



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

6 August 2010

**TECHNICAL SUMMARY OF THE
RISK ASSESSMENT AND RISK MANAGEMENT PLAN
FOR
APPLICATION NO. DIR 103
FROM
VICTORIAN DEPARTMENT OF PRIMARY INDUSTRIES**

Introduction

The Gene Technology Regulator (the Regulator) has made a decision to issue a licence in respect of application DIR 103 from the Victorian Department of Primary Industries (DPI Victoria). The licence authorises dealings involving the limited and controlled release of up to 10 lines¹ 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 public².

The application

DPI Victoria has applied for a licence for dealings involving the intentional release of up to 10 lines of GM canola on a limited scale and under controlled conditions. The GM canola lines have been genetically modified for enhanced yield and delayed leaf senescence. The trial may take place at two sites at Victorian government research stations in the local government areas of Horsham and Southern Grampians, on a maximum combined area of 0.8 ha per growing season, between the date of issue of the licence and May 2012. The applicant proposed planting in both summer and winter growing seasons.

The purpose of the trial is to conduct experiments to evaluate agronomic performance, including seed yield, of the GM canola lines under field conditions. Some seed would be

¹ The term 'line' is used to denote plants derived from a single plant containing a specific genetic modification resulting from a single transformation event.

² 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>>.

collected and retained for analysis and possible future trials, subject to further approval(s). Material from the GM canola will not be used in human food or animal feed.

The applicant intends to release GM canola modified to contain the *isopentenyltransferase* (*ipt*) gene derived from the soil bacterium *Agrobacterium tumefaciens*. The *ipt* gene encodes the isopentenyltransferase enzyme, which is involved in cytokinin biosynthesis. Expression of the *ipt* gene is expected to enhance yield and delay leaf senescence in the GM canola plants.

The GM canola lines also contain an antibiotic resistance gene, *hph*, derived from the bacterium *Escherichia coli*. The *hph* gene encodes hygromycin phosphotransferase, which confers resistance to the antibiotic hygromycin. This was used as a selectable marker during initial development of the GM plants in the laboratory.

In addition, the GM canola lines contain short regulatory elements to control expression of the introduced genes. These sequences are derived from *Arabidopsis thaliana*, *A. tumefaciens* and Cauliflower mosaic virus.

DPI Victoria proposed a number of controls to restrict the spread and persistence of the GM canola lines and their genetic material into the environment. These controls were considered during the evaluation of the application.

Confidential Commercial Information

Some details, including unpublished data from glasshouse experiments, 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), 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.

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 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, 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 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 any risks that required further assessment. The principal reasons for this include:

- limits on the size, locations and duration of the release proposed by DPI Victoria
- suitability of controls proposed by DPI Victoria 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 genes to commercial canola crops or other sexually related species
- none of the GM plant materials or products will be used in human food or animal feed
- widespread presence of the same or similar proteins encoded by the introduced genes 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 GM canola 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 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 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 total area of up to 0.8 ha per growing season at two sites at Victorian Government research stations within the local government areas of Horsham and Southern Grampians, between the date of issue of the licence and May 2012
- locate the trial sites at least 50 m away from natural waterways
- surround the GM canola with a 15 m pollen trap of non-GM canola plants and a 50 m monitoring zone in which sexually compatible species are not permitted to flower
- ensure no other *Brassica* crops are grown within 400 m of the GM canola plants
- harvest the GM canola plant material separately from other crops
- clean the sites and equipment used on the sites following harvest
- apply measures to promote germination of any canola seeds that may be present in the soil after harvest, including shallow tillage

- monitor the site for at least 24 months after harvest and destroy any canola plants that may grow until no volunteers are detected for a continuous 12 month period
- destroy all GM plant material not required for further analysis or future planting
- transport material from the GMOs in accordance with the Regulator's guidelines
- not permit any GM canola plant material to be used in 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. Dealings conducted under a licence issued by the Regulator may be subject to regulation by other agencies that also regulate GMOs or GM products include 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.

FSANZ is responsible for human food safety assessment, including GM food. As the trial involves early stage research, the applicant does not intend any material from the GM canola lines proposed for release to be used for human food. Accordingly, the applicant has not applied to FSANZ to evaluate the GM canola lines. FSANZ approval would need to be obtained before they could be sold for human food in Australia.

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 these GM canola lines, or to justify a reduction in containment conditions. This would include:

- additional data on the potential toxicity and allergenicity of plant materials from the GM canola lines
- additional phenotypic characterisation of the GM canola lines, in particular of traits which may contribute to weediness, including abiotic and biotic stress tolerance
- characterisation of the introduced genetic material in the plants, including copy number and expression pattern.

Suitability of the applicant

The Regulator is satisfied that DPI Victoria is suitable to hold a DIR licence as no relevant convictions have been recorded, no licences or permits have been cancelled or suspended 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 proposed limited and controlled release of up to 10 lines of GM canola on a maximum total area of 0.8 ha per growing season over two years in the Victorian local government areas of Horsham and Southern Grampians, poses **negligible** risks to the health and safety of people or the environment as a result of gene technology.

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>>.

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.