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

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EXECUTIVE SUMMARY OF THE RISK ASSESSMENT AND RISK MANAGEMENT PLAN FOR APPLICATION NO. DIR 112 FROM CSIRO

Introduction

The Gene Technology Regulator (the Regulator) has made a decision to issue a licence in respect of licence application (DIR 112) 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 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 up to 118 lines of GM wheat and 40 lines of GM barley on a limited scale and under controlled conditions. Of the wheat lines, 23 have been genetically modified for altered grain composition, while the remainder, and all the barley lines, have been genetically modified for enhanced nutrient (nitrogen) utilisation efficiency. The trial is authorised to take place at a site in the New Genes for New Environments (NGNE) facility, near Merredin, Western Australia (WA), between May 2012 and June 2015. This facility is operated by the Department of Agriculture and Food, Western Australia (DAFWA).

Some of the GM wheat lines contain part of a gene derived from wheat, which is expected to suppress the function of the corresponding endogenous gene in the GM plants, resulting in

[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>.

altered starch composition in grains. The remainder of the GM wheat lines, and all of the GM barley lines, contain a gene from barley that is expected to enhance nitrogen utilisation efficiency. In addition, most of the GM wheat and barley lines contain one of two selectable marker genes, derived from a common gut bacterium. These genes were used to select genetically modified plant cells and plants during initial development of the GM plants in the laboratory. Some of the GM wheat and barley lines contain no selectable marker gene.

The primary purpose of the three year field trial is to assess whether the respective genetic modifications result in increased biomass and yield of the GM plants with respect to unmodified plants. Further, some grain will be retained each year for replicated field trials in years two and three. Finally, the trial will provide material to assess the impact of the respective genetic modifications on grain protein composition, dough making properties and end product quality.

A number of the GM wheat and barley lines authorised for release have previously been approved by the Regulator for field trial under other licences. The risk assessments conducted for those applications included consideration of all the genes and partial gene sequences that are the subject of this licence.

Risk assessment

The risk assessment took into account information in the application (including proposed containment measures), relevant previous approvals and current scientific/technical knowledge. Advice relating to risks to human health and safety and the environment provided in submissions received during consultation on the RARMP was also considered. No new risks to people or the environment were identified from the advice received on the consultation RARMP.

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.

Six 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 GMOs. 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 six 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 warrant further detailed assessment.

Risks 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 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 licence conditions.

As none of the six 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, location and duration requested by the applicant, as these were important considerations in establishing the context for assessing the risks.

The licence conditions require CSIRO to limit the release to a total area of 1.0 ha per year at one site between May 2012 and June 2015, inclusive. The control measures include containment provisions at the trial site; preventing the use of GM plant materials in human food or animal feed; destroying GM plant materials not required for further studies; transporting GM plant materials in accordance with the Regulator's transportation guidelines or other specific condition; and conducting post-harvest monitoring at the trial site to ensure all GMOs are destroyed.

Conclusions of the consultation RARMP

The risk assessment concluded that this limited and controlled release of up to 118 GM wheat lines and 40 GM barley lines on a maximum total area of 1 ha per year over three growing seasons in the shire Merredin (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, location 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.