



29 June 2010

**TECHNICAL SUMMARY OF THE RISK ASSESSMENT AND
RISK MANAGEMENT PLAN
FOR
APPLICATION NO. DIR 102
FROM
THE UNIVERSITY OF ADELAIDE**

Introduction

The Gene Technology Regulator (the Regulator) has made a decision to issue a licence in respect of licence application (DIR 102) from the University of Adelaide. The licence authorises dealings involving the limited and controlled release of up to 2340 lines¹ of genetically modified (GM) wheat and 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

The University of Adelaide has applied for a licence for dealings involving the intentional release of up to 1161 lines of GM wheat and 1179 lines of GM barley on a limited scale and under controlled conditions. The GM wheat and barley lines have been genetically modified to enhance nutrient utilisation and abiotic stress tolerance. The trial will take place at three sites, two in South Australia and one in Western Australia, on a maximum area of 0.75 ha per growing season, between June 2010 and December 2015.

The applicant will release GM wheat and barley modified to contain one of 35 genes encoding proteins expected to enhance nitrogen use efficiency, increase zinc uptake and enhance tolerance to a range of abiotic stresses including drought, cold, salt and low phosphorus. Most of the genes conferring the traits have been obtained from wheat, barley or maize. The remaining genes were derived from thale cress, moss or yeast, which are also widespread in the environment. Expression of each of the genes will be under the control of a constitutive promoter or one of a number of drought, cold or salt inducible promoters.

¹ The term 'line' is used to denote plants derived from a single plant containing a specific genetic modification made by one 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/raf-3/\\$FILE/raffinal3.pdf](http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/raf-3/$FILE/raffinal3.pdf)>

All of the GM wheat and barley lines contain an antibiotic resistance gene, *hpt*. The gene provides resistance to the antibiotic hygromycin B and was used as a marker to select for successful genetic modifications during initial research and development work in the laboratory.

Short regulatory sequences that control expression of the genes will also be present in the GM wheat and barley lines. 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 GM wheat lines proposed for release were produced by transforming plants of the wheat cultivars Bobwhite, 'Drysdale' or 'Frame'. The GM barley lines were produced by transforming plants of the barley cultivars 'Golden Promise' or 'W14330'.

The purpose of the trial is to characterise growth and yield characteristics of the GM plants when grown under drought, rain fed or saline field conditions. The GM wheat and barley will not be used for human food or animal feed.

The University of Adelaide proposed a number of controls to restrict the spread and persistence of the GM wheat and barley 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 names and sequences of some of the genes and promoters, and associated references, 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.

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. This included 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 the University of Adelaide
- suitability of controls proposed by the University of Adelaide 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 lines to transfer the introduced genes to other wheat or barley crops 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 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 proposed 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 proposed 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 0.75 ha per growing season at three sites, two in the LGAs of Marion and Wakefield (SA) and the other in the LGA of Corrigin (WA), between June 2010 and December 2015
- 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 each trial site with a livestock-proof fence with lockable gate with rodent baiting inside the fence perimeter
- 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 until no volunteers are detected for a continuous 6 month period, and destroy any wheat and barley plants that may grow
- destroy all GM plant material not required for further analysis or future trials
- transport material from the GMOs in accordance with 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 as part of this release.

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.

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>.

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 of characteristics indicative of weediness, including measurement of altered reproductive capacity and competitiveness, and information relating to cross tolerance to other abiotic stressors
- 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 the University of Adelaide was suitable to hold a DIR licence under the requirements of section 58 of the Act. The Regulator is satisfied that the University of Adelaide 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 up to 1161 GM wheat lines and 1179 GM barley lines on a maximum total area of 0.75 ha per growing season over five years in the LGAs of Marion and Wakefield, South Australia, and Corrigin, Western Australia, 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.