



APPLICATION FOR LICENCE FOR INTENTIONAL RELEASE OF GMOs INTO THE ENVIRONMENT: Application No. DIR 080/2007

SUMMARY INFORMATION

Project Title:	Limited and controlled release of wheat genetically modified for drought tolerance ¹
Applicant:	Victorian Department of Primary Industries (DPI Victoria)
Common name of the parent organisms:	Bread wheat
Scientific name of the parent organisms:	<i>Triticum aestivum</i> L.
Modified trait(s):	Drought tolerance
Identity of the gene(s) responsible for the modified trait(s):	Each wheat line contains: <ul style="list-style-type: none">• One of 15 different genes for drought tolerance² derived from the plants <i>Zea mays</i> and <i>Arabidopsis thaliana</i>, the moss <i>Physcomitrella patens</i>, and the yeast <i>Saccharomyces cerevisiae</i>• <i>bar</i> gene (herbicide tolerance selectable marker)
Proposed Location(s)	Two sites in the shires of Horsham and Mildura, Victoria
Proposed Release Size:	Up to 0.225 hectares
Proposed Release Dates:	May 2008 to March 2010

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

¹ The title of the licence application submitted by DPI Victoria is *Assessment of candidate genes for drought tolerance in transgenic wheat*.

² Some details of the introduced genes have either been declared, or are the subject of an application for, Confidential Commercial Information (CCI) under section 185 of the Act.

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 a licence application from the Victorian Department of Primary Industries (DPI Victoria) for a licence for dealings involving the intentional release of genetically modified (GM) bread wheat (*Triticum aestivum* L.) into the Australian environment on a limited scale under controlled conditions.

Up to 50 GM wheat lines⁴ are proposed for release. They contain one of 15 different genes derived from the plants thale cress and maize, a moss and a yeast. The introduced genes encode proteins that are intended to improve drought tolerance.

The purpose of the trial is to conduct proof of concept experiments to evaluate the agronomic performance of the GM wheat lines under rain-fed, drought prone conditions. Some seed will be retained for seed increase or further experimentation (subject to additional approvals).

The applicant proposes to limit the release to two sites, on an area of 0.15 ha in the shire of Horsham and 0.075 ha in the shire of Mildura, over two seasons (May 2008 – March 2010).

The applicant has also proposed a number of controls 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:

- a 10 m monitoring zone free of plants around each release site
- an isolation zone of at least 490 m (not including the 10 m monitoring zone) free of Triticaceae species around each release site
- surrounding the site with a 1.2 m high wire fence with lockable gate suitable for excluding animals such as rabbits
- conducting rodent baiting in and around field trial site
- harvesting all plant material by hand to minimise GM seed spillage at the sites
- destroying, after analysis, all harvested GM plant materials except saved seed
- destroying all (GM and non-GM) plant materials from the field trial by incorporation into the soil to promote decomposition
- 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 volunteers by hand or with herbicide
- transporting GM plant materials to and from the proposed trial site in accordance with OGTR transportation guidelines
- not using the GMO in human food or animal feed.

Confidential Commercial Information

Some details of six of the introduced genes, including the names and classes of the genes and the names and origins of the promoters (regulatory sequences), have previously been declared Confidential Commercial Information (CCI) under section 185 of the Act (in relation to limited and controlled release licence DIR 071/2006). The applicant has submitted a request that the other nine introduced genes be similarly protected which is still under consideration. All CCI will be made

³ Available on the Office of the Gene Technology Regulator (OGTR) website at <<http://www.ogtr.gov.au/pubform/riskassessments.htm>>. Information on the assessment of licence applications is also available at <<http://www.ogtr.gov.au/ir/process.htm>> or Freecall 1800 181 030.

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

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 organism is bread wheat (*Triticum aestivum* L.) cultivar 'Bobwhite'. This cultivar is not grown commercially in Australia, but is commonly used in genetic modification work in Australia and overseas because it is relatively easy to transform.

Commercial wheat cultivation occurs in Australia's wheat belt which extends from south eastern Queensland through New South Wales, Victoria, southern South Australia and southern Western Australia.

The genetic modifications and their effect

Up to 50 lines of GM wheat are proposed for release. Each contains one of 15 genes encoding proteins expected to enhance drought tolerance by regulating gene expression or modulating biochemical and signal transduction pathways in the wheat plants. The genes are derived from the plants thale cress (*Arabidopsis thaliana*) and maize (*Zea mays*), the moss *Physcomitrella patens* and the yeast *Saccharomyces cerevisiae*. The expression of six of the genes is regulated by either a stress inducible promoter⁵ or a constitutive promoter. The same constructs are approved for limited and controlled release under licence DIR 071/2006. The expression of the other nine genes is regulated by a constitutive promoter only.

The GM wheat lines also contain the herbicide tolerance gene, *bar*, isolated from *Streptomyces hygroscopicus*, which was used as a marker to select for modified plants. The *bar* gene encodes the phosphinothricin acetyltransferase (PAT) enzyme, which provides tolerance to herbicides containing glufosinate ammonium. The applicant does not intend to apply glufosinate ammonium during the field trial.

Additionally, the GM wheat lines contain the *bla* gene from *Escherichia coli*, which confers resistance to the antibiotic ampicillin. This gene was used to select for bacteria containing plasmids⁶ with the desired genes in the laboratory, prior to the production of the GM plants, and is not expressed in the GM wheat lines as it is linked to a bacterial promoter that does not function in plants.

Some of the regulatory sequences that control the expression of the introduced genes in the GM wheat lines are derived from plant pathogens (*Agrobacterium tumefaciens* and Cauliflower mosaic virus). These regulatory sequences comprise only a small part of their total respective genome and are not capable of causing disease.

Method of genetic modification

The genes were introduced into bread wheat by particle bombardment. This technique involves coating plasmids containing the gene constructs onto very small gold particles that are 'shot' into embryos from wheat, which are then regenerated into whole plants in tissue culture. Particle bombardment has been widely used in Australia and overseas for introducing new genes into plants without causing any biosafety problems. Transformed plant tissues were identified using the expression of the marker genes and grown into plants in the laboratory. Molecular analysis was used to confirm the presence of the gene(s) of interest in the individual plants that were selected to produce the GM lines. Each of the 50 lines proposed for release is the result of an independent genetic modification event.

Previous releases of the same or similar GMOs

The Regulator has previously issued licence DIR 071/2006 to DPI Victoria for the conduct of field trials of GM drought tolerant wheat involving six of the genes in this current application.

⁵ A promoter is a short regulatory sequence that controls the level, timing or location of expression of the protein encoded by a gene.

⁶ Naturally occurring circles of DNA that are distinct and separate from the bacterial genome.

Under the former voluntary system overseen by the Genetic Manipulation Advisory Committee (GMAC), there have been five field trials of different types of GM wheat ranging in size from 325–1500 plants: PR65 (1996), PR66 (1996), PR102 (1998), PR102X (2000), and PR107 (1999).

In addition, the Regulator has issued licences to permit field trials with other GM wheat lines: DIR 053/2004 was issued to Grain Biotech for GM salt tolerant wheat and DIR 054/2004 was issued to CSIRO for GM wheat with altered starch content.

There have been no reports of adverse effects on human health 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 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 Regulator has determined that DPI Victoria 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 GMO and its 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 Risk Assessment and Risk Management Plan (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 080/2007.

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 and relevant local councils. 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 early May 2008.** 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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