



1 August 2008

**EXECUTIVE SUMMARY OF THE RISK ASSESSMENT AND RISK  
MANAGEMENT PLAN  
FOR  
APPLICATION NO. DIR 083/2007  
FROM  
CSIRO**

***Introduction***

The Acting Gene Technology Regulator (the Acting Regulator) has made a decision to issue a licence for dealings involving the limited and controlled release of up to 20 lines of cotton genetically modified for enhanced waterlogging tolerance into the environment in respect of application DIR 083/2007 from CSIRO.

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 up to 20 lines of genetically modified (GM) cotton on a limited scale and under controlled conditions. The cotton lines have been genetically modified for enhanced waterlogging tolerance. The trial would take place at one site in the local government area of Narrabri, NSW on a maximum total area of 0.3 hectares (0.1 hectare per growing season) between October 2008 and May 2011.

The GM cotton lines contain one or more of three introduced genes encoding proteins expected to enhance tolerance to waterlogging. Two of the introduced genes are from thale cress and the other from cotton. The introduced cotton gene has a different expression pattern from the native gene. All of the GM cotton lines contain one of the genes from thale cress. In addition, up to 10 lines also contain the cotton gene and up to 4 lines contain all three genes.

In addition, the GM cotton lines contain one or two antibiotic resistance selectable marker genes. Both genes are derived from a common gut bacterium and were used during the initial development of the GM plants in the laboratory.

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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* at <<http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/riskassessments-1>>.

The purpose of the trial is to conduct proof of concept research to assess the tolerance of the GM cotton plants to waterlogging stress under simulated conditions in the field. Cotton seed will be collected and retained for further analysis and possible future trials of lines that may be selected for further development, subject to further approval(s). The GM cotton will not be used for human food or animal feed.

CSIRO proposed a number of controls to restrict the dissemination or persistence of the GM cotton 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 takes into account information in the application (including proposed containment measures), relevant previous approvals, current scientific knowledge, advice received from a wide range of experts, agencies and authorities consulted on the RARMP and submissions from the public.

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.

Eight events were considered 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 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 plants; or produce unintended changes in their biochemistry or physiology. 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 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.

Therefore, any risks of harm to the health and safety of people, or the environment, from the proposed release of the GM cotton 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 eight 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 a total area of 0.3 ha, at one site between October 2008 and May 2011. The **control** measures to restrict the spread and persistence of the GMOs include 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 OGTR transportation guidelines; and conducting post-harvest monitoring at the trial site to ensure all GMOs are destroyed<sup>2</sup>.

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

The risk assessment concludes that this limited and controlled release of up to 20 GM cotton lines on a maximum total area of 0.3 ha (0.1 hectare per growing season) over three years in the NSW local government area of Narrabri poses **negligible** risks to the health and safety of people or the environment as a result of gene technology.

The risk management plan concludes 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 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.

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<sup>2</sup> The licence for DIR 083/2007 is available on the OGTR website <<http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/ir-1>> via the link to DIR 083/2007