



28 May 2009

**TECHNICAL SUMMARY OF THE RISK ASSESSMENT AND  
RISK MANAGEMENT PLAN  
FOR  
APPLICATION NO. DIR 092  
FROM  
CSIRO**

***Introduction***

The Gene Technology Regulator (the Regulator) has made a decision to issue a licence in respect of licence application DIR 092 from the Commonwealth Scientific and Industrial Research Organisation (CSIRO). The licence authorises dealings involving the limited and controlled release of 16 lines of genetically modified (GM) wheat with altered grain 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 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>1</sup>.

***The application***

CSIRO applied for a licence for dealings involving the intentional release of 16 lines of wheat (*Triticum aestivum* L. em Thell.) derived from 15 transformation events which have been genetically modified for altered grain composition on a limited scale and under controlled conditions. The trial will take place at one site in the Australian Capital Territory, on a maximum area of 1 ha between July 2009 and June 2012.

The GM wheat lines were produced by transforming plants of the wheat cultivars Bobwhite 26 and NB1. Fourteen lines for release represent independent transformation events of cultivar Bobwhite 26 with four different constructs; the remaining two lines for release are derived from conventional crosses between two different GM wheat lines (in cultivars Bobwhite 26 and NB1), and contain two different constructs.

All five constructs used for transformation are designed to down-regulate expression of specific gene families involved in determining final grain quality, through a mechanism known as gene silencing, or RNA interference (RNAi). Decreased expression of the down-regulated gene families results in alterations to starch, protein or metabolite composition of the grain. The GM wheat lines also contain an antibiotic

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<sup>1</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 2007) at <<http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/riskassessments-1>>.

resistance gene which was used to identify transformed plants during initial development of the GM plants in the laboratory.

The purpose of the trial is to evaluate grain properties of the GM wheat lines grown under field conditions. This requires generating sufficient grain for examination of dough rheological parameters and end quality of grain products. Some of the GM lines will also be used for rat and pig nutritional trials to determine whether altered grain properties change the nutritional value of the GM wheat. With the exception of rat and pig nutritional trials, the GM wheat will not be used for human food or animal feed.

CSIRO proposed a number of controls to restrict the dissemination and persistence of the GM wheat lines and their genetic material into the environment. These controls have been considered during the evaluation of the application.

### **Confidential Commercial Information**

Some details, including the identities of some of the gene families targeted for silencing and specific phenotypic descriptions which may allow their identification, 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 considered information in the application, relevant previous approvals, current scientific knowledge, and issues relating to risks to human health and safety and the environment raised in submissions on the application received from consultation with a wide range of prescribed experts, agencies and authorities (included in Appendix B of the RARMP) as well as the public (included in Appendix C of the RARMP).

A reference document, *The Biology of Triticum aestivum L. em Thell. (Bread Wheat)*, was used to inform the risk assessment process. The document is available from the OGTR or from the website <http://www.ogtr.gov.au>.

The risk assessment begins with a hazard identification process to consider what harm to the health and safety of people or the environment could arise during this release of GMOs due to gene technology, and how it could happen, in comparison to the non-GM parent organism and in the context of the proposed receiving environment.

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 RNAi 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 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 represent an identified risk and do not advance any further 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. The principal reasons for this include:

- limits on the size, location and duration of the release proposed by CSIRO
- suitability of controls proposed by CSIRO to restrict the dissemination and persistence of the GM wheat plants and their genetic material
- limited ability and opportunity for the GM wheat lines to transfer the introduced RNAi constructs to commercial wheat crops or other sexually related species
- none of the GM plant materials or products will be used in human food or animal feed, with the exception of rat and pig nutritional studies, from which no material will enter the human food or animal feed supply chain
- widespread presence of the same sequences from which the introduced RNAi constructs are composed in the environment and lack of known toxicity or evidence of harm from them.

Therefore, any risks of harm to the health and safety of people, or the environment, from the proposed release of the GM wheat into the environment are considered to be **negligible**. Hence, the Regulator considers that the dealings involved in this proposed 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 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 have been 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.

### ***Licence conditions to manage this limited and controlled release***

The Regulator has imposed a number of licence conditions including requirements to:

- conduct the release on a total area of up to 1 ha at one site in the ACT, between July 2009 and June 2012
- locate the trial site more than 50 m away from natural waterways
- establish a 10 m zone around the trial site that is free of any related species and is maintained in a manner that does not attract or harbour rodents, and conduct rodent baiting and/or trapping in and around each trial site
- maintain an isolation zone of at least 200 m around each trial site free of any sexually compatible species, with the exception of other GM wheat lines approved for release by the Regulator
- separate the GM wheat trial from any other GM wheat trial by at least a 4 m
- enclose the trial site with a 1.8 m high livestock-proof fence with lockable gates

- harvest the GM wheat plant material separately from other crops
- destroy all GM plant material not required for further analysis or future trials
- contain, transport and store material from the GMOs in accordance with the Regulator's guidelines
- clean the sites, buffer zones and equipment used on the sites following harvest
- not permit any GM wheat plant material to be used in human food or animal feed, with the exception of rat and pig nutritional experiments, from which no material is to enter the human food or animal feed supply
- apply measures to promote germination of any wheat seeds that may be present in the soil after harvest, including three irrigation cycles, with the last irrigation occurring during the final 6 months of the monitoring period
- monitor the site for at least 24 months after harvest and destroy any wheat plants that may grow until no volunteers are detected for a continuous 6 month period.

The Regulator has issued guidelines and policies for the transport, supply and storage of GMOs (*Guidelines for the transport of GMOs, Policy on transport and supply of GMOs*). Licence conditions based on these guidelines and policies have also been imposed to control possession, use or disposal of the GMOs for the purposes of, or in the course of, the authorised dealings.

### ***Other regulatory considerations***

Australia's gene technology regulatory system operates as part of an integrated legislative framework that avoids duplication and enhances coordinated decision making. Dealings conducted under a licence issued by the Regulator may also be subject to regulation by other agencies that also regulate GMOs or GM products including Food Standards Australia New Zealand (FSANZ), Australian Pesticides and Veterinary Medicines Authority (APVMA), Therapeutic Goods Administration (TGA), National Industrial Chemicals Notification and Assessment Scheme (NICNAS) and Australian Quarantine Inspection Service (AQIS)<sup>2</sup>.

FSANZ is responsible for human food safety assessment, including GM food. As the trial involves early stage research, the applicant does not intend any material from the GM wheat lines proposed for release to be traded as human food. Accordingly, the applicant has not applied to FSANZ to evaluate the GM wheat lines. FSANZ approval would need to be obtained before they could be sold as human food in Australia.

### ***Identification of issues to be addressed for future releases***

Additional information has been identified that may be required to assess an application for a large scale or commercial release of these GM wheat lines, or to justify a reduction in containment conditions. This would include:

- additional data on the potential allergenicity or toxicity of plant materials from the GM wheat lines

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<sup>2</sup> More information on Australia's integrated regulatory framework for gene technology is contained in the *Risk Analysis Framework* available from the Office of the Gene Technology Regulator (OGTR). Free call 1800 181 030 or at <http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/riskassessments-1>.

- additional phenotypic characterisation of the GM wheat lines, in particular of characteristics indicative of weediness including measurement of altered reproductive capacity and competitiveness
- characterisation of the introduced genetic material in the plants, including copy number and genotypic stability.

### ***Suitability of the applicant***

The previous Regulator determined, at the commencement of the assessment process for this application, that CSIRO is suitable to hold a DIR licence under the requirement of section 58 of the Act. The Regulator is satisfied that CSIRO remains suitable as no relevant convictions have been recorded, and no licences or permits have been cancelled or suspended under laws relating to the health and safety of people or the environment.

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

The risk assessment concluded that this limited and controlled release of 16 GM wheat 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 materials 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.