



11 June 2010

**TECHNICAL 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 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 lines¹ 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 public².

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 an introduced synthetic gene designed to reduce or silence the expression of a specific wheat gene by a mechanism known as RNA interference (RNAi). The gene introduced is under the control of an endosperm-specific promoter and targets Starch Metabolic Enzyme B (*SMEB*) gene which, when silenced, alters the composition of grain starch.

¹ The term 'line' is used to denote plants derived from a single plant containing a specific genetic modification resulting from a single transformation event.

² 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>>.

Seven of the GM wheat lines and all of the GM barley lines contain the *Me1* gene which encodes a metabolic enzyme. This gene is naturally present in non-GM barley plants and its expression is expected to enhance the efficiency of nitrogen utilisation. Expression of the introduced *Me1* gene is under the control of a tissue specific promoter derived from rice. The *Me1* gene has previously been overexpressed in canola and rice and resulted in a phenotype of increased plant biomass and increased yield. A similar effect is expected for overexpression of *Me1* in wheat and barley.

All of the GM wheat lines contain one of two selectable marker genes derived from bacteria: either the *nptII* gene which confers resistance to aminoglycoside antibiotics related to kanamycin and neomycin, or the *hpt* gene which confers resistance to the antibiotic hygromycin. All of the GM barley lines contain the selectable marker gene *hpt*. These were used as selectable markers during early stages of development of the GM plants in the laboratory.

Other short regulatory sequences that control expression of the genes will also be present in the GM wheat and barley lines. These are derived from wheat, 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 GM wheat lines were produced by transforming plants of the wheat cultivars Bobwhite 26 (nine lines) and Frame (two lines). The 3 GM barley lines were produced by transforming plants of the barley cultivar Golden Promise.

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 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) as well as the public (included in Appendix B of the RARMP).

The reference documents, *The Biology of Triticum aestivum L. em Thell (bread wheat)* and *The Biology of Hordeum vulgare L. (barley)*, were produced to inform the risk assessment process for licence applications involving GM wheat and barley plants. The documents are 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 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. The principal reasons for this include:

- limits on the size, locations and duration of the release proposed by CSIRO
- suitability of controls proposed by CSIRO to restrict the spread and persistence of the GM wheat and barley plants and their genetic material
- limited ability and opportunity for the GM wheat and barley 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 genetic material 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 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 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, locations 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 up to 2 ha per growing season at two sites, one in the LGA of Narrabri (NSW) and the other in the LGA of Corrigin (WA), from the date of issue of the licence until June 2013
- locate the trial sites at least 50 m away from natural waterways
- establish a 10 m zone around the trial sites in which any related species are prevented from flowering and which is maintained in a manner that does not attract or harbour rodents
- surround the GM wheat and barley with an inspection zone of up to 200 m in which growth of sexually compatible species is controlled
- ensure no other crops of wheat or barley are within 200 m of the trial sites
- enclose the trial site in the shire of Corrigin with a livestock-proof fence with lockable gates and ensure that livestock are excluded from trial site in the shire of Narrabri
- harvest the GM wheat and barley plant material separately from other crops
- clean the sites and equipment used on the sites following harvest
- apply measures to promote germination of any wheat and barley seeds that may be present in the soil after harvest, including irrigation
- monitor the site for at least 24 months after harvest and destroy any wheat and/or barley plants that may grow until no volunteers are detected for a continuous 6 month period
- destroy all GM plant material not required for further analysis or future trials
- transport material from the GMOs in accordance with the Regulator's guidelines
- not permit any GM wheat or barley plant material to be used in 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)³.

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 and barley lines proposed for release to be used for human food. Accordingly, the applicant has not applied to FSANZ to evaluate the GM wheat and barley lines. FSANZ approval would need to be obtained before they could be sold for 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 and barley 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 and barley lines
- additional phenotypic characterisation of the GM wheat and barley lines, in particular pest disease susceptibility and 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 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 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.

³ 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>.