



28 October 2008

**EXECUTIVE 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 for dealings involving the limited and controlled release of one cotton line modified for altered fatty acid composition of the cottonseed oil into the environment in respect of application DIR 085/2008 from the Commonwealth Scientific and Industrial Research Organisation (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 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 GM cotton line on a limited scale and under controlled conditions. The GM cotton line has been 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 proposed to take place at one site in the local government area of Narrabri, New South Wales on a maximum total area of 2 hectares between 2008 and 2009.

The GM cotton line contains a genetic construct comprising the partial sequences of three cotton genes involved in fatty acid synthesis. The genetic construct is intended to suppress the expression of the corresponding genes in the GM cotton line. The GM cotton line also contains an antibiotic resistance gene (*nptII*) which provides resistance to kanamycin.

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

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>>.

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 the introduced genetic materials in the environment that have been considered during the evaluation of the 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 to determine potential pathways that might lead to harm to people or the environment as a result of gene technology.

Seven events were considered whereby the proposed dealings might give rise to harm to people or the environment. Consideration was then given as to 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 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.

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 estimated 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 seven 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 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.

The licence conditions require CSIRO to **limit** the release to a total area of up to 2 hectares at one site between October 2008 and June 2009. The **control** measures 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 concludes that this proposed 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 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.