



23 June 2010

**TECHNICAL 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. They will be under control of a constitutive promoter, a developmental specific promoter, or a drought inducible promoter derived from barley or maize. 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 two selectable marker genes, *nptII* and *bar*. The *nptII* gene encodes neomycin phosphotransferase type II which provides resistance to antibiotics such as kanamycin. The *bar* gene encodes phosphinothricin acetyl transferase which provides resistance to herbicides containing glufosinate ammonium. These were used as selectable markers during early stages of development of the GM plants in the laboratory.

Other short regulatory sequences that contribute to control of expression of the introduced genes are also present in the GM wheat. These are derived from maize, rice, Cauliflower mosaic virus (CaMV) and *Agrobacterium tumefaciens* (a common soil bacterium). Although some of these sequences are derived from plant pathogens (*A. tumefaciens* and CaMV), the regulatory sequences comprise only a small part of the pathogen's total genome, and in themselves have no pathogenic properties.

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 will 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, associated references and phenotypic data, have been declared, 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 issues relating to risks to human health and safety and the environment raised in submissions received from consultation with a wide range of prescribed experts, agencies and authorities (included in Appendix A of the RARMP). The public also had the opportunity to provide comments, however no submissions were received from members of the public.

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

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 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. 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 spread and persistence of the GM wheat plants and their genetic material
- limited ability and opportunity for the GM wheat to transfer the introduced genes to other wheat plants or other sexually compatible species
- none of the GM plant materials or products will be used for human food or animal feed
- widespread presence of the same or similar proteins encoded by the introduced genes in the environment and lack of known toxicity or evidence of harm from them.

Risks to the health and safety of people, or the environment, from the proposed release of the GMOs 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 have been 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, location and duration requested by the applicant, as these were important considerations in establishing the context for assessing the risks.

### ***Licence conditions***

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

- limit the release to a total area of 0.1 ha at one site per growing season between June 2010 and December 2013
- locate the field trial site at least 50 m away from natural waterways

- establish a 10 m zone around the trial in which any related species are prevented from flowering and which is maintained in a manner that does not attract rodents
- surrounding the GM wheat and barley with an inspection zone of up to 200 m in which growth of sexually compatible species is controlled
- enclosing each trial site with a livestock-proof fence with lockable gate with mouse baiting inside the fence perimeter
- apply measures to promote germination of any wheat and barley seeds that may be present in the soil after harvest, including tillage and irrigation
- monitor the site for at least 24 months after harvest and until no volunteers are detected for a continuous 6 month period and destroy any wheat plants that may grow
- destroy all plant material from the trial not required for testing or future trials
- transport and storage of the GMOs in accordance with the Regulator's guidelines
- not allow the GM plant material or products to be used for human food or animal feed, or in the production of therapeutic goods.

### ***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>3</sup>.

APVMA has regulatory responsibility for the use of agricultural chemicals, including herbicides and insecticidal products, in Australia. The application of these herbicides is subject to regulation by the APVMA. While the GM wheat has been modified to be tolerant to glufosinate ammonium containing herbicides, the applicant does not intend to apply these herbicides during the trial.

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 used for 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 for human food in Australia.

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<sup>3</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>.

### ***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 toxicity and allergenicity of plant materials from the GM wheat lines
- phenotypic characterisation of the GM wheat lines, in particular of traits which may contribute to weediness, persistence, and ability to disperse in the environment
- molecular and biochemical characterisation of the GM wheat lines
- compositional analysis of the GM wheat lines.

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

The Regulator determined, at the commencement of the assessment process for this application, that CSIRO was suitable to hold a DIR licence under the requirements 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 proposed 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.