



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 105
FROM
MONSANTO AUSTRALIA LTD**

Introduction

The Gene Technology Regulator (the Regulator) has made a decision to issue a licence in respect of application DIR 105 from Monsanto Australia Ltd (Monsanto). The licence authorises dealings involving the limited and controlled release of genetically modified (GM) canola 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 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 public¹.

The application

Monsanto has applied for a licence for dealings involving the intentional release of one line² of GM canola on a limited scale and under controlled conditions. The GM canola line has been genetically modified for herbicide tolerance. The trial is authorised to take place over four years, from March 2011 to December 2014, with up to 2 sites planted in the first year, 8 sites in the second and third years, and 20 sites in the fourth year. Sites will be a maximum of 4 ha in the first year and 10 ha in subsequent years. Sites will be located in canola growing regions in 46 possible local government areas (LGAs) in New South Wales, 28 possible LGAs in Victoria and 53 possible LGAs in Western Australia. The exact site locations will be selected by Monsanto closer to planting.

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>>.

² The term 'line' is used to denote plants derived from a single plant containing a specific genetic modification resulting from a single transformation event.

The GM canola has been modified to contain a gene derived from a common soil bacterium. Expression of the gene in the GM canola plants is expected to confer tolerance to herbicides containing glyphosate.

The purpose of the trial is to conduct experiments to evaluate agronomic performance of the GM canola line under field conditions. Material from the GM canola will not be used in human food or animal feed.

Monsanto proposed a number of controls to restrict the spread and persistence of the GM canola line and its introduced genetic material in the environment that were considered during the evaluation of the application.

Risk assessment

The risk assessment takes 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 are postulated (risk scenarios), and these scenarios are 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 gene 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 canola; 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 canola line 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 the licence conditions.

As none of the eight risk scenarios characterised in the risk assessment gave rise to an identified risk that required further assessment, the level of risk from the proposed dealings was 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 GMO and its genetic material in the environment and to limit the 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 maximum cumulative area of 368 ha planted between the date of issue of the licence and December 2014 in nominated local government areas (LGAs). No more than 2 sites in the first year, 8 sites in the second and third years, and 20 sites in the fourth year are proposed. 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; 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 a GM canola line on a maximum cumulative area of 368 ha planted at up to 38 sites over four years in New South Wales, Victoria and Western Australia, 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 restrict 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.