



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

17 December 2008

**APPLICATION FOR LICENCE FOR INTENTIONAL RELEASE OF GMOs INTO THE ENVIRONMENT: Application No. DIR 093**

**SUMMARY INFORMATION**

Project Title:	Limited and controlled release of wheat and barley genetically modified for altered grain starch composition <sup>1</sup>
Applicant:	CSIRO
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):	Altered grain starch composition, antibiotic resistance
Identity of the gene(s) responsible for the modified trait(s):	<ul style="list-style-type: none"><li>• Two partial genes<sup>2</sup> from wheat involved in grain starch biosynthesis</li><li>• <i>hpt</i> gene from the non-pathogenic <i>E. coli</i> (antibiotic resistance)</li><li>• <i>nptII</i> gene from the non-pathogenic <i>E. coli</i> (antibiotic resistance)</li></ul>
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*<sup>3</sup> outlines the assessment process that will be followed.

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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.) and barley (*Hordeum vulgare* L.) with altered grain starch composition'.

<sup>2</sup> CSIRO has sought approval to declare the precise identity of some genes as Confidential Commercial Information.

<sup>3</sup> 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.

Three lines<sup>4</sup> of GM wheat and one line of GM barley are proposed for release. The GM wheat and GM barley will contain partial sequences from two genes derived from wheat. Expression of the gene sequences is expected to suppress the function of the corresponding genes in the parent plant resulting in altered grain starch composition which may have enhanced nutritional properties.

The purpose of the trial is to evaluate grain properties of the GM wheat and barley lines grown under field conditions. This would involve generating sufficient grain to make flour for laboratory evaluation of how the flour performs in foods, and to feed to rats and pigs in laboratory experiments to determine whether altered grain properties change the nutritional value of the GM wheat and barley. Products containing GM wheat from this trial may also be consumed by a small group of volunteers as part of a carefully controlled nutritional study.

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 200m 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
- minimising gene flow to the surrounding 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, with the exception of the above mentioned laboratory experiments from which no material will enter the commercial human or animal food supply.

## Confidential Commercial Information

Some details, including names and sequences of 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

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<sup>4</sup> 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 genetic modifications and their effect**

The GM wheat lines contain partial sequences of a gene involved in starch biosynthesis. The GM barley line contains partial sequences of two genes involved in starch biosynthesis. Evaluation of the GM wheat and barley lines in contained facilities has shown altered grain starch composition as a result of the genetic modification.

The expression of partial gene sequences in the GM lines leads to altered starch composition by suppression of the starch enzyme (SE) I gene in the case of wheat and suppression of the SE I and SE II genes in the case of barley. Transcription of the partial gene sequences is regulated by a grain specific promoter derived from wheat. The GM wheat lines also contain the *nptII* gene which provides resistance to antibiotics such as kanamycin. The GM barley line contains the *hpt* gene which provides resistance to the antibiotic hygromycin B.

Short regulatory sequences that control expression of the genes are also present in the GM wheat and barley. These are derived from wheat, 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 are not in themselves capable of causing disease.

### **Method of genetic modification**

The gene constructs used were originally introduced into the wheat and barley on a plasmid vector carried by *A. tumefaciens*. The vector is 'disarmed' since it lacks the genes that encode the tumorigenic functions of *A. tumefaciens*. This method 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.

### **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 GMO and its 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 093.

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 late March 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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