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**TECHNICAL SUMMARY OF THE RISK ASSESSMENT AND RISK
MANAGEMENT PLAN
FOR
APPLICATION NO. DIR 077/2007
FROM
THE UNIVERSITY OF ADELAIDE**

Introduction

The Acting Gene Technology Regulator (the Regulator) has made a decision to issue a licence (DIR 077/2007) to The University of Adelaide for dealings involving the intentional release of genetically modified (GM) wheat and barley lines into the Australian 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 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 public¹.

The application

The University of Adelaide applied for a licence for dealings involving the intentional release of up to 30 lines² of wheat (*Triticum aestivum* L.) and barley (*Hordeum vulgare* L.) on a limited scale and under controlled conditions. The GM wheat and barley lines have been genetically modified for increased abiotic stress tolerance or dietary fibre. The trial is authorised to take place at one site in the local government area of Marion, South Australia on a maximum total area of up to 400 m² over one season between June 2008 and June 2009.

The GM wheat and barley lines contain one of four genes derived from either wheat or barley which encode proteins that are expected to enhance their tolerance to different abiotic stressors.

Up to four of the GM wheat lines and up to four of the GM barley lines contain one of two drought responsive transcription factors (*TaDREB2* and *TaDREB3*) derived from wheat. These genes have been introduced into both wheat (cv. Bob White) and barley (cv. Golden Promise). GM plants from these lines are expected to have enhanced drought tolerance.

¹ 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/ir/process.htm>>), and in the Regulator's *Risk Analysis Framework* (OGTR 2007) at <<http://www.ogtr.gov.au/pubform/riskassessments.htm>>.

² The term 'line' is used to denote plants derived from a single plant containing a specific genetic modification made by one transformation event.

Up to three of the GM barley lines contain a boron tolerance gene (*Bot1*) derived from barley that has been introduced into barley (cv. Flagship). Plants from these lines are expected to display enhanced soil boron tolerance.

Up to four of the GM barley lines contain an abiotic stress tolerance transcription factor derived from wheat that has been introduced into barley (cv. Golden Promise), which is subject to a commercial confidential information declaration (see below). Plants from these lines are expected to display enhanced tolerance to abiotic stressors.

Up to fifteen of the GM barley lines contain one of three cellulose synthase-like F genes (*HvCslF4*, *HvCslF6* and *HvCslF8*) derived from barley that have been introduced into barley (cv. Golden Promise). In glass house trials, plants from these lines displayed increased levels of beta glucan³ in the leaves and grain.

The GM wheat and barley lines also contain an antibiotic resistance marker gene, *hpt*, from the bacterium, *Escherichia coli*. The *hpt* gene encodes hygromycin phosphotransferase. Additionally, the three GM barley lines containing the *Bot1* gene also contain the selective marker gene, *SacB*, from the bacterium *Bacillus amyloliquefaciens* which encodes an enzyme (levansucrase) involved in sucrose metabolism. These genes were used as selective markers during the initial development of the GM plants in the laboratory.

The purpose of the trial is to conduct proof of concept research involving experiments with the GM wheat and barley lines to assess the agronomic performance of the lines under field conditions, and to obtain tissue samples for subsequent analysis of characteristics such as gene and protein expression levels, and metabolite profiles. Some seed will be saved for possible future trials of promising lines, subject to further approvals. 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 dissemination or persistence of the GM wheat and barley lines and their genetic material into the environment. These controls were considered during the evaluation of the application.

Confidential Commercial Information

Some details, including the name of an introduced gene expected to enhance abiotic stress tolerance, the precise function of the gene product and its application, 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 contained in the application, relevant previous approvals, 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.

Reference documents on the parent organisms, '*The Biology of Triticum aestivum L. (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. These documents are available from the OGTR or from the website <<http://www.ogtr.gov.au>>.

³ Beta glucan is a plant polysaccharide (carbohydrate) which forms part of the soluble fibre in cereal grains.

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 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 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 principle reasons for this include:

- ♦ limits on the size and duration of the release proposed by The University of Adelaide
- ♦ suitability of controls proposed by The University of Adelaide to restrict the dissemination or persistence of the GM wheat and barley plants and their genetic material
- ♦ limited capacity of the GM wheat and barley lines to spread and persist outside the areas proposed for release
- ♦ limited ability and opportunity for the GM wheat and barley lines to transfer the introduced genes to commercial wheat and barley crops or other sexually related species
- ♦ none of the GM plant materials or products will be used in human food or animal feed
- ♦ widespread presence of the same or similar proteins encoded by, and end products produced as a result of the activity of, the introduced genes 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 and barley lines into the environment are considered to be **negligible**. Hence the Acting Regulator considers that the dealings involved in this proposed release **do not pose a significant risk** to the health and safety of people or to the environment⁴.

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

⁴ As none of the proposed dealings were considered to pose a significant risk to people or the environment, section 52(2)(d)(ii) of the *Gene Technology Act 2000* mandates a minimum period of 30 days for consultation on the RARMP. However, the Regulator allowed up to 6 weeks for the receipt of submissions from prescribed experts, agencies and authorities and the public.

characterised in the risk assessment are considered to give rise to an identified risk that requires further assessment, the level of risk is estimated as **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, a range of measures have been imposed to limit the release to the size, location and duration requested by the applicant, as these were an important part of 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 at one site of up to 400 m² in the local government area of Marion, South Australia, between June 2008 and June 2009
- ◆ establish a 10 m monitoring zone around the trial site that is free of any related species and maintained in a manner that does not attract or harbour rodents
- ◆ maintain an isolation zone of at least 200 m around each trial site free of any sexually compatible species
- ◆ enclose the trial site within a 1 m high fence with lockable gates and placing rodent baits within the fenced area
- ◆ locate the trial site at least 50 m away from natural waterways
- ◆ harvest the GM wheat and barley plant material by hand and separately from other crops
- ◆ not permit any materials from the release to be used in human food or animal feed
- ◆ destroy all plant materials not required for further analysis
- ◆ clean all equipment, including clothing, used on the site
- ◆ after harvest, apply measures to promote germination of any wheat and/or barley seeds that may be present in the soil
- ◆ monitor the site for at least 24 months and destroy any wheat and/or barley 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, July 2007; Policy on transport and supply of GMOs, July 2005*). Licence conditions based on these guidelines and policies have also been proposed 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 Standard 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)⁵.

FSANZ is responsible for human food safety assessment, including GM food. As the trial involves proof of concept research, the applicant does not intend any material from the GM wheat and barley lines proposed for release to be used in human food. Accordingly, the applicant has not applied to FSANZ to evaluate any of the GM wheat and barley lines. FSANZ approval would need to be obtained before they could be used in 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 any of these GM wheat and barley lines that may be selected for further development or to justify a reduction in containment conditions. This would include:

- ◆ characterisation of the introduced genetic material in the plants, including gene copy number and genotypic stability, and additional information on the 50 kb insert present in some of the GM barley lines;
- ◆ additional data on the potential toxicity of plant materials from the GM wheat and barley lines;
- ◆ additional data on the allergenicity of proteins encoded by the introduced genes for enhanced tolerance to abiotic stresses or increased levels of beta glucan; and
- ◆ characteristics indicative of weediness including measurement of altered reproductive capacity; tolerance to environmental stresses; and disease susceptibility.

Suitability of the applicant

The Regulator determined, at the commencement of the assessment process for this application, that The University of Adelaide is suitable to hold a DIR licence under the requirements of section 58 of the Act. The Acting Regulator is satisfied that The University of Adelaide remains suitable as no relevant convictions have been recorded, no licences or permits have been cancelled or suspended under OGTR legislation relating to the health and safety of people or the environment, and the organisation has confirmed its ability to comply with the licence conditions.

Conclusions of the RARMP

The risk assessment concludes that this limited and controlled release of up to 30 GM wheat and barley lines on a total area of up to 400 m² over one season in the South Australian local government area of Marion poses **negligible** risks to the health and safety of people or the environment as a result of gene technology.

⁵ 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/pubform/riskassessments.htm>>.

The risk management plan concludes 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 requested by the applicant as these were important considerations in establishing the context for assessing the risks.