



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

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**TECHNICAL 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 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 public¹.

The application

Monsanto has applied for a licence for dealings involving the intentional release 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 proposed 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 applicant proposes to release GM canola modified to contain the *5-enolpyruvylshikimate-3-phosphate synthase (cp4 epsps)* gene derived from the soil bacterium *Agrobacterium tumefaciens* strain CP4. The gene encodes EPSPS, an enzyme of the shikimic acid pathway which is involved in the biosynthesis of plant phenolics. In non-GM plants, glyphosate binds to and blocks the activity of this enzyme, which results in the plant being deprived of essential amino acids for growth and development. Expression of the introduced gene is expected to enable the GM canola plants to produce aromatic amino acids required for growth and development in the presence of glyphosate. Herbicides containing glyphosate could then be used for weed control in the GM canola crop.

The GM canola intended for release differs from the commercially released Roundup Ready[®] canola as it is expected to tolerate higher rates of glyphosate herbicides and have a wider window for herbicide application.

The introduced *cp4 epsps* gene is under the control of a chimeric constitutive promoter containing enhancer sequences from the Figwort mosaic virus 35S promoter. Other short regulatory sequences that contribute to control of expression of the introduced gene are also present in the GM canola. These are derived from *Arabidopsis thaliana*, *Pisum sativum* (common garden pea) and *A. tumefaciens*.

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 during the release.

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), 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 has also been considered. No new risks to people or the environment were identified from the advice received on the consultation RARMP.

A reference document, *The Biology of Brassica napus L. (canola)*, was produced to inform the risk assessment process for licence applications involving GM canola plants. The document is available from the OGTR or from the website <http://www.ogtr.gov.au>.

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 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 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. The principal reasons for this include:

- limits on the size, locations and duration of the release proposed by Monsanto
- suitability of controls proposed by Monsanto to restrict the spread and persistence of the GM canola plants and their genetic material
- limited ability and opportunity for the GM canola plants to transfer the introduced gene to other canola plants or other sexually related species
- none of the GM plant materials or products will be used for human food or animal feed
- widespread presence of the protein encoded by the introduced gene, or similar proteins, in the environment and lack of known toxicity or evidence of harm from them.

Risks to the health and safety of people, or the environment, from the proposed release of the GMO 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.

Licence conditions

The Regulator has imposed a number of licence conditions, including requirements to:

- limit the release to a maximum cumulative area of 368 ha planted between the date of issue of the licence and December 2014 at up to 38 sites to be selected in nominated local government areas in New South Wales, Victoria and Western Australia
- limit each trial site to a maximum of 4 ha in the first year and 10 ha in subsequent years
- locate the trial sites at least 50 m away from waterways
- establish a 50 m zone around each trial site in which sexually compatible species are prevented from flowering
- maintain an isolation zone of at least 400 m, or at least 1 km if no pollen trap is used, around each trial site within which no sexually compatible species may be intentionally grown
- harvest the GM canola plant material separately from other crops
- clean all equipment used in connection with the GMO before it is used for any other purpose

- clean trial sites and surrounding areas after harvest
- apply measures to promote germination of any canola seeds that may remain in the soil, including at least two shallow tillage events
- monitor the site for at least 24 months after harvest until no volunteers are detected for a continuous 12 month period and destroy any canola plants that may grow
- destroy all plant material that is not required for experimentation or future planting
- transport and store all GMO in accordance with the Regulator's guidelines
- not allow the GM plant material or products to be used for human food or animal feed.

Other regulatory considerations

Australia's gene technology regulatory system operates as part of an integrated legislative framework that avoids duplication and enhances coordinated decision making. The Regulator is responsible for assessing risks to the health and safety of people and the environment associated with the use of gene technology. However, dealings conducted under a licence issued by the Regulator may also be subject to regulation by other Australian government agencies that regulate GMOs or GM products, including Food Standards Australia New Zealand (FSANZ), Australian Pesticides and Veterinary Medicines Authority (APVMA), Therapeutic Goods Administration (TGA), National Industrial Chemicals Notification and Assessment Scheme (NICNAS) and Australian Quarantine Inspection Service (AQIS)³.

APVMA has regulatory responsibility for the use of agricultural chemicals, including herbicides and insecticidal products, in Australia. The GM canola has been modified to be tolerant to glyphosate herbicides and the applicant intends to apply these and other herbicides during the trial. The application of these herbicides is subject to regulation by the APVMA.

FSANZ is responsible for human food safety assessment and food labelling, including GM food. The applicant does not intend to use materials from the GM canola line in human food, accordingly an application to FSANZ has not been submitted. FSANZ approval would need to be obtained before materials from this GM canola line could be sold as food.

In addition, dealings authorised by the Regulator may be subject to the operation of State legislation declaring areas to be GM, GM free, or both, for marketing purposes.

Identification of issues to be addressed for future releases

Additional information has been identified that may be required to assess an application for a large scale or commercial release of this GM canola line, or to justify a reduction in containment conditions. This would include:

- additional biochemical characterisation of the GM canola line
- additional phenotypic characterisation of the GM canola line, particularly with respect to traits that may contribute to biotic or abiotic stress tolerance, weediness or persistence.

Suitability of the applicant

The Regulator is satisfied that Monsanto is suitable to hold a DIR licence as no relevant convictions have been recorded, no licences or permits have been cancelled or suspended

³ More information on Australia's integrated regulatory framework for gene technology is contained in the *Risk Analysis Framework* available from the Office of the Gene Technology Regulator (OGTR). Free call 1800 181 030 or at <<http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/riskassessments-1>>.

under laws relating to the health and safety of people or the environment, and the organisation has the capacity to meet the conditions of the licence.

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 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.