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

APPLICATION FOR LICENCE FOR INTENTIONAL RELEASE OF GMOs INTO THE ENVIRONMENT: Application No. DIR 094

SUMMARY INFORMATION

Project Title:	Limited and controlled release of wheat and barley genetically modified for enhanced nutrient utilisation efficiency[1]
Applicant:	CSIRO
Common name of the parent organism:	Wheat and Barley
Scientific name of the parent organism:	*Triticum aestivum* L. and *Hordeum vulgare* L.
Modified trait(s):	Nutrient utilisation efficiency, antibiotic resistance
Identity of the gene(s) responsible for the modified trait(s):	• Metabolic enzyme 1 gene (*Me1*) from barley (nutrient utilisation efficiency) • *nptII* gene from *Escherichia coli* (antibiotic resistance) • *hpt* gene from *Escherichia coli* (antibiotic resistance)
Proposed Location(s):	One site in the ACT
Proposed Release Size:	One hectare
Proposed Release Dates:	July 2009 - June 2012

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 the legislation 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 the requirements for considering applications for licences for dealings with GMOs and the matters that the Regulator must take into account before deciding whether, or not, to issue a licence. The Regulator's *Risk Analysis Framework*[2] outlines the assessment process that will be followed.

[1] The title of the licence application submitted by CSIRO is 'Field trials of genetically modified wheat (*Triticum aestivum* L.) and barley (*Hordeum vulgare* L.) with altered efficiency of nutrient utilisation'.

[2] More 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>.

The application and the proposed dealings

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

Seventeen lines[3] of GM wheat and ten lines of GM barley are proposed for release. Nine of the GM wheat lines and five of the GM barley lines contain a metabolic enzyme gene derived from barley and the gene is expected to improve the plants' ability to utilise nutrients from the soil. All of the GM wheat and barley lines contain a selectable marker gene.

The purpose of the trial is to:

- assess whether expression of the introduced gene results in increased biomass and yield in the GM plants compared with non-GM plants when grown under field conditions
- assess the impact of expression of the introduced gene on grain characteristics and evaluate how such changes may affect the performance of flour from the GM grain in foods.

The applicant proposes to limit the release to one site at a CSIRO research facility in the ACT on a maximum area of 1 ha between July 2009 and June 2012. Access to the site would be limited to CSIRO staff only.

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

- locating the trial site approximately 1 km away from natural waterways
- restricting animal access by surrounding the trial with a fence, mouse baiting the perimeter of the fence and covering the GMOs with bird-netting
- locating the trial site at least 200 m from all other wheat and barley plantings with the exception of other GM trials, and at least 500 m from other wheat and barley breeding lines
- surrounding the GM wheat and barley with a 2 m wide buffer of non-GM wheat and preventing related species in the area from flowering at the same time as the GMOs
- promoting the germination of any residual seed following harvest through three monthly irrigation cycles and destroying any volunteer wheat or barley with herbicide
- 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 and/or barley with herbicide
- destroying all plant material from the trial not required for testing or future trials
- transporting and storing of the GMO in accordance with OGTR guidelines
- not allowing the GM plant materials or products to be used for human food or animal feed.

Confidential Commercial Information

Some details, including the name and sequence of the introduced metabolic enzyme gene and the promoter, and the identity of one of the plasmids are the subject of an application for declaration of Confidential Commercial Information (CCI) under section 185 of the Act. The application is currently under consideration. The confidential information will be made available to the

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

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 wheat (*Triticum aestivum* L.) and barley (*Hordeum vulgare* L.), 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.

The wheat and barley cultivars used to produce the GMOs proposed for release were selected for their relative ease of transformation. The two wheat cultivars are 'Bobwhite' and 'Frame', and the barley cultivar is 'Golden Promise'. Of these cultivars, only 'Frame' is grown commercially in Australia.

The genetic modifications and their effect

Nine of the GM wheat lines and five of the GM barley lines contain a metabolic enzyme gene *Me1* from barley. This gene is naturally present in non-GM barley plants and the expression of the introduced gene is under the control of a tissue specific promoter derived from rice. The *Me1* gene has previously been overexpressed in rice and resulted in a phenotype of increased plant biomass and increased yield. A similar effect is expected for overexpression of *Me1* in wheat and barley.

All of the GM wheat lines contain one of two selectable marker genes derived from bacteria: either (*nptII*) which confers resistance to aminoglycoside antibiotics related to kanamycin and neomycin, or *hpt* which confers resistance to the antibiotic hygromycin. All of the GM barley lines contain the selectable marker gene *hpt*.

Short regulatory sequences that control expression of the genes are also present in the GM wheat and barley. These are derived from *Agrobacterium tumiefaciens* (a common soil bacterium), Cauliflower mosaic virus (CaMV) and rice, maize and potato. Although some of these sequences are derived from plant pathogens (*Agrobacterium* and CaMV), the regulatory sequences comprise only a small part of the pathogen's total genome, and are not in themselves capable of causing disease.

Method of genetic modification

The metabolic enzyme gene *Me1*, the selectable marker gene (either *nptII* or *hpt*) and associated regulatory sequences were introduced into the wheat cultivars through the use of biolistic transformation. A co-bombardment strategy was used in which *Me1* was transferred either by vector or by linearised DNA and the marker gene was introduced via a second vector.

Me1 and *hpt* genes were introduced into the barley cultivar Golden Promise on a plasmid vector carried by *Agrobacterium 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.

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 relevant convictions, revocation of a licence or permit relating to the health and safety of people, and capacity to meet the conditions of the licence.

The Acting 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 Acting 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 Acting Regulator has decided that the application qualifies as a limited and controlled release.**

This means that the Acting 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 094.

The Acting 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 her decision whether or not to issue a licence.

At this stage, **the RARMP is expected to be released for comment in May 2009.** 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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