



11 June 2010

**EXECUTIVE SUMMARY OF THE RISK ASSESSMENT AND  
RISK MANAGEMENT PLAN  
FOR  
APPLICATION NO. DIR 099  
FROM  
CSIRO**

***Introduction***

The Gene Technology Regulator (the Regulator) has made a decision to issue a licence in respect of licence application (DIR 099) from Commonwealth Scientific and Industrial Research Organisation (CSIRO). The licence authorises dealings involving the limited and controlled release of up to 11 lines<sup>1</sup> of genetically modified (GM) wheat and 3 lines of GM 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 or not 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 11 lines of GM wheat and 3 lines of GM barley on a limited scale and under controlled conditions. Four of the GM wheat lines have been genetically modified for altered grain composition. The remaining GM wheat lines and the 3 GM barley lines have been genetically modified for enhanced nutrient utilisation efficiency. The trial will take place at two sites, one in the shire of Narrabri (NSW) and the other in the shire of Corrigin (WA), on a maximum area of 2 ha per year, between June 2010 and June 2013.

Four of the GM wheat lines contain a gene fragment designed to decrease expression of a gene involved in determining grain qualities important for dough making and human nutrition. Decreased expression of the targeted gene results in alterations to the starch composition of the grain. Seven of the GM wheat lines and the three GM barley lines contain a gene from barley that encodes an enzyme involved in nitrogen

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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 resulting from a single 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/riskassessments-1>>.

utilisation. Expression of this gene is expected to result in an increase in plant biomass and yield. All of the GM wheat and barley lines contain a selectable marker gene.

The purpose of the trial is to assess the growth and yield characteristics of the GM plants when grown under field conditions. The applicant also intends to generate sufficient grain to assess any changes in grain composition for the GM plants relative to non-GM plants and how this may affect dough characteristics and end-product quality. The GM wheat and barley 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 and barley 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 name and sequence of the genes and some regulatory sequences, the identity of vectors, specific phenotypes, and some testing methods 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), previous approvals, relevant scientific/technical 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 are postulated (risk scenarios), and these scenarios are 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 and barley; or produce unintended changes in the biochemistry of the GMO. 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 and barley 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 the 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 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 CSIRO to **limit** the release to a total area of 2 ha per year at two sites from the date of issue of the licence until June 2013. 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 destroyed.

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

The risk assessment concluded that this proposed limited and controlled release of up to 11 GM wheat lines and 3 GM barley lines on a maximum total area of 2 ha per year over three growing seasons in the shire of Narrabri (NSW) and the shire of Corrigin (WA), 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, locations 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.