Australian Government
Department of Health and Ageing
Office of the Gene Technology Regulator

16 September 2008

EXECUTIVE SUMMARY OF THE RISK ASSESSMENT AND RISK MANAGEMENT PLAN
FOR
APPLICATION NO. DIR 081/2007
FROM
MONSANTO AUSTRALIA LIMITED

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 enhanced for enhanced water use efficiency into the environment in respect of application DIR 081/2007 from Monsanto Australia Ltd.

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[1].

The application

Monsanto applied for a licence for dealings involving the intentional release of up to 504 genetically modified (GM) cotton lines[2] on a limited scale and under controlled conditions. The GM cotton lines have been modified for enhanced water use efficiency (WUE). The trial would be conducted at up to 20 sites of no more than 2 ha each, on a maximum total area of 40 ha per year between September 2008 and June 2010.

The proposed sites[3] may be located in the New South Wales local government areas (LGAs) of Balranald, Bourke, Central Darling, Carathool, Coonamble, Gunnedah, Hay, Lachlan, Moree Plains, Narrabri, Narromine, Walgett, Warren and Lake Tandou (an unincorporated area); the Queensland LGAs of Paroo, Balonne, Dalby Regional, Goondiwindi Regional, Toowoomba Regional, Somerset Regional, Brisbane City and Lockyer Valley Regional; and the Western Australia LGA of Wyndham-East Kimberley. Glasshouses in the LGAs of

[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>.

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

[3] The original application indicated that the sites may be located in up to 25 different LGAs. The applicant has requested the addition of Gunnedah (NSW) to the list of LGAs, but due to council amalgamation in Queensland, the number of proposed locations has decreased from 25 to 23.

Brisbane City and Toowoomba Regional would be producing the seed for planting at field sites.

The cotton lines were genetically modified using one of 56[4] different gene constructs. All the constructs contain one gene for WUE, except for one construct which contains two different genes. The introduced genes were derived from various plants, bacteria, yeast or fungi and encode proteins that are intended to confer enhanced water use efficiency.

The GM cotton lines contain either an antibiotic resistance selectable marker gene, derived from *Escherichia coli*, or a herbicide tolerance selectable marker gene derived from *Agrobacterium* sp. strain CP4. These genes were used as selective markers 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 to evaluate agronomic characteristics including water use efficiency, yield and fibre quality of the GM cotton lines under optimal and water stress conditions. Seed will be collected for further studies, including possible future releases (subject to additional assessments and approvals). The GM cotton will not be used for human food or animal feed

Monsanto proposed a number of controls to restrict the dissemination or persistence of the GM cotton lines into the environment that have been considered during the evaluation of the application.

Confidential Commercial Information

Some details, including the names of the introduced genes and their encoded proteins, and the gene constructs, including plasmid maps and certain regulatory sequences, 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 takes into account information in the application (including proposed containment measures), relevant previous approvals and current scientific knowledge, advice received from a wide range of experts, agencies and authorities consulted on the RARMP and submissions from the public.

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. 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.

[4] The original application was for 63 gene constructs containing 56 different genes. However, Monsanto withdrew 7 constructs leaving 56 constructs containing 50 different genes.

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 lines 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 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 restrict the dissemination and persistence of the GMOs and their 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 Monsanto to **limit** the duration of the release to between September 2008 and June 2010 on a maximum total area of 40 ha per year at up to 20 sites. The **control** measures to restrict the spread and persistence of the GMOs include preventing the use of GM plant materials in human food or animal feed; destroying waste GM plant materials; 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[5].

Conclusions of the consultation RARMP

The risk assessment concludes that this limited and controlled release of the GM cotton lines on up to 20 sites, located in various LGAs in NSW, QLD and WA, totalling no more than 40 ha per year over a two year period between 2008 and 2010 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 dissemination and persistence of the GMOs and their genetic material in the environment and

[5] The licence for DIR 081/2007 is available on the OGTR website <http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/ir-1> via the link to DIR 081/2007

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.