(2)(f) of the Act requires the Regulator to be satisfied regarding the suitability of the applicant to hold a licence as a pre-requisite for considering DIR applications. The matters to be considered are outlined in Section 58 of the Act and include capacity to meet the conditions of a licence, relevant convictions and revocation of a licence or permit held under law relating to the health and safety of people.

The Regulator has determined that CSIRO currently meets the suitability requirements and will verify this continues to be the case prior to making any decision regarding the issuing of a licence.

## **Consultation process for this DIR application**

The Regulator has made an assessment of whether the application should be considered as a limited and controlled release, under section 50A of the Act. As its principal purpose is to enable the conduct of experiments, and the applicant has proposed limits on the size and duration of the release and controls to restrict the dissemination and persistence of both the GMOs and their genetic material in the environment, **the Regulator has decided that the application qualifies as a limited and controlled release.**

This means that the Regulator is not required to consult on the assessment of this application until after a RARMP has been prepared in accordance with section 51 of the Act. In the interim, copies of the application are available on request from the OGTR. Please quote application number DIR 100.

The Regulator will seek comment on the consultation RARMP from the public as well as a wide range of experts, agencies and authorities including the Gene Technology Technical Advisory Committee, State and Territory Governments, Australian Government agencies and the Minister for the Environment, Heritage and the Arts. The RARMP will then be finalised, taking into account matters raised relating to risks to human health and safety and the environment, and form the basis of his decision whether or not to issue a licence.

At this stage, **the RARMP is expected to be released for comment in April 2010.** The public will be invited to provide submissions on the RARMP via advertisements in the media and direct mail to anyone registered on the OGTR mailing list. The RARMP and other related documents will be available on the OGTR website, or in hard copy from the OGTR.

If you have any questions about the application or the assessment process, or wish to register on the mailing list, please contact the OGTR at:

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