EXECUTIVE SUMMARY OF THE RISK ASSESSMENT AND RISK MANAGEMENT PLAN FOR APPLICATION NO. DIR 115 FROM THE COMMONWEALTH SCIENTIFIC AND INDUSTRIAL RESEARCH ORGANISATION

Introduction
The Gene Technology Regulator (the Regulator) has made a decision to issue a licence in respect of licence application (DIR 115) from the Commonwealth Scientific and Industrial Research Organisation (CSIRO). The licence authorises dealings involving the limited and controlled release of genetically modified (GM) cotton into the 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 Gene Technology Regulator (the Regulator) before making a decision whether or not to issue a licence to deal with a genetically modified organism (GMO).

The decision is based upon a Risk Assessment and Risk Management Plan (RARMP) prepared by the Regulator in accordance with requirements of the legislation. RARMPs apply the Risk Analysis Framework and are finalised following consultation with a wide range of experts, agencies and authorities, and the public.

The application
CSIRO has applied for a licence for dealings involving the intentional release of eight types of GM cotton into the environment on a limited scale and under controlled conditions. The GM cotton plants have been modified to enhance expression of up to three cotton genes that are involved in regulation of fibre development with the aim of increasing fibre yield.

The purpose of the trial is to evaluate the potential for increasing cotton fibre yield under field conditions. The trial will also generate information on genetic regulation of fibre development.

The trial is authorised to take place at one site per growing season in the local government area of Narrabri, New South Wales between August 2012 and August 2015. The maximum area of a site will be 0.5 ha.

The GM cotton will not be permitted to enter the human or animal food supply chains.

CSIRO proposed a number of controls to restrict the spread and persistence of the GM cotton plants and the introduced genetic materials in the environment that were 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 and current scientific/technical knowledge. Advice relating to risks to human health and safety and the environment provided in submissions received during consultation on the RARMP was also considered. No new risks to people or the environment were identified from the advice received on the consultation RARMP.

Initially, potential pathways that might lead to harm to people or the environment as a result of gene technology are postulated (risk scenarios), and those that warrant detailed characterisation are determined. This process is described as risk identification.

Four risk scenarios were postulated, including consideration of whether or not expression of the introduced genes could result in products that are toxic or allergenic to people or other organisms or alter characteristics that may impact on the spread and persistence of the GM cotton. The opportunity for gene flow to other organisms, and its effects if it were to occur, was also assessed.

A risk is only identified for further assessment when a risk scenario is considered to have some chance of causing harm. Pathways 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 four risk scenarios in relation to both the seriousness and likelihood of harm, in the context of the control measures proposed by the applicant and considering both the short and the long term, did not give rise to any identified risks that required further assessment.

Risks to the health and safety of people, or the environment, from the proposed release of the GM cotton plants into the environment are assessed to be negligible.

**Risk management plan**

Risk management is used to protect the health and safety of people and to protect the environment by controlling or mitigating risk. The risk management plan evaluates and treats identified risks, evaluates controls and limits proposed by the applicant, and considers general risk management measures. The risk management plan is given effect through the imposed licence conditions.

As none of the four risk scenarios characterised in the risk assessment give rise to an identified risk that requires further assessment, the level of risk from the proposed dealings is assessed 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 licence conditions have been imposed to restrict the spread and persistence of the GMOs and their genetic material in the environment and to limit the release to the size, location and duration proposed in the application, as these were important considerations in establishing the context for assessing the risks.
The licence conditions require CSIRO to limit the release to a maximum area of 0.5 ha per growing season planted between the date of issue of the licence and August 2015 in the local government area of Narrabri, New South Wales. 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 the Regulator’s transportation guidelines or other specific conditions; 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 eight types GM cotton planted at one site per growing season with a maximum area of 0.5 ha over three years in Narrabri, New South Wales 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 limit the release in size, location and duration, and to require controls in line with those proposed by the applicant as these were important considerations in establishing the context for assessing the risks.