



30 June 2008

**TECHNICAL SUMMARY OF THE RISK ASSESSMENT AND RISK
MANAGEMENT PLAN
FOR
APPLICATION NO. DIR 080/2007
FROM
VICTORIAN DEPARTMENT OF PRIMARY INDUSTRIES**

Introduction

The Acting Gene Technology Regulator (the Acting Regulator) has made a decision to issue a licence (DIR 080/2007) to the Victorian Department of Primary Industries (DPI Victoria) for dealings involving the intentional release of genetically modified (GM) wheat lines into the Australian environment.

The *Gene Technology Act 2000* (the Act), the Gene Technology Regulations 2001 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 decision is based upon a Risk Assessment and Risk Management Plan (RARMP) prepared by the Acting Regulator in accordance with the *Risk Analysis Framework* and finalised following consultation with a wide range of experts, agencies and authorities and the public¹.

The application

DPI Victoria has applied for a licence for dealings involving the intentional release of up to 50 lines² of wheat (*Triticum aestivum* L.) that have been genetically modified to enhance drought tolerance on a limited scale and under 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 0.4 hectares³ per year over two growing seasons between July 2008 and March 2010.

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 15 different genes derived from the plants thale cress (*Arabidopsis thaliana*) and maize (*Zea mays*), a moss (*Physcomitrella patens*) and a 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

¹ More information on the process for assessment of licence applications to release a genetically modified organism (GMO) into the environment is available from the Office of the Gene Technology Regulator (Free call 1800 181 030 or at <<http://www.ogtr.gov.au>>), and in the Regulator's Risk Analysis Framework (OGTR 2007) at <<http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/riskassessments-1>>.

² The term 'line' is used to denote plants derived from a single plant containing a specific genetic modification made by one transformation event.

³ As a result of a request from the applicant, the total maximum size of the proposed trial was increased from 0.225 hectares per year to 0.4 hectares per year. The applicant also proposed changes to harvest and post harvest licence conditions. The proposed changes were considered when finalising this RARMP and no new risks to people or the environment were identified.

the wheat plants. The identity and specific function of these genes are subject to a commercial confidential information declaration (see below).

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 β -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 proof of concept research, including continuing assessment of some lines that were initially authorised for release under DIR 071/2006. The agronomic performance, including yield, of the GM wheat lines will be evaluated under rain-fed, drought prone conditions. Seed and tissue samples would be collected and retained for analysis and possible future trials of lines that may be selected for further development, subject to further approval(s). The GM wheat will not be used for human food or animal feed.

DPI Victoria proposed a number of controls to restrict the dissemination or persistence of the GM wheat lines and their genetic material into the environment. These controls have been considered during the evaluation of the application.

Confidential Commercial Information

Some details, including the names, classes and specific functions 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, have been declared Confidential Commercial Information (CCI) under section 185 of the Act. The confidential information was made available to the prescribed experts and agencies that were consulted on the RARMP for this application.

Risk assessment

The risk assessment considered information contained in the application, relevant previous approvals, 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 consultation RARMP (four submissions) and how it was considered, is summarised in Appendix C.

A reference document, *The Biology of Triticum aestivum L. em Thell. (Bread Wheat)*, 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 <http://www.ogtr.gov.au>.

The risk assessment begins with a hazard identification process to consider what harm to the health and safety of people or the environment could arise during this release of GMOs due to gene technology, and how it could happen, in comparison to the non-GM parent organism and in the context of the proposed receiving environment.

Seven events were considered whereby the proposed dealings might give rise to harm to people or the environment. This included consideration of whether, or not, 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. The opportunity for gene flow to other organisms and its effects if this occurred was also assessed.

A **risk** is only identified when a hazard is considered to have some chance of causing harm. Events that do not lead to an adverse outcome, or could not reasonably occur, do not represent an identified risk and do not advance any further in the risk assessment process.

The characterisation of the seven events in relation to both the magnitude and probability of harm, in the context of the control measures proposed by the applicant, did not give rise to any identified risks that required further assessment. The principle reasons for this include:

- limits on the size, locations and duration of the release proposed by DPI Victoria;
- suitability of controls proposed by DPI Victoria to restrict the dissemination or persistence of the GM wheat plants and their genetic material;
- limited ability and opportunity for the GM wheat lines to transfer the introduced genes to commercial wheat crops or other sexually related species;
- limited capacity of the GM wheat lines to spread and persist in the areas proposed for release;
- 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, and end products produced as a result of the activity of, the introduced genes in the environment and lack of known toxicity or evidence of harm from them.

Therefore, any risks of harm to the health and safety of people, or the environment, from the proposed release of the GM wheat into the environment are considered to be **negligible**. Hence, the Regulator considers that the dealings involved in this proposed release **do not pose a significant risk** to either people or the environment⁴.

Risk management

The risk management process builds upon the risk assessment to determine whether measures are required in order to protect people and/or the environment. As none of the seven events characterised in the risk assessment are considered to give rise to an identified risk that requires further assessment, the level of risk 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 in the risk management plan. However, a

⁴ As none of the proposed dealings were considered to pose a significant risk to people or the environment, section 52(2)(d)(ii) of the *Gene Technology Act 2000* mandates a minimum period of 30 days for consultation on the RARMP. However, the Regulator allowed 6 weeks for the receipt of submissions from prescribed experts, agencies and authorities and the public.

range of measures have been imposed to restrict the dissemination and persistence of the GMO and its genetic material in the environment and to limit the proposed release to the size, locations and duration requested by the applicant as these were important considerations in establishing the context for assessing the risks.

Licence conditions to manage this limited and controlled release

The Acting Regulator has imposed a number of licence conditions including requirements to:

- conduct the release on a total area of up to 0.4 hectares per year at two sites in the local government areas of Horsham and Mildura, Victoria, between July 2008 and March 2010
- establish a 10 m monitoring zone around each trial site that is free of any related species and is maintained in a manner that does not attract or harbour rodents
- maintain an isolation zone of at least 200 m around each trial site free of any sexually compatible species
- enclose each trial site with a 1.2 m high fence with lockable gates
- conduct rodent baiting and/or trapping in and around each trial site
- locate the trial sites at least 50 m away from natural waterways
- harvest the GM wheat plant material by hand, or by machine, 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
- after harvest, apply measures to promote germination of any wheat seeds that may be present in the soil
- monitor the site for at least 24 months and destroy any wheat plants that may grow until no volunteers are detected 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; Policy on transport and supply of GMOs*). Licence conditions based on these guidelines and policies have also been proposed 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 that avoids duplication and enhances coordinated decision making. Dealings conducted under a licence issued by the Regulator may also be subject to regulation by 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) and Australian Quarantine Inspection Service (AQIS)⁵.

⁵ 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 or at <<http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/riskassessments-1>>.

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

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 and therefore no approval is required from APVMA.

Identification of issues to be addressed for future releases

Additional information has been identified that may be required to assess an application for a large scale or commercial release of any of these GM wheat lines that may be selected for further development, or to justify a reduction in containment conditions. This would include:

- characterisation of the introduced genetic material in the plants, including copy number and genotypic stability
- additional data on the potential toxicity of plant materials from the GM wheat lines
- additional data on the allergenicity of proteins encoded by the introduced genes
- data on the dispersal of viable wheat seeds by Australian birds
- data on the level of long distance gene flow under Australian conditions
- characteristics indicative of weediness including measurement of altered reproductive capacity; tolerance to drought and other environmental stresses; and disease susceptibility

Suitability of the applicant

The Regulator determined, at the commencement of the assessment process for this application, that DPI Victoria is suitable to hold a DIR licence under the requirements of section 58 of the Act. The Acting Regulator is satisfied that DPI Victoria remains suitable as no relevant convictions have been recorded, no licences or permits have been cancelled or suspended under OGTR legislation relating to the health and safety of people or the environment, and the organisation has confirmed its ability to comply with the licence conditions.

Conclusions of the RARMP

The risk assessment concludes that this limited and controlled release of up to 50 GM wheat lines on a maximum total area of 0.4 hectares per season over two growing seasons in the Victorian local government areas of Horsham and Mildura poses **negligible** risks to the health and safety of people or the environment 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 restrict the dissemination and persistence of the GMO and its genetic material in the environment and to limit the proposed release to the size, locations and duration requested by the applicant as these were important considerations in establishing the context for assessing the risks.