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

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EXECUTIVE SUMMARY OF THE RISK ASSESSMENT AND RISK MANAGEMENT PLAN FOR APPLICATION NO. DIR 101 FROM MONSANTO AUSTRALIA LIMITED

Introduction

The Gene Technology Regulator (the Regulator) has made a decision to issue a licence in respect of licence application DIR 101 from Monsanto Australia Ltd (Monsanto). The licence authorises dealings involving the limited and controlled release of two genetically modified (GM) cottons 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 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 the requirements of the legislation. RARMP's 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

Monsanto has applied for a licence for dealings involving the intentional release of two GM cottons (Bollgard III and Bollgard III/Roundup Ready Flex®) on a limited scale and under controlled conditions. The GM cottons have been genetically modified for insect resistance either alone or in combination with herbicide tolerance. The trial is proposed to take place at up to 50 sites per year in up to 34 New South Wales (NSW),Queensland (Qld) and Western Australian (WA) LGAs. The trial may occur on a maximum total area of 1150 ha, between October 2010 and October 2014.

The GM cottons are produced by conventionally crossing GM VIP3A insect resistant cotton with the commercially released GM cottons Bollgard II® cotton (insect resistant) and Bollgard II®/Roundup Ready Flex® cotton (insect resistant/herbicide tolerant). In addition to the insect resistance gene and herbicide tolerance gene, the GM cottons contain marker

[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>.

genes, including antibiotic resistance genes that were used to identify transformed plants during initial development of the GM plants in the laboratory. All of the introduced genes were originally derived from common bacteria.

The purpose of the trial is to generate data for future submissions to regulatory agencies, to breed and develop varieties using elite germplasm suitable for use under Australian conditions, and for seed increase. Material from the GM cotton will not be used in human food or animal feed during the release.

Monsanto proposed a number of controls to restrict the spread and persistence of the GM cottons 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), previous approvals and relevant scientific/technical knowledge. Advice relating to risks to human health and safety and the environment provided in submissions received during consultation on the RARMP has also been 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 were postulated (risk scenarios), and these scenarios were evaluated to identify those that warrant detailed characterisation. This process is described as risk identification.

Eight risk scenarios were postulated. 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 cottons; or produce unintended changes in the biochemistry of the GMO. 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 eight risk scenarios in relation to both the seriousness and likelihood of harm, in the context of the control measures proposed by the applicant, did not identify risks that required further assessment.

Risks to the health and safety of people, or the environment, from the proposed release of the GM cottons 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 eight 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 are imposed to restrict the spread and persistence of the GMOs and their genetic material in the environment and to limit the proposed release to the size, locations 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 release to a total area of 1150 ha between October 2010 and October 2014. Each year, no more than 50 sites are permitted for planting. 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 Regulator's transportation guidelines; and conducting post-harvest monitoring at all trial sites to ensure all GMOs are destroyed.

Conclusions of the RARMP

The risk assessment concluded that this proposed limited and controlled release of the two GM cottons (Bollgard III and Bollgard III/Roundup Ready Flex®) on a maximum total cumulative area of 1150 ha in up to 34 LGAs in Qld, NSW and WA between October 2010 and October 2014, 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 by the applicant, 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.