



10 July 2009

**EXECUTIVE SUMMARY OF THE RISK ASSESSMENT AND
RISK MANAGEMENT PLAN
FOR
APPLICATION NO. DIR 094
FROM
CSIRO**

Introduction

The Gene Technology Regulator (the Regulator) has made a decision to issue a licence in respect of licence application DIR 094 from the Commonwealth Scientific and Industrial Research Organisation (CSIRO). The licence authorises dealings involving the limited and controlled release of 27 lines¹ of genetically modified (GM) wheat and barley into the 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 genetically modified organism (GMO). The decision is based on 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

CSIRO applied for a licence for dealings involving the intentional release of 17 lines of GM wheat and 10 lines of GM barley on a limited scale and under controlled conditions. The GM wheat and barley lines have been genetically modified for enhanced nutrient utilisation efficiency. The trial will take place at one site in the Australian Capital Territory (ACT), on a maximum area of 1 ha, between July 2009 and June 2012.

Nine of the GM wheat lines and five of the GM barley lines contain a metabolic enzyme gene (*Me1*) derived from barley. Expression of *Me1* is expected to enhance the efficiency of nitrogen utilisation and result in an increase in plant biomass and yield. The remainder of the

¹ The term 'line' is used to denote plants derived from a single plant containing a specific genetic modification made by one transformation event.

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 (OGTR) (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>>.

GM wheat and barley lines are control lines that do not contain the *Me1* gene. All of the GM wheat and barley lines contain a selectable marker gene.

The purpose of the trial is to characterise growth and yield characteristics of the GM plants when grown under field conditions. In addition, it is proposed to generate sufficient grain to assess any changes in grain protein composition for the GM plants relative to non-GM plants and how this may affect dough characteristics and end-product quality. Plant materials from the GM wheat and barley will not be used for either human or animal consumption.

CSIRO proposed a number of controls to restrict the dissemination and persistence of the GM wheat and barley 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 name and sequence of the introduced *Me1* gene and the promoter, and the identity of two of the vectors, 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 and advice relating to risks to human health and safety and the environment provided in submissions received during consultation on the RARMP. No new risks to people or the environment were identified from the advice received on the consultation RARMP.

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 identified 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 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 considered to be **negligible**. Hence, the 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 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, conditions are imposed to restrict the dissemination and persistence of the GMOs and their genetic material in the environment and to limit the proposed release to the size, location and duration requested by the applicant as these were important considerations in establishing the context for assessing the risks.

The licence conditions require CSIRO to **limit** the release to a total area of 1 ha per year at one site in the ACT between July 2009 and June 2012. The **control** measures include containment provisions at the trial site; 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 the Regulator's transportation guidelines; and conducting post-harvest monitoring at the trial site to ensure all GMOs are destroyed³.

Conclusions of the RARMP

The risk assessment concluded that this proposed limited and controlled release of 17 GM wheat lines and 10 GM barley lines on a maximum total area of 1 ha over three years in the ACT, poses **negligible** risks to the health and safety of people or the environment as a result of gene technology.

The risk management plan concluded 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 GMOs and their genetic material in the environment and 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.

³ The licence for DIR 094 is available on the OGTR website via the link to DIR 094 <<http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/dir094>>