



5 June 2009

## **TECHNICAL SUMMARY OF THE RISK ASSESSMENT AND RISK MANAGEMENT PLAN**

FOR

**APPLICATION NO. DIR 093**

FROM

**CSIRO**

### ***Introduction***

The Gene Technology Regulator (the Regulator) has made a decision to issue a licence in respect of licence application DIR 093 from the Commonwealth Scientific and Industrial Research Organisation (CSIRO). The licence authorises dealings involving the limited and controlled release of three lines of genetically modified (GM) wheat and one line of GM barley with altered grain starch 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 three lines<sup>2</sup> of wheat (*Triticum aestivum* L.) and one line of barley (*Hordeum vulgare* L.) which have been genetically modified for altered grain starch composition on a limited scale and under controlled conditions. The trial is will to take place at one site in the Australian Capital Territory (ACT), on a maximum area of 1 hectare per year between July 2009 and June 2012.

The purpose of the trial is to evaluate grain properties of the GM wheat and barley lines grown under field conditions. This would involve generating sufficient grain to make flour for laboratory evaluation of how the flour performs in foods, and to feed to rats and pigs in

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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>>.

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

laboratory experiments to determine whether altered grain properties change the nutritional value of the GM wheat and barley. Products made from GM wheat may also be consumed by a limited number of people as part of a carefully controlled nutritional study.

The GM wheat and barley lines contain a construct with partial sequences of genes involved in starch biosynthesis. The gene construct containing the partial gene sequences is designed to suppress expression of specific genes through a mechanism known as RNA interference (RNAi). Expression of the RNAi construct in the GM lines leads to altered starch composition by suppression of the starch enzyme (SE) I gene in the wheat lines and suppression of the SE I and SE II genes in the barley line. Transcription of the partial gene sequences is regulated by a grain specific promoter derived from wheat. The GM wheat lines also contain the *nptII* gene which provides resistance to antibiotics such as kanamycin. The GM barley line contains the *hpt* gene which provides resistance to the antibiotic hygromycin B.

Evaluation of glasshouse grown GM wheat and barley lines has shown altered grain starch composition as a result of the genetic modification. This results in grains with increased resistant starch content which in turn contributes to the total dietary fibre intake. These changes may contribute to enhanced nutritional properties and improve digestive bowel health.

Short regulatory sequences that control expression of the genes are also present in the GM wheat and barley. 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 are not in themselves capable of causing disease.

CSIRO proposed a number of controls to restrict the dissemination 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 of genes expected to alter grain starch composition, the specific phenotypic changes occurring when they are down-regulated and its application, 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).

The reference documents, *The Biology of Triticum aestivum* L. em Thell (Bread Wheat) and *The Biology of Hordeum vulgare* L. (Barley), were produced by the OGTR to inform the risk

assessment process for licence applications involving GM wheat and/or barley plants. The documents are 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. The risk assessment considers what harm might arise from the genetic modification, how it might occur, how it compares to the non-GM parent organism and 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 construct 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 and from other organisms and the 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 and barley plants and their genetic material
- limited ability and opportunity for the GM wheat and barley lines to transfer the introduced RNAi constructs to commercial wheat and/or barley or other sexually related species outside the site
- widespread presence of the same partial gene sequences contained within the RNAi constructs in the environment and lack of known toxicity or evidence of harm from the components they impact on.
- none of the GM plant materials or products will be used for general consumption in human food or animal feed.

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 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<sup>3</sup>.

## ***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

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<sup>3</sup> As none of the proposed dealings are 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 has 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 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 at least 50 m away from natural waterways
- enclose the trial site with a 1.8 m high livestock-proof fence with lockable gates
- establish a 10 m monitoring zone around the trial site that is free of any related species and is maintained in a manner that does not attract or harbour mice, and conduct mice 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 and barley lines approved for release by the Regulator
- separate the GM wheat and barely trial from any other GM wheat or barley trial by at least 4 m
- harvest the GM wheat and barley plant material separately from other crops
- apply measures to promote germination of any wheat or barley 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 and barely plants that may grow until no volunteers are detected for a continuous 6 month period
- harvesting of the GM wheat and/or barley may only be undertaken by a small hand held mechanical single row harvester or by hand harvesting
- cleaning of the harvester must occur between harvesting of different GMOs
- clean the sites, buffer zones and equipment used on the sites following harvest
- contain, transport and store material from the GMOs in accordance with Regulator's guidelines
- nutritional studies involving human volunteers may not commence until endorsed a human research ethics committee
- destroy all GM plant material not required for further analysis or future trials
- not allowing the GM plant materials or products to be used for human food or animal feed, with the exception of the nutritional studies from which no material will enter the commercial human or animal food supply.

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 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)<sup>4</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 and barley 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 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 the GM wheat and/or GM barley 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 and barley lines
- additional data in relation to the specificity of the endosperm specific promoter
- additional data on compositional analyses including any potential changes to anti-nutrient levels
- weediness of the GM wheat and barley under Australian field conditions, including invasiveness, enhanced reproductive capacities and enhanced seed survival
- additional data on gene transfer to non-GM wheat and barley.

### ***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, no licence 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 three GM wheat lines and one GM barley line on a maximum total area of 1 ha over 3 years in the

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<sup>4</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>>.

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 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