



5 June 2009

**EXECUTIVE SUMMARY OF THE RISK ASSESSMENT AND RISK  
MANAGEMENT PLAN**  
FOR  
**APPLICATION NO. DIR 093**  
FROM  
**CSIRO**

### ***Introduction***

The Gene Technology Regulator (the Regulator) has made a decision to issue a licence in respect of licence application DIR 093 from the Commonwealth Scientific and Industrial Research Organisation (CSIRO). The licence authorises dealings involving the limited and controlled release of three lines<sup>1</sup> of genetically modified (GM) wheat and one line of GM barley with altered grain starch composition 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 Gene Technology Regulator (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 the *Risk Analysis Framework* and finalised following consultation with a wide range of experts, agencies and authorities and the public<sup>2</sup>.

### ***The application***

CSIRO applied for a licence for dealings involving the intentional release of three lines of wheat and one line of barley which have been genetically modified for altered grain starch composition on a limited scale and under controlled conditions. The trial will take place at one site in the Australian Capital Territory (ACT), on a maximum area of 1 hectare per year between July 2009 and June 2012.

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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 (Free call 1800 181 030 or at <<http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/process-1>>), and in the Regulator's *Risk Analysis Framework* (OGTR 2007) at <<http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/riskassessments-1>>.

The genetic modifications are expected to suppress the function of endogenous genes resulting in altered grain starch composition. Evaluation of glasshouse grown GM wheat and barley lines has shown altered grain starch composition as a result of the genetic modification. This has resulted in grains with a higher resistant starch content which in turn contributes to the total dietary fibre intake. These changes may contribute to enhanced nutritional properties and improve digestive bowel health. The GM wheat and barley lines also contain an antibiotic resistance gene which was used to identify transformed plants during the initial development of the GM plants in the laboratory.

The purpose of the trial is to evaluate grain properties of the GM wheat and barley lines grown under field conditions. This would involve generating sufficient grain to make flour for laboratory evaluation of how the flour performs in foods. This would then be fed to rats and pigs in laboratory experiments to determine whether altered grain properties change the nutritional value of the GM wheat and barley. Products made from GM wheat may also be consumed by a limited number of volunteers as part of a carefully controlled nutritional study.

CSIRO proposes 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 names of genes expected to alter grain starch composition, the specific phenotypic changes occurring when they are down-regulated and its application, have been declared Confidential Commercial Information (CCI) under section 185 of the Act. The confidential information will be made available to the prescribed experts and agencies that will be 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 and 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 constructs 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 were 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 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, except for rat and pig nutritional experiments, and the human nutritional experiments; 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 three GM wheat lines and one GM barley line on a maximum total area of 1 ha over 3 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.