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

19 September 2011

APPLICATION FOR LICENCE FOR INTENTIONAL RELEASE OF GMOs INTO THE ENVIRONMENT: Application No. DIR 112

SUMMARY INFORMATION

Project Title:	Limited and controlled release of wheat and barley genetically modified for altered grain composition or enhanced nutrient utilisation efficiency [1]
Applicant:	Commonwealth Scientific and Industrial Research Organisation (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):	• Altered grain composition; • Enhanced nutrient utilisation efficiency • Selectable marker gene expression
Identity of the gene(s) responsible for the modified trait(s):	• One partial gene from wheat (*T. aestivum*) for altered grain composition • One gene from barley (*H. vulgare*) for nutrient utilisation efficiency • *hpt* gene from the bacterium *Escherichia coli (E. coli)* (antibiotic resistance selectable marker) • *nptII* from the bacterium *E. coli* (antibiotic resistance selectable marker)
Proposed Location(s):	One site in Western Australia
Proposed Release Size:	Up to 1 hectare (ha)
Proposed Release Dates:	May 2012– June 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.

[1] The title of the licence application submitted by CSIRO is "Limited and controlled release of wheat and barley with altered grain composition or nutrient utilisation efficiency"

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 to issue a licence. The Regulator's *Risk Analysis Framework*[2] 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 and barley into the Australian environment on a limited scale under controlled conditions.

CSIRO proposes to trial up to 118 GM wheat and 40 barley lines[3] containing genes to alter grain composition and improve agronomic characteristics under field conditions.

The purpose of the trial is to:

- assess under field conditions whether the respective genetic modifications result in increased biomass and yield in the GM plants compared to controls
- produce sufficient grain to allow replicated field trials in years two and three to characterise biomass and yield characteristics
- analyse any changes in grain composition, dough making properties and end product quality.

The applicant proposes to limit the trial to one site within the Merredin New Genes for New Environments facility located in Western Australia on a maximum area of 1 ha per year between May 2012 and June 2015. Access to the site would be limited to authorised staff only.

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

- the trial site is located 1.8 km from the nearest natural waterway
- separating the trial site from other wheat and barley plantings by an isolation zone of at least 200m, unless such plants are also being grown inside the facility as part of other DIRs approved by the Regulator
- restricting animal access by surrounding the trial site with a livestock proof fence and covering with a bird net
- destroying all plant materials not required for testing or future trials
- cleaning of any equipment used prior to removal from the site
- monitoring of the trial site post-harvest for a period of two years and destroying any volunteer GMOs before they flower
- transporting and storing all GM material outside the trial site according to the Regulator's *Guidelines for the Transport, Storage and Disposal of GMOs (2011)*
- not allowing GM plant material or products to be used for human food or animal feed

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[2] The *Risk Analysis Framework* 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>.

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

Confidential Commercial Information

Details of the names and sequences of the genes used for altered grain composition and enhanced nutrient utilisation efficiency, have already been declared Confidential Commercial Information (CCI) under section 185 of the Act. Any 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 organisms

The parent organisms are wheat (cultivars Bobwhite 26, Frame, and Gladius) and barley (cultivar Golden Promise), 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 26 and Golden Promise are not grown commercially in Australia but are commonly used for their relative amenability to genetic modification. Frame and Gladius are commercial wheat varieties.

The genetic modifications and their effect

The applicant proposes to trial a maximum of 118 GM wheat and 40 GM barley lines (in total 158 GM lines). The GMOs can be broadly classified into two categories:

- Category 1 consists of 95 wheat lines and 40 barley lines genetically modified for enhanced nutrient utilisation efficiency using a gene derived from barley.
- Category 2 consists of 23 wheat lines genetically modified for altered grain composition using a partial gene derived from wheat for the down-regulation of the expression of an endogenous wheat gene.

These two categories are also part of the proposed trial of GMOs in application DIR111 that is currently under consideration by the Regulator.

The GM wheat and barley lines may also contain one of the two selectable marker genes: *hpt* and *nptII*. The antibiotic resistance selectable marker genes *hpt* and *nptII*, derived from the common gut bacterium *E. coli*, encode the enzymes hygromycin phosphotransferase and neomycin phosphotransferase II, respectively; the former confers resistance to hygromycin and the latter to kanamycin and neomycin. These genes were used in the laboratory to select transformed GM plants during early stages of development.

Short regulatory sequences derived from plants (including wheat, barley, maize and rice), a soil bacterium (*Agrobacterium tumefaciens*), a plant virus (cauliflower mosaic virus) and *E. coli* that control expression of the genes may also be present in the GM wheat and barley lines.

Method of genetic modification

The GM wheat lines were generated using either biolistic (also known as particle bombardment) or *Agrobacterium*-mediated transformation methods. The GM barley lines were generated using *Agrobacterium*-mediated transformation only.

The biolistic technique involves coating very small gold particles with the gene constructs and 'shooting' these into immature wheat embryos. In the *Agrobacterium*-mediated transformation method, genes were introduced into wheat and barley using plasmid vectors carried by *A. tumefaciens*. Both the biolistic and *Agrobacterium*-mediated transformation methods have been widely used in Australia and overseas for introducing genes into plants.

Previous releases of the same or similar GMOs

Some of the GM wheat and barley lines included in this licence application have been previously approved for trial on a limited scale under controlled conditions within CSIRO's licences DIR 092, 094 and 099 (current trials). The Regulator has also authorised trials of wheat genetically modified for salt tolerance (Grain Biotech: licence DIR 053/2004), altered grain composition (CSIRO: DIR 054/2004) drought tolerance (DPI Victoria: licences DIR 71/2006 and DIR 080/2007), enhanced carbon assimilation in drought and heat prone environments (CSIRO: licence DIR 100), and trials of wheat and barley genetically modified for abiotic stress tolerance (University of Adelaide: licences DIR 077/2007 and DIR 102) and altered grain composition (CSIRO: licence DIR 093).

There have been no reports of adverse effects on human health and safety or the environment resulting from any of these releases.

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 or the environment.

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 decided the application qualifies as a limited and controlled release, under section 50A of the Act. The principal purpose of the application 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.

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 112.

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. 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 December 2011.** 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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