



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

3 December 2008

**EXECUTIVE SUMMARY OF THE RISK ASSESSMENT AND RISK MANAGEMENT PLAN**  
**FOR**  
**APPLICATION No. DIR 086/2008**  
**FROM**  
**CSIRO**

***Introduction***

The Acting Gene Technology Regulator (the Acting Regulator) has made a decision to issue a licence with respect of licence application DIR 086/2008 from the Commonwealth Scientific and Industrial Research Organisation (CSIRO). The licence authorises dealings involving the limited and controlled release of up to eleven maize (corn) lines into the environment. The GM maize lines have been genetically modified to investigate gene function.

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 Acting 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 eleven GM maize (corn) lines on a limited scale and under controlled conditions. The maize lines have been genetically modified to investigate gene function. The field trial may take place on one site of up to 750 m<sup>2</sup> at a CSIRO research facility in the Australian Capital Territory (ACT). The same site may be re-planted with GM maize for up to five growing seasons from 2008-13<sup>2</sup>.

No GM plant material from the trial can be used in human food, animal feed or the manufacture of any maize product.

The GM maize lines contain a modified version of a maize genetic element known as a transposable genetic element. Under certain conditions, this modified transposable element can move within the maize genome. If the introduced transposable element moves into a

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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 (Free call 1800 181 030 or at <<http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/process-1>>), 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 notification indicated that the release would occur over three growing seasons. The applicant has clarified that their intention is to release the GMOs over five growing seasons.

region controlling the expression of a particular gene, that gene may be over-expressed. The over-expression of the gene is used as a tag or marker, which helps to identify that gene for further investigation of its function. The offspring of the GM maize lines would be assessed for traits not observed in the parent plants.

The GM maize lines also contain an antibiotic resistance selectable marker gene and a reporter gene, both derived from a common gut bacterium and a herbicide tolerance selectable marker gene derived from a common soil bacterium. These genes were used as selective markers to identify transformed plants during initial development of GM plants in the laboratory.

They also contain additional short regulatory sequences that control expression of the introduced and maize endogenous genes.

The purpose of the trial is to conduct basic research involving experiments to investigate gene function in maize. Seed will be collected for further studies, including possible future releases (subject to additional assessments and approvals).

CSIRO proposed a number of controls to restrict the dissemination or persistence of the GM maize lines and the introduced genetic materials into the environment. These controls have been considered during the evaluation of the application.

### ***Risk assessment***

The risk assessment took into account information in the application (including proposed containment measures), 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.

A **hazard** identification process was used to determine potential pathways that might lead to harm to people or the environment as a result of gene technology.

Seven events were considered whereby the proposed dealings might give rise to harm to people or the environment. This included consideration of whether, or not, presence and/or expression of the introduced genetic elements could result in adverse outcomes such as allergenicity in people and/or toxicity in people or other organisms or alter characteristics that may impact on the spread and persistence of the GM plants. 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 advance in the risk assessment process.

The characterisation of the seven 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.

Therefore, any risks of harm to the health and safety of people, or the environment, from the proposed release of the GM maize lines into the environment are considered to be **negligible**. Hence, the Acting 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***

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 seven events characterised in the risk assessment are considered to give rise to an identified risk that requires further assessment, the level of risk from the proposed dealings 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, a range of measures 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.

The licence conditions require CSIRO to **limit** the release to one site of up to 750 m<sup>2</sup> at a CSIRO research facility in the ACT. The **control** measures to restrict the spread and persistence of the GMOs include preventing the use of GM plant materials in human food, animal feed or in the manufacture of any maize product; removing the male flowers from the GM maize plants to prevent the production and shed of pollen; growing the GMOs in an area that is enclosed above and on all sides in bird-proof mesh; destroying GM plant materials not needed for further analysis; transporting GM plant materials in accordance with OGTR transportation guidelines; and conducting monitoring for volunteer plants at the trial site to ensure all GMOs are destroyed.

## ***Conclusions of the RARMP***

The risk assessment concluded that this limited and controlled release of the GM maize lines on one site at a research facility in the ACT on an area of up to 750 m<sup>2</sup> per year over a five year period between 2008 and 2013 poses **negligible** risks to the health and safety of people or the environment as a result of gene technology<sup>3</sup>.

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 materials 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.

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<sup>3</sup> The licence is available from the OGTR website via the link to DIR 086/2008 (<http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/dir086-2008>).