



28 October 2008

**TECHNICAL SUMMARY OF THE RISK ASSESSMENT AND RISK
MANAGEMENT PLAN
FOR
APPLICATION NO. DIR 085/2008
FROM
CSIRO**

Introduction

The Acting Gene Technology Regulator (the Regulator) has made a decision to issue a licence (DIR 085/2008) to Commonwealth Scientific and Industrial Research Organisation (CSIRO) for a limited and controlled release of genetically modified (GM) cotton line into the Australian environment.

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 Regulator in accordance with the *Risk Analysis Framework* and finalised following consultation with a wide range of experts, agencies and authorities and the public¹.

The application

CSIRO applied for a licence for dealings involving the intentional release of one line² of cotton (*Gossypium hirsutum* cv. Coker 315) that has been genetically modified for altered fatty acid composition of the cottonseed oil. The intent in changing the fatty acid profile of the cottonseed oil, in the GM cotton line, is to increase the stability of the oil for food industry applications and improve the health effects of cottonseed oil. The trial is authorised to take place at one site in the local government area of Narrabri, New South Wales (NSW) on a maximum total area of 2 hectares between 2008 and 2009.

The GM cotton line contains a single copy of the introduced genetic construct comprising the partial sequence of three cotton genes: *palmitoyl-ACP thioesterase* (*ghFatB-1*), *microsomal $\Delta 12$ -desaturase* (*ghFAD2-1*) and *cyclopropane fatty acid synthase* (*ghCPA-FAS-2*). The introduced sequences were originally isolated from *G. hirsutum* and are intended to suppress the expression of the corresponding genes in the GM cotton line.

In addition, the GM cotton line contains the antibiotic resistance selectable marker gene, neomycin phosphotransferase type II (*nptII*). This gene, encoding for the enzyme neomycin

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/>>), and in the Regulator's *Risk Analysis Framework* (OGTR 2007) at <<http://www.ogtr.gov.au/pubform/riskassessments.htm>>.

² The term 'line' is used to denote plants derived from a single plant containing a specific genetic modification made by one transformation event.

phosphotransferase, was derived from *Escherichia coli*, and confers kanamycin or neomycin resistance on the GM plant. The *nptII* gene was used as a selective marker to identify transformed plants during initial development of GM plants in the laboratory.

The purpose of the trial is to conduct proof of concept research involving experiments with the GM cotton line to assess a range of agronomic characteristics of the GM cotton line, when grown under natural field conditions, including seed germination rate, fibre yield and quality, seed yield, oil content and fatty acid composition. 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 line and its genetic material into the environment. These controls were considered during the evaluation of the application.

Risk assessment

The risk assessment took into account information contained in the application, relevant previous approvals and 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 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.

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, 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 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 cotton plants and their genetic material
- ♦ limited capacity of the GM cotton line to spread and persist outside the area proposed for release

- ◆ limited ability and opportunity for the GM cotton line to transfer the introduced genes to commercial cotton crops or other sexually related species
- ◆ none of the GM plant materials or products will be used in human food or animal feed
- ◆ widespread presence of the antibiotic resistance gene and the protein encoded by it in the environment and lack of known toxicity or evidence of harm from either the gene or the encoded protein
- ◆ widespread presence of the end products produced as a result of the activity of the introduced partial gene sequences 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 cotton line 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, a range of measures have been imposed to limit the release to the size, location and duration requested by the applicant, as these were an important part of 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 2 hectares for one year at one site in the NSW local government area of Narrabri, between October 2008 and June 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
- ◆ following harvest, clean the site, monitoring zone 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; Policy on transport and supply of GMOs*). Licence conditions based on these guidelines and policies have also been proposed 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 that avoids duplication and enhances coordinated decision making. 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 Standards 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)³.

FSANZ is responsible for human food safety assessment, including GM food. As the trial involves proof of concept research, the applicant does not intend any material from the GM cotton line proposed for release to be used in human food. Accordingly, the applicant has not applied to FSANZ to evaluate the GM cotton line. FSANZ approval would need to be obtained before it could be used in 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 this GM cotton line or to justify a reduction in containment conditions. This would include:

- ◆ additional data on the potential toxicity of plant materials from the GM cotton line
- ◆ characteristics indicative of weediness including measurement of altered reproductive capacity, germination rates, degree of seed dormancy, tolerance to environmental stresses, and disease susceptibility.

Suitability of the applicant

The Regulator determined, at the commencement of the assessment process for this application, that CSIRO is suitable to hold a DIR licence under the requirements 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 OGTR legislation 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 limited and controlled release of one GM cotton line on a maximum total area of 2 hectares over one year in the New South Wales local

³ 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/> >.

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 release to the size, location and duration requested by the applicant as these were important considerations in establishing the context for assessing the risks.