



**EXECUTIVE SUMMARY OF THE RISK ASSESSMENT AND RISK  
MANAGEMENT PLAN  
FOR  
APPLICATION NO. DIR 087  
FROM  
BAYER CROPSCIENCE PTY LTD**

***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 cotton genetically modified for insect resistance and herbicide tolerance into the environment in respect of application DIR 087 from Bayer CropScience Pty Ltd (Bayer)

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***

Bayer applied for a licence for dealings involving the intentional release of genetically modified (GM) cotton on a limited scale and under controlled conditions. The cotton plants have been genetically modified for insect resistance and herbicide tolerance. The trial would take place at one site in the local government area of Narrabri, NSW on a maximum total area of 0.36 ha over the summer growing season 2008-2009.

The GM cotton contains three introduced genes encoding proteins expected to confer insect resistance and herbicide tolerance. All three genes have been isolated from bacteria.

The purpose of the trial is to conduct research to evaluate the agronomic performance of the GM cotton plants and to assess the efficacy of the insecticidal protein combination against cotton bollworm. Cotton seed will also be collected and used for further research and development (subject to additional approvals) The GM cotton will not be used for human food or animal feed.

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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>>.

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

### **Confidential Commercial Information**

Some details, including details of the GM cotton breeding program, expression levels of the three introduced genes, toxicity of the insecticidal proteins against target organisms, details of the plasmid vector and construct used for the *cry2Ae* transformation event and some details of the *cry2Ae* gene, have been declared Confidential Commercial Information (CCI) under section 185 of the Act. The confidential information was made available to the prescribed experts and agencies that were consulted on the RARMP for this 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 in the first instance 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 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 GMO and its 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 Bayer to **limit** the release to a total area of 0.36 ha at one site over the summer cotton growing season 2008-2009. The **control** measures to restrict the dissemination and persistence of the GMO 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 OGTR transportation guidelines; and conducting post-harvest monitoring 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 GM cotton on a maximum total area of 0.36 ha over one growing season 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 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 GMO and its 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.