



APPLICATION FOR LICENCE FOR INTENTIONAL RELEASE OF GMOs INTO THE ENVIRONMENT: Application No. DIR 053/2004

SUMMARY INFORMATION

Project Title:	Field trial of genetically modified salt tolerant wheat on saline land
Applicant:	Grain Biotech Australia Pty Ltd
Common name of the parent organism:	Bread wheat
Scientific name of the parent organism:	<i>Triticum aestivum</i> L.
Modified trait(s):	Salt tolerance, cyanamide resistance
Identity of the genetic elements responsible for the modified trait(s):	<ul style="list-style-type: none">• Ornithine amino transferase (OAT) from <i>Arabidopsis thaliana</i> (salt tolerance)• Cyanamide hydratase (CAH) from <i>Myrothecium verrucaria</i> (selective marker, cyanamide resistance)
Proposed Location(s):	Corrigin shire, Western Australia (WA)
Proposed Release Size:	0.45 ha (4500m ²)
Proposed Time of Release:	April 2005 – January 2006

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 Grain Biotech Australia Pty Ltd (GBA) for a licence to conduct a small scale field trial of genetically modified (GM) salt tolerant wheat (*Triticum aestivum* L.) under controlled conditions. The aim of the proposed release is to

evaluate the salt tolerance and agronomic performance of the GM salt tolerant wheat on a site affected by different levels of salinity.

The genetic modification consists of an ornithine amino transferase gene (*oat*) derived from another plant species that expresses a protein, the ornithine amino transferase enzyme (OAT). Over-expression of this enzyme can increase proline levels in the plant. Proline is found in many plants. It is an inert compound that can enable plants to grow in the presence of elevated salt levels in soil. A fungal gene, cyanamide hydratase gene (*cah*), was also introduced in the genetic modification process which acts as a selective marker.

The proposed release would take place in the Corrigin shire in Western Australia (WA) at a single site of 0.45 ha (or 4500m²) from April 2005 to January 2006. During the proposed release, the GM wheat, non-GM bread wheat, non-GM barley, non-GM durum wheat and non-GM salt adapted bread wheat will be planted and compared.

The applicant proposes to surround the field trial with a 20 m pollen trap of non-GM wheat. A rabbit-proof fence will be erected to protect the trial from native and feral fauna. Bird-scarers (whistling tape) will also be strung across the trial at a height of 1200 mm to deter birds. Although the occurrence of floods is unlikely, the applicant also proposes to construct a diversion bank to divert any water away from the trial site.

After harvest, seed will be transported from the trial site in plastic containers to a storage facility certified to physical containment level 2 (PC2) in accordance with the OGTR transport guidelines. Residual plant material will be removed from the site in plastic bags, placed in plastic containers and incinerated.

The applicant proposes to monitor the site for two years after harvest and destroy any emerging volunteers. In the three month period after harvest, the site will be irrigated three times to germinate any remnant seed, the area will then be sprayed with a non-selective herbicide to eliminate these volunteer plants. None of the GM wheats and pollen trap plants from the trial, or their by-products will be used for human food or animal feed.

Previous releases of the GMO

There have been no previous releases of the proposed GMO. However, five field releases of other GM wheats were approved under the former voluntary system that was overseen by the Genetic Manipulation Advisory Committee (GMAC). The size of the 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; and
- PR107 (1999-2000) conducted by the University of Adelaide in South Australia.

In addition to these field releases, the OGTR has listed 16 Notifiable Low Risk Dealings (NLRDs) involving wheat: Grain Biotech Australia was the applicant for 4 of the NLRDs (039/2001, 236/2002, 237/2002, 238/2002, 239/2002).

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

Parent organism

The parent organism is bread wheat (*Triticum aestivum* L.). In this proposed release two commercial bread wheat cultivars, 'Westonia' and 'Carnamah', have been genetically modified independently.

Bread wheat is exotic to Australia, but has been grown since European settlement in 1788. It is now grown extensively in Australia 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 genetic modification consists of an ornithine amino transferase gene (*oat*) derived from the plant *Arabidopsis thaliana* and expresses the ornithine amino transferase enzyme (OAT). This enzyme catalyses the conversion of ornithine into pyrroline-5-carboxylate (P5C), the subsequent conversion of P5C into proline is catalysed by pyrroline-5-carboxylate reductase (P5CR). Over-expression of the *oat* gene is capable of increasing proline levels. Proline acts as an osmoprotectant and confers salt tolerance to the plant.

A second genetic modification present in the GM wheat is the selective marker gene, cyanamide hydratase (*cah*) isolated from the soil fungus *Myrothecium verrucaria*. The *cah* gene produces the enzyme cyanamide hydratase (CAH) which confers tolerance to the presence of cyanamide by hydrating the nitrile group of cyanamide to produce urea.

The expression of both *oat* and *cah* genes is controlled by regulatory sequences obtained from maize.

Method of gene transfer

The genes were introduced into the wheat genome by microprojectile bombardment. The linear fragments of DNA containing the *oat* and *cah* genes were spliced from the plasmids, coated onto gold particles and shot into wheat embryos using a helium pressure gun.

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 and the control measures that will be imposed to the limit the 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 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 053/2004.

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 the relevant local council, 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.

This proposal is for a small scale 'proof of concept' field trial. Before this new GM wheat could be used for human consumption, it would also require approval from Food Standards Australia New Zealand.

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

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