



23 June 2010

**EXECUTIVE SUMMARY OF THE RISK ASSESSMENT AND  
RISK MANAGEMENT PLAN  
FOR  
APPLICATION NO. DIR 100  
FROM  
CSIRO**

***Introduction***

The Gene Technology Regulator (the Regulator) has made a decision to issue a licence in respect of licence application (DIR 100) from the Commonwealth Scientific and Industrial Research Organisation (CSIRO). The licence authorises dealings involving the limited and controlled release of up to 150 lines<sup>1</sup> of genetically modified (GM) wheat 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 upon a Risk Assessment and Risk Management Plan (RARMP) prepared by the Regulator in accordance with requirements of the legislation. RARMPs apply the *Risk Analysis Framework* and are finalised following consultation with a wide range of experts, agencies and authorities, and the public<sup>2</sup>.

***The application***

CSIRO has applied for a licence for dealings involving the intentional release of up to 150 lines of GM wheat on a limited scale and under controlled conditions. The GM wheat lines have been genetically modified for enhanced carbon assimilation in drought and heat prone environments. The trial will take place at one site in the Queensland LGA of Redland, on a maximum area of 0.1 ha per growing season, between June 2010 and December 2013.

The applicant will release GM wheat modified to contain one or more of 26 genes derived from wheat and barley. Expression of the genes is expected to show improved grain weight and yield of the GM wheat in heat and drought prone environments through enhanced water use efficiency, photosynthesis and carbon assimilation. The applicant also intends to cross some of the lines using conventional breeding to produce GM wheat which contain a combination of these traits.

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

<sup>2</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 (OGTR) (Free call 1800 181 030 or at <<http://www.ogtr.gov.au/>>), and in the Regulator's *Risk Analysis Framework* (OGTR 2009) at <[http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/raf-3/\\$FILE/raffinal3.pdf](http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/raf-3/$FILE/raffinal3.pdf)>

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 in the field.

The purpose of the trial is to assess the agronomic performance of the GM wheat lines for biomass production, grain weight and yield under rain-fed and drought/heat prone conditions. The GM wheat would not be used for human food or animal feed.

CSIRO proposed a number of controls to restrict the spread and persistence of the GM wheat lines and the introduced genetic materials in the environment. These controls were considered during the evaluation of the application.

### ***Confidential Commercial Information***

Some details, including the identities of some of the genes and sequences, and associated references 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, 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.

Initially, potential pathways that might lead to harm to people or the environment as a result of gene technology were postulated (risk scenarios), and these scenarios were evaluated to identify those that warrant detailed characterisation. This process is described as risk identification.

Eight risk scenarios were postulated, including 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 wheat; or produce unintended changes in the biochemistry of the GMOs. The opportunity for gene flow to other organisms, and its effects if it were to occur, was also assessed.

A **risk** is only identified for further assessment when a risk scenario is considered to have some chance of causing harm. Pathways 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 risk scenarios in relation to both the seriousness and likelihood 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.

Risks to the health and safety of people, or the environment, from the proposed release of the GM wheat into the environment are assessed 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 plan***

Risk management is used to protect the health and safety of people and to protect the environment by controlling or mitigating risk. The risk management plan evaluates and treats identified risks, evaluates controls and limits proposed by the applicant, and considers general risk management measures. The risk management plan is given effect through licence conditions.

As none of the eight risk scenarios characterised in the risk assessment give rise to an identified risk that requires further assessment, the level of risk from the proposed dealings is assessed 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 spread and persistence of the GMOs and their genetic material in the environment and to limit the proposed release to the size and location 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 0.1 ha per growing season at one site between June 2010 and December 2013. The **control** measures include containment provisions at the trial site, prohibiting 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 Regulator's transportation guidelines; and conducting post-harvest monitoring at the trial site to ensure all GMOs are destroyed.

## ***Conclusions of the RARMP***

The risk assessment concluded that this limited and controlled release of up to 150 GM wheat lines on a maximum total area of 0.1 ha per growing season over three years in the Queensland LGA of Redland, 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 limit the release to the size, location and duration proposed by the applicant, and to require controls in line with those proposed by the applicant, as these were important considerations in establishing the context for assessing the risks.