



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

3 December 2008

**TECHNICAL 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 in 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 Gene Technology Regulator (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 up to eleven maize lines genetically modified to investigate gene function on a limited scale and under controlled conditions. The trial is authorised to take place at one site at a research facility in the Australian Capital Territory (ACT) on a total area of 750 m<sup>2</sup> each year (in the eastern half of an area that is enclosed above and on all sides with wire mesh, referred to as the 'birdcage'). The release may occur between December 2008 and May 2013<sup>2</sup>. The applicant may replant the same site with GM maize in each of the up to five growing seasons.

The GM maize lines contain a modified version of a genetic element known as a transposable genetic element. In the presence of the enzyme transposase, this modified transposable element can move within the maize genome. If the introduced transposable element moves into a region controlling the expression of a particular gene, that gene may be over-expressed.

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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.

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.

Additionally, the GM maize lines contain the antibiotic resistance selectable marker gene, *hph*, the herbicide tolerance selectable marker gene, *bar*, and the reporter gene *uidA*. The *hph* gene encodes an enzyme, hygromycin B phosphotransferase. A catalase-1 intron from *Ricinus communis* was inserted into the original *hph* gene to prevent expression of the gene in *Agrobacterium*. The *hph* gene was originally derived from the common gut bacterium *Escherichia coli* and confers hygromycin resistance on the GM plant. The *bar* gene, which encodes the phosphinothricin acetyltransferase (PAT) protein, is from the common soil bacterium *Streptomyces hygroscopicus* and confers tolerance to the L-isomer of phosphinothricin (PPT, glufosinate ammonium), the active ingredient in various herbicides. The *uidA* gene encodes an enzyme,  $\beta$ -glucuronidase (GUS), which enables visual identification of plant tissues in which this gene is expressed. These marker genes were used in the laboratory to select modified plant tissues during the initial development of the plants from which the GM lines are derived.

The purpose of the trial is to conduct basic research involving gene function in maize. Seed may be collected for further studies, including possible future releases (subject to additional assessments and approvals). The GM maize is not permitted to be used for human food, animal feed or in the manufacture of any maize product.

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 considered information contained 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 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 on the application (included in Appendix C of the RARMP). No new risks to people or the environment were identified from the advice received on the consultation RARMP.

A reference document on the parent organism, *The Biology of Zea mays L. ssp mays (maize or corn)*, was produced to inform the risk assessment process for licence applications involving GM maize plants. The document is available from the OGTR or from the website <<http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/riskassessments-1>>.

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.

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 represent an identified risk and do not advance any further 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. The principle 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 or persistence of the GM maize plants and their genetic material
- none of the GM plant materials or products would be used in human food, animal feed or in the manufacture of any maize product
- widespread presence of the same or similar genetic elements and encoded proteins 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 maize 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 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 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, 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 Acting Regulator has imposed a number of licence conditions including requirements to:

- conduct the release on a total area of up to 750 m<sup>2</sup> per year at one site in the ACT, between December 2008 and May 2013
- locate the trial site at least 50 m away from natural waterways
- surround the birdcage with a 10 m monitoring zone
- be able to clearly identify the non-GM pollen parent plants
- detassel or destroy all GM maize plants before mature pollen is shed

- harvest seed maize from the release separately from any other maize
- not permit any materials from the release to be used in human food, animal feed or manufacture of any maize product
- destroy all plant materials not required for further analysis
- clean all equipment used on site before using it for any other purpose
- following harvest, clean the site and any other areas associated with the release
- after harvest, apply measures to promote germination of any maize seeds that may be present in the soil
- monitor the site regularly during the release and after the final harvest for at least 12 months and destroy any volunteer plants that may grow before flowering, until no volunteer plants 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; 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. 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>3</sup>. The primary transformant GM maize lines that were used to produce the GMOs proposed for release were produced overseas and have been approved by AQIS for import.

FSANZ is responsible for human food safety assessment, including GM food. As the trial involves basic research, the applicant does not intend any material from the GM maize lines proposed for release to be used in human food. Accordingly, the applicant has not applied to FSANZ to evaluate any of the GM maize lines. FSANZ approval would need to be obtained before they could be sold as 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 maize lines that may be selected for further development, 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 maize lines

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<sup>3</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>>.

- characteristics indicative of weediness including measurement of altered reproductive capacity; altered germination; altered flowering time; tolerance to environmental stress; and disease susceptibility
- additional data on dispersal of maize seeds by animals.

### ***Suitability of the applicant***

The Acting 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 Acting Regulator is satisfied that CSIRO remains suitable as no relevant convictions have been recorded, no licences or permits have been cancelled or suspended under Gene Technology legislation relating to the health and safety of people or the environment. The applicant did not raise any concerns regarding their ability to comply with the proposed licence conditions during the consultation period.

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

The risk assessment concluded that this proposed limited and controlled release of up to eleven GM maize lines on one site of the up to 750 m<sup>2</sup> at a CSIRO research facility in the Australian Capital Territory for up to five growing seasons from 2008-13 poses **negligible** risks to the health and safety of people or the environment as a result of gene technology<sup>4</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>4</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>).