



22 January 2010

APPLICATION FOR LICENCE FOR INTENTIONAL RELEASE OF GMOs INTO THE ENVIRONMENT: Application No. DIR 102

SUMMARY INFORMATION

Project Title:	Limited and controlled release of wheat and barley genetically modified for abiotic stress tolerance ¹
Applicant:	The University of Adelaide
Common name of the parent organism:	Wheat and barley
Scientific name of the parent organism:	<i>Triticum aestivum</i> L. and <i>Hordeum vulgare</i> L.
Modified trait(s):	Salinity, drought and cold/frost tolerance, tolerance to low phosphorus, nitrogen use efficiency, enhanced zinc uptake, antibiotic resistance
Identity of the gene(s) responsible for the modified trait(s):	<ul style="list-style-type: none">• 35 genes² for abiotic stress tolerance from barley (<i>Hordeum vulgare</i> L.), wheat (<i>Triticum aestivum</i> L.), maize (<i>Zea mays</i> L.), thale cress (<i>Arabidopsis thaliana</i>), moss (<i>Physcomitrella patens</i>) and yeast (<i>Saccharomyces cerevisiae</i>)• <i>hpt</i> gene from the bacterium <i>Escherichia coli</i> (antibiotic resistance)
Proposed Location(s):	Three locations, two in the local government areas (LGAs) of Marion and Wakefield (South Australia) and one in the LGA of Corrigin (Western Australia).
Proposed Release Size:	Up to 0.75 hectare per growing season
Proposed Release Dates:	June 2010 - December 2015

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

¹ The title of the licence application submitted by the University of Adelaide is '*Intentional release of wheat and barley modified for abiotic stress*'.

² The University of Adelaide has sought to have the identity and sequence of some genes declared as Confidential Commercial Information.

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

The application and the proposed dealings

The Regulator has received an application from the University of Adelaide for a licence for dealings involving the intentional release of genetically modified (GM) wheat and barley into the Australian environment on a limited scale under controlled conditions.

Up to 2340 lines⁴ of GM wheat and barley are proposed for release. The GM wheat and barley will contain genes derived from wheat, barley, maize, thale cress, moss and yeast. Expression of the genes is expected to confer improved yield of the GM wheat and barley when grown in the field under abiotic stress.

The purpose of the trial is to assess the agronomic performance, including biomass production, grain weight and yield of the GM wheat and barley lines under field conditions.

The applicant proposes to limit the release to three locations, two in the LGAs of Marion and Wakefield (South Australia) and one in Corrigin (Western Australia) on a maximum total area of 0.75 ha per growing season between May 2010 and December 2013.

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

- locating the trial away from natural waterways
- restricting animal access by surrounding the trial with a fence and rodent baiting inside the fence perimeter
- surrounding the fenced area with a 10 m wide area that is mown or herbicide treated to keep plant growth below 10 cm
- maintaining a 50 m isolation zone outside the fence, in addition to the 10m cleared zone, clear of any wheat or barley plants
- locating the trial site at least 200 m from any related commercial cereal crops and at least 500 m from other wheat or barley breeding lines
- promoting the germination of any residual seed following harvest through tilling and irrigation, and destroying any volunteer wheat or barley by herbicide or uprooting
- post harvest monitoring of the trial site for 24 months or until the site has been clear of volunteers for one growing season, and destroying any volunteer wheat or barley
- 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

³ 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>>.

⁴ The term 'line' is used to denote plants derived from a single plant containing a specific genetic modification made by one transformation event.

Confidential Commercial Information

The identity and sequences of some of the genes are the subject of an application for declaration as 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.

Parent organism

The parent organisms are wheat (cultivars 'Bobwhite', 'Drysdale' and 'Frame') and barley (cultivars 'Golden Promise' and 'W14330'), which are exotic to Australia. Commercial wheat and barley cultivation occurs in the wheat belt from south eastern Queensland through New South Wales, Victoria, southern South Australia and southern Western Australia. A small amount of barley is also grown in Tasmania.

'Bobwhite' and 'Golden Promise' are not grown commercially in Australia but are commonly used because they are relatively easy to genetically modify. 'Drysdale' and 'Frame' are commercial wheat varieties and 'W14330' was formerly used in barley breeding programs.

The genetic modifications and their effect

The applicant proposes to release up to 1161 GM wheat lines and 1179 GM barley lines containing genes that will enhance tolerance to various forms of abiotic stress.

Each GM wheat or barley line will contain one of 35 genes encoding proteins expected to enhance salinity, drought and cold/frost tolerance, tolerance to low phosphorus, nitrogen use efficiency or enhanced zinc uptake and translocation. The genes introduced into the GM plants are derived from wheat, barley, maize, *Arabidopsis*, moss or yeast and include:

- one gene from thale cress that encodes a protein associated with salinity, drought and low phosphorus tolerance
- one gene from barley that encodes a protein involved in improved nitrogen use efficiency
- twenty five genes from wheat, maize and barley that encode transcription factors (proteins that control expression of genes through binding specific DNA sequences) involved in regulation of drought and cold/frost tolerance
- four genes from wheat and maize encoding proteins involved in drought tolerance
- one gene from barley that encodes a protein associated with zinc uptake and translocation, and increased zinc content in grain
- three genes from moss, thale cress and yeast, that encode proteins involved in salinity tolerance.

The GM wheat and barley lines also contain an antibiotic resistance marker gene *hpt*, from the bacterium *E. coli*. The *hpt* gene encodes hygromycin phosphotransferase, which provides resistance to the antibiotic hygromycin and was used to select for modified plants in the laboratory.

Expression of each of these genes will be under the control of one of a number of constitutive, inducible (drought, cold or salt) or root specific promoters derived variously from cauliflower mosaic virus (CaMV), maize, rice, barley or wheat. Other short regulatory sequences that contribute to control of expression of the genes are also present in the GM wheat and barley lines. These are derived from maize, cauliflower mosaic virus (CaMV) and *Agrobacterium tumefaciens* (a common soil bacterium).

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.

Genes were introduced into barley using *Agrobacterium*-mediated transformation. The genes were introduced via a plasmid vector carried by *A. tumefaciens*. The vector is ‘disarmed’ since it lacks the genes that encode the tumorigenic functions of *A. tumefaciens*.

Previous releases of the same or similar GMOs

There has been no previous release of these GM wheat and barley lines in Australia. However, other GM wheat and barley plants have been grown in field trials in Australia on a limited scale under controlled conditions. These include GM wheat modified for drought tolerance (DIR 080/2007, DIR 071/2006), GM wheat modified for salt tolerance (DIR 053/2004), and wheat and barley genetically modified for abiotic stress tolerance (DIR 077/2007) or nutrient utilisation efficiency (DIR 094).

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 a law relating to the health and safety of people or the environment.

The Regulator has determined that the University of Adelaide 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 spread 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 102.

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:

The Office of the Gene Technology Regulator, MDP 54 GPO Box 9848 Canberra ACT 2601

Telephone: 1800 181 030 Facsimile: 02 6271 4202 E-mail: ogtr@health.gov.au

Website <http://www.ogtr.gov.au>