



APPLICATION FOR LICENCE FOR INTENTIONAL RELEASE OF GMOs INTO THE ENVIRONMENT: Application No. DIR 054/2004

SUMMARY INFORMATION

Project Title:	Field trial of genetically modified wheat with altered grain starch
Applicant:	CSIRO PO Box 255 Dickson ACT 2602
Common name of the parent organism:	Bread wheat
Scientific name of the parent organism:	<i>Triticum aestivum</i> L.
Modified trait(s):	Altered grain starch, antibiotic resistance
Identity of the gene(s) responsible for the modified trait(s):	<ul style="list-style-type: none">• Genesilencing constructs directed at starch enzyme (SE) I and II of wheat (alters the type of starch in the wheat grain by knocking out these enzymes)• <i>nptII</i> gene from <i>Escherichia coli</i> (antibiotic resistance) <p>(CSIRO has sought and received approval to declare the details of the gene constructs, gene sequence information and the precise identity of the genes as Confidential Commercial Information)</p>
Proposed Location(s):	Australian Capital Territory (ACT)
Proposed Release Size:	0.25 ha*
Proposed Time of Release:	May 2005 – January 2007*

* The application originally proposed a field trial for a single growing season on a maximum area of 0.05 ha. Early in the processing of the application the applicant applied for, and was permitted to increase the scale of the field trial to two growing seasons on a maximum area of 0.25 ha. Both of these changes will be incorporated and taken into account in the risk assessment and risk management plan (RARMP) prepared for this application.

Introduction

The *Gene Technology Act 2000* (the Act) took effect on 21 June 2001. The Act, supported by the *Gene Technology Regulations 2001*, an inter-governmental agreement and corresponding legislation that is being enacted in each State and Territory, underpins 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 application and the proposed dealings

The OGTR has received an application from CSIRO Plant Industry (CSIRO) for a licence to conduct a small scale field trial of genetically modified (GM) wheat (*Triticum aestivum* L.) with altered starch characteristics under strictly controlled conditions. The aim of the proposed release is to assess the field performance of GM wheat with altered starch characteristics and to generate seed stocks of the wheat lines for future research.

The GM wheat proposed for release has been genetically modified with a gene silencing construct designed to prevent the expression of either starch enzyme (SE) I or SE II which influence starch metabolism in wheat grains. Changes in the level of expression of these enzymes will alter the ratio of the different types of starch normally found in the wheat grain. The GM wheat lines are expected to store amylose-type starch rather than the more quickly digested amylopectin-type starch in the wheat grain. High amylose starch is slower to digest and foods made with this type of starch are thought to have properties that are beneficial to human health.

The release is proposed to take place at one site covering a maximum total area of 0.05 ha at a research facility in the Australian Capital Territory (ACT) from May 2005 to January 2006. The applicant proposes to surround the GM wheat by a buffer row of non-transgenic wheat, enclosed by a macropod (eg. kangaroos, wallabies), bird and rat-proof fence and netting. Rodent traps and bird scarers (whistling tape) will also be employed. No other trial plots of wheat will be grown within 500 m of the proposed site. The nearest wheat crop is approximately 11 km from the trial site.

The applicant proposes to harvest the trial by hand in late 2005, thresh the wheat on-site and transport the seed to a facility certified to physical containment level 2 (PC2) in accordance with the OGTR transportation guidelines. In the two-month period after harvest, the site will be irrigated twice to germinate any remnant seed and the area will then be sprayed with a non-selective herbicide to eliminate any volunteer plants. The applicant proposes to conduct regular inspections for volunteer plants for 12 months after completion of the trial.

None of the material harvested from the trial will be used for human food or stock feed and any material not used for further research will be destroyed. This GM wheat would require approval by Food Standards Australia New Zealand (FSANZ) before it could be used for human consumption.

Previous releases of the GMO

There have been no previous releases of the proposed GMO. However, five field releases of similar and other types of GM wheat were approved under the former voluntary system that

was overseen by the Genetic Manipulation Advisory Committee (GMAC). The size of the previous releases ranged from 325 plants –1500 plants. These releases were:

- PR65 (1996-1997), PR66 (1996-1997), PR102 (1998-1999) and PR102X (2000-2001) conducted by CSIRO Plant Industry in the Australian Capital Territory (ACT); and
- PR107 (1999-2000) conducted by the University of Adelaide in South Australia.

In addition to these field releases, the OGTR has been advised of 16 Notifiable Low Risk Dealings (NLRDs) involving wheat, which are being conducted in contained research facilities around Australia. The plants to be released in the proposed field trial are derived from NLRD 770/2003 held by CSIRO Plant Industry. There have been no reports of adverse effects on human health or the environment resulting from these experiments.

Parent organism

The parent organism is bread wheat (*Triticum aestivum* L.).

Bread wheat is exotic to Australia, but has been grown since European settlement in 1788. It is now grown extensively in Australia (10.8 million ha in 2002/03) as a winter crop. Planting can occur between early April and late June and is determined by soil moisture availability and whether the cultivar is a winter type or spring type. Harvest normally takes place between late November and late December.

Genetic modification and its effect

The proposed trial involves six transgenic lines of GM starch-altered wheat. Gene silencing (RNA interference, RNAi technology) has been used to knockout the expression of starch enzymes (SE) I (4 lines) or II (2 lines). The GM starch-altered wheat also contains the neomycin phosphotransferase (*nptII*) gene from the bacteria *Escherichia coli* that confers antibiotic resistance, which was used as a selective marker in the laboratory. All SE sequences were derived from wheat.

The SE genes are under the control of the Bx17 high molecular weight (HMW) glutenin promoter, also derived from wheat, which directs expression specifically in the endosperm of the wheat grain. A short terminator sequence, derived from the soil bacterium *Agrobacterium tumefaciens*, is present in the GM wheat to direct the expression of the SE genes. Although *A. tumefaciens* is a plant pathogen, this terminator sequence comprises only a small part of the total genome, and is not in itself capable of causing disease.

Method of gene transfer

The SE genes were introduced into wheat on a plasmid vector carried by *A. tumefaciens*. The vector is disarmed since it lacks the genes that encode the tumour-inducing functions of *A. tumefaciens*.

Confidential Commercial Information

CSIRO has sought and received approval to have some details of the gene construct, gene sequence information and the precise identity of the genes used in the transgenic wheat lines declared as Confidential Commercial Information (CCI) under section 185 of the Act. However, the CCI information will be made available to the various prescribed expert groups

that will be consulted on the preparation of the risk assessment and risk management plan for this application.

Consultation on preparation of the Risk Assessment and Risk Management Plan

The Regulator has made an initial assessment as to whether the proposed release may pose significant risks to human health and safety or the environment, in accordance with section 49 of the Act.

Due to the low risk potential of the GMO, the control measures that will be imposed, and the limited scale and scope of the dealings, **the Regulator has decided that the proposed release does not pose a significant risk to human health and safety or the environment.**

This means that the Regulator is not required to seek public comment on the assessment of this proposal until after a risk assessment and risk management plan (RARMP) has been prepared. In the interim, copies of the application are available on request from the OGTR. Please quote application number DIR 054/2004.

In preparing the RARMP, the Regulator will seek input from a wide range of key stakeholders and expert groups comprising State and Territory Governments, relevant Australian Government agencies, the Minister for the Environment and Heritage, the Gene Technology Technical Advisory Committee and appropriate local councils, as required by section 50 of the Act. In accordance with section 52 of the Act, the Regulator will again consult with these prescribed agencies and authorities as well as the public in finalising the RARMP.

At this stage, the consultation version of the RARMP is expected to be released in December 2004 for an extended consultation period. 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. Summaries and copies of the RARMP will be available from the OGTR, or on the OGTR website.

If you have any questions about the application or the assessment process, please contact the OGTR at:

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