



**EXECUTIVE SUMMARY OF THE RISK ASSESSMENT  
AND RISK MANAGEMENT PLAN**  
for  
**APPLICATION NO. DIR 067/2006**  
from **CSIRO**

**INTRODUCTION**

The Gene Technology Regulator (the Regulator) has made a decision to issue a licence for dealings involving the intentional release of genetically modified (GM) cotton lines which are tolerant to waterlogging, into the environment in respect of application DIR 067/2006 from the Commonwealth Scientific and Industrial Research Organisation (CSIRO).

The DIR 067/2006 licence permits the release of up to 30 GM cotton lines on a limited scale and under controlled conditions.

The *Gene Technology Act 2000* (the Act) and the *Gene Technology Regulations 2001* (the Regulations) govern the process undertaken by the Regulator before a decision is made on whether or not to issue a licence. The decision is based upon a Risk Assessment and Risk Management Plan (RARMP) prepared by the Regulator in accordance with the *Risk Analysis Framework* and in consultation with a wide range of experts, agencies and authorities and the public.

More information on the comprehensive assessment required for 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/>>.

**THE APPLICATION**

CSIRO applied for a licence to release up to 30 GM cotton lines with tolerance to waterlogging into the environment under limited and controlled conditions. The trial is to take place at one site in the shire of Narrabri, New South Wales (NSW) on a maximum total area of 0.1 ha during each of the three summer growing seasons of 2006/07, 2007/08 and 2008/09.

The GM cotton lines contain a new gene (*Ahb1*) derived from thale cress that encodes a protein (AHB1) expected to provide tolerance to waterlogging stress. A variant of the *Ahb1* gene also occurs naturally in cotton as well as a number of other plant species and the AHB1 protein is common in many food plants such as barley, maize, wheat, rice, soybean and tomato.

The GM cotton lines also contain a bacterial gene (*nptII*, conferring resistance to the antibiotics kanamycin or neomycin) that was used to select successfully modified plants during initial research and development work in the laboratory.

The purpose of the trial is to conduct early stage ('proof of concept') research to measure the expression levels of the introduced gene; to evaluate the tolerance of the GM cotton plants to waterlogging stress under simulated conditions; and to conduct a preliminary assessment of their agronomic performance in the field. Cotton seed will be collected for further studies and possible future releases (subject to additional applications). No products from the release will be used for human food, animal feed or for the production of fabrics and/or other cotton products.

CSIRO proposed a number of measures to limit the spread and persistence of the GMOs and the introduced genetic materials that were considered during the evaluation of the application.

## **RISK ASSESSMENT**

The hazard identification process considered the circumstances by which people or the environment may be exposed to the GMOs, GM plant materials, GM plant by-products, the introduced genes, or products of the introduced genes.

A hazard (source of potential harm) may be an event, substance or organism. A risk is identified when a hazard is considered to have some chance of causing harm. Those events that do not lead to an adverse outcome, or could not reasonably occur, do not advance in the risk assessment process.

Eighteen events were identified and assessed whereby the release of the GM cotton lines might give rise to harm to people or the environment.

These 18 events included consideration of whether 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. In addition, consideration was given to the opportunity for gene flow to other organisms and its effects.

None of the 18 events are considered to give rise to an identified risk that requires further assessment. The principle reasons comprise:

- small scale of the trial that is limited in both area and duration
- containment and disposal measures proposed by the applicant to limit the spread and persistence of the GM plants
- none of the GM plant materials will be used for human food, animal feed or for the production of fabrics and/or other cotton products
- widespread presence of the same or similar proteins encoded by the introduced genes in the environment and lack of known toxicity or allergenicity from these proteins
- limited capacity of the GM cotton lines to spread and persist in the area of the release
- limited ability and opportunity for the GM cotton lines to transfer the introduced genes to other sexually related species.

Therefore, any risks of harm to the health and safety of people, or the environment, from the release of the GM cotton lines into the environment is considered to be **negligible**.

## **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 18 events identified and characterised in the risk assessment are considered to give rise to an identified risk that requires further assessment, the level of risk 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. However, containment and disposal measures have been imposed to restrict the release to the location, size and duration to those requested by the applicant, as these were an important part of establishing the context for assessing the risks.

The licence conditions require the applicant to limit the duration of the release to three summer cotton growing seasons (2006/07, 2007/08 and 2008/09) on a maximum total area of 0.1 hectares per season; prevent the use of the GMOs, or materials from the GMOs for any other purposes; maintain physical isolation of the release site; and conduct post-harvest monitoring to ensure all GM plants are destroyed<sup>1</sup>.

## **CONCLUSIONS OF THE RARMP**

The risk assessment concludes that this limited and controlled release of up to 30 GM cotton lines with tolerance to waterlogging in the shire of Narrabri, NSW, poses **negligible** risks to the health and safety of people and the environment posed by or 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 contain the release to the location, size and duration requested by the applicant.

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<sup>1</sup> The licence for DIR 067/2006 is available on the OGTR website (<<http://www.ogtr.gov.au/gmorec/ir.htm#table>> via the link to DIR 067/2006).