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

30 April 2012

EXECUTIVE SUMMARY OF THE RISK ASSESSMENT AND RISK MANAGEMENT PLAN FOR APPLICATION NO. DIR 113 FROM BAYER CROPSCIENCE PTY LTD

Introduction

The Gene Technology Regulator (the Regulator) has made a decision to issue a licence in respect of a licence application (DIR 113) from Bayer CropScience Pty Ltd (Bayer). 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[1].

The application

Bayer has applied for a licence for dealings involving the intentional release of GM cotton into the environment on a limited scale and under controlled conditions. The GM cotton varieties have been genetically modified for insect resistance and herbicide tolerance. The field trial is authorised to take place at up to six sites per year in the Local Government Areas (LGAs) of Narrabri, NSW, Wyndham-East Kimberly, WA, and Central Highlands, Qld, between May 2012 and May 2015. The maximum area of plantings will be 6 ha in the first year and 36 ha in the second and third years, giving a maximum cumulative area of 78 ha.

The purpose of the trial is to assess the agronomic performance of the GM cotton varieties, and to produce seed for use in further studies or releases (subject to additional approvals). The

[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 (OGTR) (Free call 1800 181 030 or at <http://www.ogtr.gov.au/>), and in the Regulator's *Risk Analysis Framework* (OGTR 2009) at <http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/riskassessments-1>.

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

Up to 11 varieties of GM cotton are authorised for release. These cotton varieties contain different combinations of introduced genes conferring insect resistance and introduced genes conferring herbicide tolerance. Some varieties also contain an antibiotic resistance marker gene, which was used to select GM plants during initial development of the plants in the laboratory.

Bayer proposed a number of controls to restrict the spread and persistence of the GM cotton and the introduced genetic materials in the environment that were considered during the evaluation of the application.

Confidential Commercial Information

Details of the genes and other sequences inserted into the GM cotton varieties 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 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.

Six 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; alter characteristics that may impact on the spread and persistence of the GM cotton; or produce unintended changes in the biochemistry of the GMOs. 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 six 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 identify any risks that could be greater than negligible. Therefore, they did not warrant further assessment.

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

As none of the six 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, 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, locations and duration proposed in the application, as these were important considerations in establishing the context for assessing the risks.

The licence conditions require Bayer to limit the release to a maximum cumulative area of 78 ha at up to six sites per year between May 2012 and May 2015, inclusive. The control measures include containment provisions at the trial sites; 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 sites to ensure all GMOs are destroyed.

Conclusions of the RARMP

The risk assessment concluded that this limited and controlled release of up to 11 varieties of GM cotton on a maximum cumulative area of 78 ha over three years in the LGAs of Narrabri, NSW, Wyndham-East Kimberley, WA, and Central Highlands, Qld, 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 to the size, locations and duration proposed in the application, 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.