



6 JUNE 2008¹

**EXECUTIVE SUMMARY OF THE RISK ASSESSMENT AND RISK
MANAGEMENT PLAN
FOR
APPLICATION NO. DIR 077/2007
FROM
THE UNIVERSITY OF ADELAIDE**

Introduction

The Acting Gene Technology Regulator (the Regulator) has made a decision to issue a licence for dealings involving the limited and controlled release of up to 30 wheat and barley lines modified for enhanced tolerance to certain abiotic stresses or for increased levels of beta glucan into the environment in respect of application DIR 077/2007 from The University of Adelaide.

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 Regulator in accordance with the *Risk Analysis Framework* and finalised following consultation with a wide range of experts, agencies and authorities and the public².

The application

The University of Adelaide applied for a licence for dealings involving the intentional release of up to 30 lines of genetically modified (GM) wheat and barley on a limited scale and under controlled conditions. The GM wheat and barley lines have been modified for enhanced tolerance to different environmental stressors, such as high soil boron levels or drought, or for increased dietary fibre. The trial is proposed to take place at one site in the local government area of Marion, South Australia on a maximum total area of 400 m² between June 2008 and June 2009.

Up to four of the GM wheat lines and up to four of the GM barley lines contain one of two genes that are expected to confer increased drought tolerance. These genes are derived from wheat.

Up to three of the GM barley lines contain a gene that is expected to confer increased tolerance to toxic levels of boron in the soil. This gene is derived from barley.

¹ This Executive Summary was updated in September 2008 to address a typographical error.

² 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/ir/process.htm>>), and in the Regulator's *Risk Analysis Framework* (OGTR 2007) at <<http://www.ogtr.gov.au/pubform/riskassessments.htm>>.

Up to four of the GM barley lines contain a gene that is expected to confer increased resistance to environmental stressors. This gene is derived from wheat.

Up to fifteen lines of the GM barley contain one of three genes that are expected to increase the levels of dietary fibre in the leaves and grains of the mature barley plants. These genes are derived from barley.

All of the GM wheat and barley lines contain an antibiotic resistance selectable marker gene. The GM barley lines that contain the gene expected to confer increased tolerance to boron also contain an additional selectable marker gene. These genes were used as selective markers during the initial development of the GM plants in the laboratory.

The purpose of the trial is to conduct proof of concept research involving experiments with the GM wheat and barley lines to assess their agronomic performance under field conditions, and to obtain tissue samples for subsequent analysis of characteristics such as gene and protein expression levels, and metabolite profiles. Some seed will be stored for possible future trials of promising lines, subject to further approval(s). The GM wheat and barley will not be used for human food or animal feed.

The University of Adelaide proposed a number of controls to restrict the dissemination or persistence of the GM wheat and barley lines into the environment that have been considered during the evaluation of the application.

Confidential Commercial Information

Some details, including the name of an introduced gene expected to enhance abiotic stress tolerance, the precise function of the gene product and its application, 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 took 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, and submissions from the public³.

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

Eight 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.

³ The Executive Summary dated 6 June 2008 referred to “a submission from the public” this was a typographical error which was rectified in September 2008.

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 eight 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 and barley lines into the environment are estimated to be **negligible**. Hence, the Regulator considers that the dealings involved in this limited and controlled release **do not pose a significant risk** to the health and safety of people or to 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 eight 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 limit the release to the size, location and duration requested by the applicant, as these were an important part of establishing the context for assessing the risks.

The licence conditions require The University of Adelaide to **limit** the duration of the release to between June 2008 and June 2009 on a maximum total area of 400 m² at one site. 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 destroyed⁴.

Conclusions of the RARMP

The risk assessment concludes that this proposed limited and controlled release of up to 30 GM wheat and barley lines on a total area of up to 400 m² over one growing season in the South Australian local government area of Marion 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 limit the release to the size, location and duration requested by the applicant as these were important considerations in establishing the context for assessing the risks.

⁴ The licence for DIR 077/2007 is available on the OGTR website (<http://www.ogtr.gov.au/gmorec/ir.htm#table>) via the link to DIR 077/2007