Australian Government
Department of Health
Office of the Gene Technology Regulator

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TECHNICAL SUMMARY OF THE RISK ASSESSMENT AND RISK MANAGEMENT PLAN
for

APPLICATION NO. DIR 071/2006
from

VICTORIAN DEPARTMENT OF PRIMARY INDUSTRIES

Introduction

The Gene Technology Regulator (the Regulator) has decided to issue a licence (DIR 071/2006) to the Victorian Department of Primary Industries (DPI Victoria) for dealings involving the intentional release of genetically modified (GM) drought tolerant wheat into the environment, on a limited scale and under controlled conditions.

The *Gene Technology Act 2000* (the Act), the *Gene Technology Regulations 2001* (the Regulations) and corresponding State and Territory law govern the comprehensive and highly consultative process undertaken by the Regulator before making a decision whether to issue a licence to deal with a GMO.

The Regulator's *Risk Analysis Framework* explains the approach used to evaluate licence applications and to develop the Risk Assessment and Risk Management Plans (RARMPs) that form the basis of her decisions[1].

This RARMP for DIR 071/2006 has been finalised in accordance with the gene technology legislation. Matters raised in the consultation process regarding risks to the health and safety of people or the environment from the proposed dealings were taken into account by the Regulator in deciding to issue a licence and the licence conditions that have been imposed.

[1] More information on the assessment of licence applications and copies of the *Risk Analysis Framework* are available from the Office of the Gene Technology Regulator (OGTR). Free call 1800 181 030.

Application

Title:	Limited and controlled release of GM drought tolerant wheat*
Applicant:	Victorian Department of Primary Industries (DPI Victoria)
Common name of the parent organism:	Bread wheat
Scientific name of the parent organism:	*Triticum aestivum* L.
Modified traits:	Drought tolerance and herbicide tolerance
Identity of the genes responsible for the modified traits:	Each wheat line contains: • One of six different genes for drought tolerance derived from the plants *Zea mays* and *Arabidopsis thaliana*, the moss *Physcomitrella patens*, and the yeast *Saccharomyces cerevisiae* • *bar* gene (herbicide tolerance selectable marker)
Proposed locations:	Two sites in the local government areas of Horsham and Mildura, Victoria
Proposed release size:	Up to 0.315† hectares
Proposed time of release:	May 2007 to March 2008

* The title of the licence application submitted by DPI Victoria is *Field assessment of candidate genes for drought tolerance in transformed wheat*.

† In its initial application, DPI-Victoria proposed individual sites of 0.15 ha in the local government area of Horsham and 0.075 ha in the local government area of Mildura. The applicant subsequently clarified their experimental design and as a consequence the area of the proposed site at Horsham has increased slightly to 0.24 ha.

DPI Victoria applied for a licence to release up to 30 lines of wheat that have been genetically modified to enhance drought tolerance into the environment under limited and controlled conditions. The trial is authorised to take place at two sites in the local government areas of Horsham and Mildura, Victoria, on a maximum total area of 0.315 hectares over one growing season (May 2007 – March 2008).

The GM wheat lines were produced by transforming plants of the bread wheat cultivar Bobwhite 26, which is not grown commercially in Australia. Each line contains one of six different genes derived from the plants *Arabidopsis thaliana* and *Zea mays*, the moss *Physcomitrella patens* and the yeast *Saccharomyces cerevisiae*. The introduced genes encode proteins that are intended to improve drought tolerance by regulating gene expression or modulating biochemical and signal transduction pathways in the wheat plants.

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

Additionally, the GM wheat lines contain the beta-lactamase (*bla*) gene from *Escherichia coli*, which confers ampicillin resistance and was used to select for bacteria containing the desired genes in the laboratory. The *bla* gene is not expressed in the GM wheat lines as it is linked to a bacterial promoter that does not function in plants.

The purpose of the trial is to conduct early stage ('proof of concept') research to evaluate the agronomic performance, including yield, of the GM wheat lines under rain-fed, drought prone conditions. Seed will also be collected and retained for analysis and possible future trials of lines that may be selected for further development (subject to additional approvals).

The applicant proposed measures to limit the spread and persistence of the GM wheat lines in the environment. These were taken into account in establishing the risk assessment context for the release, and their suitability for limiting the release to the size, duration and locations proposed by the applicant was considered as part of the risk assessment process. No material from the GM wheat plants will be used for human food or animal feed.

In accordance with the provisions of section 185 of the Act, DPI Victoria sought and received approval for some details of the application, including the names and classes of the introduced genes, the names and origins of the promoters (regulatory sequences), and data from previous international field releases of other plants expressing the same genes, to be declared Confidential Commercial Information (CCI). The CCI was made available to the various prescribed experts and agencies that are consulted on the preparation of all RARMPs for DIR applications.

Risk assessment

The risk assessment considered information contained in the application, current scientific knowledge, and issues relating to risks to human health and safety and the environment raised in submissions received from consultation with a wide range of prescribed experts, agencies and authorities on the application (summarised in Appendix B of the RARMP). No new risks to people or the environment were identified from the advice received on the consultation RARMP. However, feedback on the consideration of previously raised issues enabled their clarification in the final RARMP.

Advice received from the public on the application (one submission) and from consultation on the RARMP (15 submissions), and how it was considered, is summarised in Appendices C and D, respectively.

A reference document, *The Biology and Ecology of Bread Wheat* (Triticum aestivum *L. em Thell.) in Australia*, was produced to inform the risk assessment process for licence applications involving GM wheat plants. The document is available from the OGTR or from the website.

The hazard identification process considered the circumstances or events by which people or the environment may be exposed to the GMOs, GM plant materials, GM plant by-products, the introduced genes, or products of the introduced genes.

A hazard (source of potential harm) may be an event, substance or organism. A risk is identified when a hazard is considered to have some chance of causing harm. Those events that do not lead to an adverse outcome, or could not reasonably occur, do not advance in the risk assessment process.

Fifteen events were identified and assessed whereby the release of the GM wheat lines might give rise to harm to people or the environment.

These 15 events included consideration of whether expression of the introduced genes could result in products that are toxic or allergenic to people or other organisms; alter characteristics that may impact on the spread and persistence of the GM plants; or produce unintended changes in their biochemistry or physiology. In addition, consideration was given to the opportunity for gene flow to other organisms, and its effects if this occurred.

All events were characterised in relation to both the magnitude and probability of harm in the context of the controls proposed by the applicant to limit the spread and persistence of the GMOs in both time and space. This detailed consideration concluded that none of the 15

events gave rise to an identified risk that required further assessment. The principal reasons comprise:

- the scale of the trial is limited in both area and duration
- containment, monitoring and disposal measures proposed by the applicant to limit the spread and persistence of the GM wheat plants
- none of the GM plant materials or products will be used in human food or animal feed
- widespread presence of the same or similar proteins encoded by the introduced genes in the environment and lack of known toxicity or allergenicity from these proteins
- limited capacity of the GM wheat lines to spread and persist outside the release sites
- limited ability and opportunity for the GM wheat lines to transfer the introduced genes to commercial wheat crops or other sexually related species.

Therefore, as no risks to the health and safety of people or the environment were identified from the limited and controlled release of the GM wheat lines into the environment, the level of risk is considered to be **negligible**.

Risk management

A risk management plan builds upon the risk assessment to consider whether any action is required to mitigate the identified risks, and what can be done to protect the health and safety of people and the environment.

As none of the 15 events that were characterised in the risk assessment process are considered to give rise to an identified risk that requires further assessment, the level of risk to human health and safety and the environment from the release of the GM wheat lines is considered to be **negligible.**

The Regulator's *Risk Analysis Framework* defines negligible risks as insubstantial, with no present need to invoke actions for their mitigation. However, containment measures have been imposed to restrict the trial to the size, duration and locations requested by the applicant, as these were important parameters in establishing the context for assessing the risks.

Licence conditions to manage this limited and controlled release

A number of licence conditions have been imposed to limit and control the release, based on the risk management plan and measures proposed by the applicant. These include requirements to:

- maintain a 10 m monitoring zone around each release site free of any related species and with reduced plant cover to limit rodent refuges
- maintain an isolation zone of at least 490 m (not including the 10 m monitoring zone) around each release site free of any sexually compatible species
- enclose each site with a 1.2 m high fence with lockable gates
- locate the release sites at least 50 m away from natural waterways
- harvest the GM wheat plant material by hand and separately from other crops
- not permit any materials from the release to be used in human food or animal feed
- destroy all plant materials not required for further analysis

- following harvest, clean the sites, monitoring zones and equipment used on the sites
- following cleaning of sites, monitor for and destroy any GM wheat that may grow for at least 24 months and until the site is clear of volunteers for a continuous 6 month period.

The Regulator has issued guidelines and policies for the transport, supply and storage of GMOs (*Guidelines for the transport of GMOs, June 2001; Policy on transport and supply of GMOs, July 2005*). Licence conditions based on these guidelines and policies have also been imposed to control possession, use or disposal of the GMOs for the purposes of, or in the course of, the authorised dealings.

Other regulatory considerations

Australia's gene technology regulatory system operates as part of an integrated legislative framework. The Regulator sought input on the preparation of the RARMP from other agencies that also regulate GMOs or GM products including Food Standard Australia New Zealand (FSANZ), Australian Pesticides and Veterinary Medicines Authority (APVMA), Therapeutic Goods Administration (TGA), National Industrial Chemicals Notification and Assessment Scheme (NICNAS), National Health and Medical Research Council (NHMRC) and Australian Quarantine Inspection Service (AQIS). Dealings conducted under a licence issued by the Regulator may also be subject to regulation by one or more of these agencies[2].

FSANZ is responsible for human food safety assessment, including GM food. As the trial involves early stage research, the applicant does not intend any material from the GM wheat lines to be used in human food. Accordingly, the applicant has not applied to FSANZ to evaluate of any of the GM wheat lines. FSANZ approval would need to be obtained before they could be used in human food.

Although the GM wheat lines have been modified to be tolerant to glufosinate ammonium, the applicant does not intend to apply this herbicide during the trial; therefore no approval is required from APVMA.

Identification of issues to be addressed for future releases

The risk assessment identified additional information that may be required to assess an application for a large scale trial, reduced containment conditions or a commercial release of any of these GM wheat lines. This would include:

- molecular characterisation of GM wheat lines selected for possible future releases
- additional data on the potential toxicity and allergenicity of proteins encoded by the introduced genes for drought tolerance, and of plant materials from the GM wheat lines selected for possible future releases
- physiological and agronomic characteristics of the GM wheat lines indicative of weediness including measurement of altered reproductive capacity; tolerance to drought and other environmental stresses, including salinity; and disease susceptibility.

Conclusions of the RARMP

The risk assessment concludes that this limited and controlled release of up to 30 GM wheat lines into the local government areas of Horsham and Mildura in Victoria poses **negligible**

[2] More information on Australia's integrated regulatory framework for gene technology is contained in the *Risk Analysis Framework* available from the Office of the Gene Technology Regulator (OGTR). Free call 1800 181 030.

risks to the health and safety of people and the environment posed by, or as a result of, gene technology.

The risk management plan concludes that these **negligible** risks do not require specific risk treatment measures. However, licence conditions have been imposed to contain the release to the size, duration and locations requested by the applicant, as these were important parameters in establishing the context for assessing the risks.