



Australian Government

**Department of Health and Ageing
Office of the Gene Technology Regulator**

29 July 2010

**APPLICATION FOR LICENCE FOR INTENTIONAL RELEASE OF GMOs INTO THE
ENVIRONMENT: Application No. DIR 105**

SUMMARY INFORMATION

Project Title:	Limited and controlled release of canola genetically modified for herbicide tolerance ¹
Applicant:	Monsanto Australia Ltd (Monsanto)
Common name of the parent organism:	Canola
Scientific name of the parent organism:	<i>Brassica napus</i> L.
Modified trait(s):	Herbicide tolerance
Identity of the gene(s) responsible for the modified trait(s):	5-enolpyruvylshikimate-3-phosphate synthase (<i>cp4 epsps</i>) gene derived from the bacterium <i>Agrobacterium</i> sp. strain CP4 (herbicide tolerance)
Proposed Location(s):	A maximum of 2 sites in the first year, 8 sites in the second and third years, and 20 sites in the fourth year. 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
Proposed Release Size:	Up to 10 hectares per site (8 ha in first year, 80 ha in second year, 80 ha in third year, 200 ha in fourth year)
Proposed Release Dates:	March 2011 – December 2014

Introduction

The *Gene Technology Act 2000* (the Act) in conjunction with the *Gene Technology Regulations 2001*, an inter-governmental agreement and corresponding legislation that is being enacted in each State and Territory, comprise Australia's nationally consistent regulatory system for gene technology. Its objective is to protect the health and safety of people, and the environment, by identifying risks posed by or as a result of gene technology, and managing those risks by regulating certain dealings with genetically modified organisms (GMOs).

The Act establishes a statutory officer, the Gene Technology Regulator (the Regulator), to administer and make decisions under the legislation. The Regulator is supported by the Office of the Gene Technology Regulator (OGTR), an Australian Government regulatory agency located within the Health and Ageing portfolio.

The legislation sets out requirements for considering applications for licences for dealings with GMOs, including matters that the Regulator must take into account before deciding whether or not

¹ The title of the licence application submitted by Monsanto is 'Field testing of Roundup Ready 2 Canola'.

to issue a licence. The Regulator's *Risk Analysis Framework*² outlines the assessment process that will be followed.

The application and the proposed dealings

The Regulator has received an application from Monsanto for a licence for dealings involving the intentional release of genetically modified (GM) canola into the Australian environment on a limited scale under controlled conditions.

The GM canola line³ proposed for release contains a gene that confers herbicide tolerance.

The GM canola proposed for release is similar to the commercially approved Roundup Ready[®] canola. The purpose of the trial is to conduct experiments to evaluate the agronomic performance of the herbicide tolerant line under field conditions. The applicant proposes to limit the release to 2 sites in the first year, 8 sites in the second and third years, and up to 20 sites in the fourth year. Sites may be located 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 determined closer to planting. Each site will be a maximum of 10 ha and the trial will be conducted for four years from March 2011 to December 2014.

The applicant has proposed a number of control measures to restrict the spread and persistence of the GM plants and their introduced genetic material, which will be considered in the assessment of this application, including:

- surrounding trial sites with a 50 m monitoring zone that is free of *Brassica* weeds. In addition, one of the following measures will be adopted:
 - a 1 km isolation zone will be maintained from the outer perimeter of the planted area, or
 - the trial site will be surrounded by a 15 m wide pollen trap and a 400 m isolation zone will extend from the outer perimeter of the pollen trap
- removing and destroying all viable GM plant material from the trial sites and adjacent areas following harvest
- locating the trial sites at least 50 m away from natural waterways
- restricting access to trial sites to authorised persons
- post harvest monitoring of the trial site, pollen trap area and any areas used to clean equipment on a monthly basis for 24 months and destroying any volunteer canola plants (if no volunteers are found during 6 consecutive inspections, then reduce inspections to once every 3 months for the remainder of the inspection period)
- cleaning of equipment and places within 2 weeks of harvest
- harvesting of GM canola from trials separately to other canola
- destroying seed not used for evaluation or seed increase
- transporting and storing GM plant materials in accordance with Regulator's guidelines
- not using the GM plant material for human food or animal feed.

³ The *Risk Analysis Framework* and further information on the assessment of licence applications is available from the Office of the Gene Technology Regulator (OGTR). Free call 1800 181 030 or at <<http://www.ogtr.gov.au>>.

⁴ The term 'line' is used to denote plants derived from a single plant containing a specific genetic modification(s) resulting from a single transformation event.

Parent organism

The parent organism, *Brassica napus* L., is commonly known as canola, and is exotic to Australia. Commercial canola production occurs mainly in New South Wales, Victoria, South Australia and Western Australia, and to a much lesser extent in Tasmania and southern Queensland.

The Ebony canola variety was used to produce the GMO proposed for release. Ebony is not commercially grown in Australia but is commonly used for genetic modification.

The genetic modification and its effect

The GM plants contain the 5-enolpyruvylshikimate-3-phosphate synthase (*cp4 epsps*) gene from the common 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 proposed 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 genes are also present in the GM canola. These are derived from *Arabidopsis thaliana*, *Pisum sativum* (common garden pea), and *A. tumefaciens*.

Method of genetic modification

The *cp4 epsps* gene and associated regulatory sequences were introduced into canola on a plasmid vector carried by *A. tumefaciens*. This method has been widely used in Australia and overseas for introducing new genes into plants.

Transformed plant tissues were identified on glyphosate selection media, using expression of the *cp4 epsps* gene.

Previous releases of the same or similar GMOs

There has been no previous release of this GM canola line in Australia but it is similar to Roundup Ready[®] canola, which has been approved for commercial release under licence DIR 020/2002.

Other GM canola containing genes for herbicide tolerance and/or a hybrid breeding system have been approved in Australia for limited and controlled release (DIR 010/2001, DIR 011/2001, DIR 032/2002 and DIR 069/2006), and for commercial release (DIR 021/2002: InVigor[®] canola).

The GM canola line has been released in the USA, Canada and Chile for early stage field testing.

Suitability of Applicant

Section 43(2)(f) of the Act requires the Regulator to be satisfied regarding the suitability of the applicant to hold a licence as a pre-requisite for considering DIR applications. The matters to be considered are outlined in section 58 of the Act and include capacity to meet the conditions of a

licence, relevant convictions and revocation of a licence or permit held under law relating to the health and safety of people or the environment.

The Regulator has determined that Monsanto currently meets the suitability requirements and will verify this continues to be the case prior to making any decision regarding the issuing of a licence.

Consultation process for this DIR application

The Regulator has made an assessment of whether the application should be considered as a limited and controlled release, under section 50A of the Act. As its principal purpose is to enable the conduct of experiments, and the applicant has proposed limits on the size and duration of the release and controls to restrict the spread and persistence of both the GMO and its genetic material in the environment, **the Regulator has decided that the application qualifies as a limited and controlled release.**

This means that the Regulator is not required to consult on the assessment of this application until after a RARMP has been prepared in accordance with section 51 of the Act. In the interim, copies of the application are available on request from the OGTR. Please quote application number DIR 105.

The Regulator will seek comment on the consultation RARMP from the public as well as a wide range of experts, agencies and authorities including the Gene Technology Technical Advisory Committee, State and Territory Governments, Australian Government agencies and the Minister for the Environment. The RARMP will then be finalised, taking into account matters raised relating to risks to human health and safety and the environment, and form the basis of his decision whether or not to issue a licence.

At this stage, **the RARMP is expected to be released for comment in October 2010.** The public will be invited to provide submissions on the RARMP via advertisements in the media and direct mail to anyone registered on the OGTR mailing list. The RARMP and other related documents will be available on the OGTR website, or in hard copy from the OGTR.

If you have any questions about the application or the assessment process, or wish to register on the mailing list, please contact the OGTR at:

The Office of the Gene Technology Regulator, MDP 54 GPO Box 9848 Canberra ACT 2601

Telephone: 1800 181 030 Facsimile: 02 6271 4202 E-mail: ogtr@health.gov.au

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