



**EXECUTIVE 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 for dealings involving the limited and controlled release of up to 50 lines of wheat modified for drought tolerance into the environment in respect of application DIR 080/2007 from the Victorian Department of Primary Industries (DPI Victoria).

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 public<sup>1</sup>.

***The application***

DPI Victoria applied for a licence for dealings involving the intentional release of up to 50 lines of genetically modified (GM) wheat on a limited scale and under controlled conditions. The wheat lines have been genetically modified to enhance drought tolerance. 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 hectares<sup>2</sup> per year between 2008 and 2010.

The GM wheat lines contain one of fifteen different introduced genes derived from the plants thale cress and maize, a moss and a yeast. The introduced genes encode proteins that are intended to enable normal plant growth with reduced amounts of water (drought tolerance) either by regulating gene expression or modulating biochemical pathways in the wheat plants.

The GM wheat lines also contain a herbicide tolerance gene and an antibiotic resistance gene that were used as markers to select for successful genetic modifications during initial research and development work in the laboratory. The applicant does not intend to apply the herbicide to which the GM plants are tolerant during the trial and the antibiotic resistance gene will not be expressed in the plants.

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<sup>1</sup> 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>.

<sup>2</sup> 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 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 the introduced genetic materials in the environment that 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 takes into account information in the application (including proposed containment measures), relevant previous approvals, current scientific knowledge, advice received from a wide range of experts, agencies and authorities consulted on the RARMP, submissions from the public and from the applicant.

A **hazard** identification process was used to determine potential pathways that might lead to harm to people or the environment as a result of gene technology.

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 advance 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.

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

## ***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 from the proposed dealings 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 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.

The licence conditions require DPI Victoria to **limit** the release to a total area of 0.4 hectares per year at two sites between July 2008 and March 2010. The **control** measures to restrict the spread and persistence of the GMOs include preventing the use of GM plant materials in human food or animal feed; destroying GM plant materials not required for further studies; transporting GM plant materials in accordance with OGTR transportation guidelines; and conducting post-harvest monitoring at the trial site to ensure all GMOs are destroyed<sup>3</sup>.

## ***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.

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<sup>3</sup> The licence for DIR 080/2007 is available on the OGTR website <<http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/ir-1>> via the link to DIR 080/2007