Australian Government
Department of Health and Ageing
Office of the Gene Technology Regulator

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TECHNICAL SUMMARY OF THE RISK ASSESSMENT AND RISK MANAGEMENT PLAN FOR APPLICATION NO. DIR 111 FROM CSIRO

Introduction

The Gene Technology Regulator (the Regulator) has made a decision to issue a licence in respect of application DIR 111 from the Commonwealth Scientific and Industrial Research Organisation (CSIRO). The licence authorises dealings involving the limited and controlled release 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 Gene Technology Regulator (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 public[1].

The application

CSIRO has applied for a licence for dealings involving the intentional release of GM wheat and barley into the environment on a limited scale and under controlled conditions. The GM wheat and barley lines[2] have been genetically modified for altered grain composition, nutrient utilisation efficiency, disease resistance or stress tolerance. The field trial is authorised to take place at one site in the Australian Capital Territory (ACT), on a maximum area of 2.3 ha per year between May 2012 and June 2017.

The purpose of the trial is to:

- evaluate the agronomic performance of the GMOs under conditions of biotic (exposure to fungal disease) and abiotic (drought/heat) stress

[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 (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>.

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

- analyse any changes in grain composition, nutritional characteristics, dough making properties and end product quality
- collect GM material and seeds for subsequent trials.

Flour derived from the grain of a few GM wheat and barley lines with altered grain composition may be used for a range of carefully controlled, small scale animal nutritional trials, and the same GM wheat lines may be used in nutritional trials with human volunteers. The GM wheat and barley are not permitted to enter the commercial human food or animal feed supply chains.

The applicant proposed to release a maximum of 292 GM wheat and 41 GM barley. Based on similarities in the introduced genes and modified traits, the GMOs can be classified into six groups belonging to two broad categories:

- Category 1 consists of 50 wheat lines and one barley line genetically modified for altered grain composition using four partial gene sequences derived from wheat (Groups 1 and 3) and two genes from barley (Group 5)
- Category 2 consists of 242 wheat lines and 40 barley lines genetically modified for improved agronomic performance in drought/heat-prone environments (Groups 2 and 4) and enhanced disease resistance (Group 6) using a total of 28 genes derived from wheat or barley. Among these, 26 genes are expected to enhance carbon assimilation, water use efficiency and photosynthesis (Group 4), one gene is expected to enhance nutrient use efficiency (Group 2) and one gene is responsible for enhanced rust resistance (Group 6).

In addition, most of the GM wheat and barley lines also contain one of three selectable marker genes: *bar*, *hpt* and *nptII*. The herbicide resistance gene *bar*, derived from the bacterium *Streptomyces hygroscopicus*, encodes the enzyme phosphinothricin acetyl transferase which provides resistance to herbicides containing glufosinate ammonium. The antibiotic resistance selectable marker genes *hpt* and *nptII*, derived from the common gut bacterium *E. coli*, encode the enzymes hygromycin phosphotransferase and neomycin phosphotransferase type II, respectively; the former confers resistance to hygromycin and the latter to neomycin and related antibiotics. These genes were used in the laboratory to select transformed GM plants during early stages of development.

The expression of the introduced genes in the GM wheat and barley lines is under the control of short regulatory sequences. These are derived from: the plants wheat, barley, maize and rice; the soil bacterium *Agrobacterium tumefaciens*; and the plant virus cauliflower mosaic virus (CaMV).

A number of the GM wheat and barley lines proposed for release have previously been approved by the Regulator for field trial under other licences (DIRs 092, 093, 094, 099 and 100). The risk assessments conducted for those applications also included consideration of all the genes and partial genes that are the subject of the current application, with the exception of some of those for enhanced fibre content (Group 5) and rust resistance (Group 6).

CSIRO 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 were considered during the evaluation of the application.

Confidential Commercial Information

Some details, including the identities of some of the genes and sequences, and associated references have been declared Confidential Commercial Information (CCI) under section 185

of the Act. The confidential information is made available to the prescribed experts and agencies that are consulted on the RARMP for this application.

Risk assessment

The risk assessment takes into account information in the application (including proposed containment measures), relevant previous approvals and current scientific/technical knowledge.

Two 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 those that warrant detailed characterisation are determined. This process is described as risk identification.

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.

Seven 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 lines; 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.

The characterisation of the seven risk scenarios in relation to both the seriousness and likelihood of harm, in the context of the control measures proposed by the applicant and considering both the short and long term, did not identify any risks that could be greater than negligible. Therefore they did not require 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 and barley plants and their genetic material
- limited ability and opportunity for the GM wheat and barley plants 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 enter commercial human food or animal feed supply chains
- Other than the selectable marker genes, which have been extensively studied and not considered to pose risks to people or the environment, all of the introduced genes and partial gene sequences are derived from wheat and barley and are widespread in the environment with no 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.

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 seven 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 up to 2.3 ha per year at one site in the ACT, between May 2012 and June 2017
- locate the trial site at least 50 m away from natural waterways
- enclose the trial site with a fence capable of excluding livestock, with lockable gates
- establish a 2 m buffer zone and a 10 m monitoring zone around each location, maintained in a manner that does not attract or harbour rodents
- maintain at least 200 m distance between the GMOs and other wheat or barley crops, and destroy other sexually compatible plants found within this area
- harvest the GM wheat and barley plant material separately from other crops
- clean the site, buffer zones and equipment used on the site following harvest
- apply measures to promote germination of any wheat or barley seeds that may be present in the soil after harvest, including irrigation and tillage
- monitor the site for at least 24 months after harvest, and destroy any wheat and barley plants that may grow, until no volunteers are detected for a continuous 6 month period
- transport and store material from the GMO in accordance with Regulator's guidelines
- not commence nutritional studies involving animals or human volunteers until endorsed by an Animal Ethics Committee or a Human Research Ethics Committee, respectively
- not allow the GM plant materials or products to be used for human food or animal feed, with the exception of the nutritional studies
- destroy all GM plant material not required for further analysis or future trials.

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. The Regulator is responsible for assessing risks to the health and safety of people and the environment associated with the use of gene technology. However, dealings conducted under a licence issued by the Regulator may also be subject to regulation by other Australian government agencies that regulate GMOs or GM products, including Food Standards Australia New Zealand (FSANZ), Australian Pesticides and Veterinary Medicines Authority, Therapeutic

Goods Administration, National Industrial Chemicals Notification and Assessment Scheme and Australian Quarantine Inspection Service[3].

APVMA has regulatory responsibility for the supply of agricultural chemicals, including herbicides and insecticidal products, in Australia. The application of these herbicides is subject to regulation by the APVMA. While some GM wheat lines have 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 and food labelling, including GM food. The applicant does not intend to commercially use any material from the GM wheat and barley lines in human food, accordingly an application to FSANZ has not been submitted. FSANZ approval would need to be obtained before any material from the GM wheat and barley lines could be sold as food.

In addition, dealings authorised by the Regulator may be subject to the operation of State legislation declaring areas to be GM, GM free, or both, for marketing purposes.

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 toxicity and allergenicity of plant materials from the GM wheat and barley lines
- additional phenotypic characterisation of the GM wheat and barley lines, particularly with respect to traits that may contribute to weediness, including tolerance to environmental stresses and disease susceptibility
- additional molecular and biochemical characterisation of the GM wheat and barley lines.

Suitability of the applicant

The Regulator has assessed the suitability of CSIRO to hold a DIR licence as required by the Act. CSIRO is considered suitable as the Regulator is satisfied that no relevant convictions have been recorded, no licences or permits have been cancelled or suspended under laws relating to the health and safety of people or the environment, and the organisation has the capacity to meet the conditions of the licence.

Conclusions of the RARMP

The risk assessment concluded that this limited and controlled release of up to 292 GM wheat and 41 GM barley lines on a maximum total area of 2.3 ha per year over five years in the 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, 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

[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>.

proposed by the applicant as these were important considerations in establishing the context for assessing the risks.