



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

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 in respect of licence 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 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, authorities and the public¹.

The application

Bayer applied for a licence for dealings involving the intentional release of cotton (*Gossypium hirsutum* cv. Coker) that has been genetically modified for insect resistance and herbicide tolerance on a limited scale and under controlled conditions. The trial is authorised to 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 cotton growing season of 2008-2009.

The GM cotton (known as TwinLink[®]) contains three introduced genes encoding proteins expected to confer insect resistance and herbicide tolerance. These genes are *cry1Ab* and *cry2Ae* from the bacterium *Bacillus thuringiensis*, encoding Bt toxins that are active against lepidopteran insect pests, and the *bar* gene from the bacterium *Streptomyces hygroscopicus*, encoding the enzyme phosphinothricin acetyltransferase (PAT) which provides tolerance to herbicides containing glufosinate ammonium.

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 *Helicoverpa armigera* (cotton bollworm). Cotton seed will be collected and used for further

¹ 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>>.

research and development (subject to additional approvals). The GM cotton will not be used for human food or animal feed.

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 has been made available to the prescribed experts and agencies that have been consulted on the RARMP for this 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 Gossypium hirsutum L. and Gossypium barbadense L. (cotton)*, was produced to inform the risk assessment process for licence applications involving GM cotton plants. The document is available from the OGTR or from the website <<http://www.ogtr.gov.au>>.

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.

Eight events were identified 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 represent an identified risk and do not advance any further 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. The principle reasons for this include:

- limits on the size, location and duration of the release proposed by Bayer

- suitability of controls proposed by Bayer to restrict the dissemination or persistence of the GM cotton plants and their genetic material
- limited ability and opportunity for the GM cotton to transfer the introduced genes to commercial cotton crops or other sexually related species
- limited capacity of the GM cotton to spread and persist outside the areas proposed for release
- none of the GM plant materials or products will be used in human food or animal feed
- widespread presence of the same or similar proteins encoded by the introduced genes in the environment and lack of known toxicity to non-target organisms 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 cotton 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 eight events 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 in the risk management plan. However, conditions 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.

Licence conditions to manage this limited and controlled release

The Acting Regulator has imposed a number of licence conditions to limit and control the release, including requirements to:

- conduct the release on a total area of up to 0.36 ha at one site in the NSW local government area of Narrabri, over the summer growing season 2008-2009
- surround the release site with a 20 m pollen trap
- locate the trial site at least 50 m away from natural waterways
- harvest and gin seed cotton from the release separately from any other cotton crop
- not permit any materials from the release to be used in human food, or animal feed or for the production of fabrics and/or other cotton products
- destroy all plant materials not required for further analysis or future release
- following harvest, clean the site and equipment used on the site

- after harvest, apply measures to promote germination of any cotton seeds that may be present in the soil
- monitor the site for at least 12 months and destroy any cotton plants that may grow until no volunteers 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, July 2007*²; *Policy on transport and supply of GMOs, July 2005*³). Licence conditions based on these guidelines and policies have also been imposed to control possession, use or disposal of the GMO 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)⁴.

FSANZ is responsible for human food safety assessment, including GM food. As the trial involves early stage research, the applicant does not intend any material from the GM cotton proposed for release to be used in human food. Accordingly, the applicant has not applied to FSANZ to evaluate the GM cotton. FSANZ approval would need to be obtained before it could be used in human food in Australia.

APVMA has regulatory responsibility for the use of agricultural chemicals, including herbicides and insecticidal products, in Australia. The GM cotton proposed for release meets the definition of an agricultural chemical product under the *Agricultural and Veterinary Chemicals Code Act 1994*, due to its production of insecticidal substances, and therefore these plants are subject to regulation by the APVMA. Bayer would require a research permit from APVMA for the proposed release of the GM cotton containing the insecticidal genes. Although the GM cotton has also been modified to be tolerant to glufosinate ammonium, the applicant does not intend to apply this herbicide during the trial. If the applicant decided to apply glufosinate ammonium a research permit would be required.

AQIS is responsible for monitoring imports to prevent the introduction of exotic pests and diseases into the environment. An importer is required to notify AQIS if they are importing GMOs, or products known to be mixed with any amount of GM material. As the importation would constitute a dealing under the Act, the importer requires an authorisation under this Act for the import to lawfully proceed. Seeds from TwinLink[®] cotton have been imported by CSIRO under an AQIS seed import permit.

²Guidelines for the transport of GMOs

<<http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/transport-guide-1>>

³ Policy on transport and supply of GMOs

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

⁴ 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>>.

No other approvals are required.

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 the GM cotton, or to justify a reduction in containment conditions. This would include:

- characterisation of the genetic material inserted into the plants, including gene copy number and genotypic stability
- additional data on the potential toxicity of plant materials from the GM cotton, specifically in regard to the Cry2Ae protein alone and in combination with Cry1Ab
- additional data on the allergenicity of proteins encoded by the introduced genes for insect resistance, specifically that relating to Cry2Ae
- characteristics indicative of weediness including measurement of altered reproductive capacity, and disease and insect resistance.

Suitability of the applicant

The Acting Regulator determined, at the commencement of the assessment process for this application, that Bayer is suitable to hold a DIR licence under the requirement of section 58 of the Act. The Acting Regulator is satisfied that Bayer remains suitable as no relevant convictions have been recorded, no licences or permits have been cancelled or suspended under laws relating to the health and safety of people or the environment, and the organisation has confirmed its ability to comply with the licence conditions.

Conclusions of the RARMP

The risk assessment concludes that this proposed limited and controlled release of GM cotton plants 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 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.