



Australian Government

Department of Health and Ageing Office of the Gene Technology Regulator

22 February 2010

APPLICATION FOR LICENCE FOR INTENTIONAL RELEASE OF GMOs INTO THE ENVIRONMENT: Application No. DIR 103

SUMMARY INFORMATION

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| Project Title: | Limited and controlled release of canola genetically modified for enhanced yield and delayed leaf senescence ¹ |
| Applicant: | Department of Primary Industries Victoria |
| Common name of the parent organism: | Canola |
| Scientific name of the parent organism: | <i>Brassica napus</i> L. |
| Modified trait(s): | Yield, leaf senescence, antibiotic resistance |
| Identity of the gene(s) responsible for the modified trait(s): | <ul style="list-style-type: none">• <i>Isopentyl transferase (ipt)</i> gene from the bacterium <i>Agrobacterium tumefaciens</i> (enhanced yield and delayed leaf senescence)• <i>hph</i> gene from the bacterium <i>Escherichia coli</i> (antibiotic resistance) |
| Proposed Location(s): | Two sites in the local government areas of Horsham and Southern Grampians, Victoria |
| Proposed Release Size: | Up to 0.8 hectares per growing season |
| Proposed Release Dates: | May 2010 – May 2012 |

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

¹ The title of the licence application submitted by DPI Victoria is 'Limited and controlled release of GM canola for yield enhancement and delayed leaf senescence'.

² 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>>.

The application and the proposed dealings

The Regulator has received an application from the Department of Primary Industries Victoria (DPI Victoria) for a licence for dealings involving the intentional release of genetically modified (GM) canola (*Brassica napus* L.) into the Australian environment on a limited scale under controlled conditions.

Up to ten lines³ of GM canola are proposed for release. The GM canola contains the *isopentyltransferase (ipt)* gene derived from *Agrobacterium tumefaciens* (a common soil bacterium), and an antibiotic resistance marker gene. Expression of the *ipt* gene is expected to enhance yield and delay leaf senescence in the GM canola plants.

The purpose of the trial is to conduct experiments to evaluate the agronomic performance, including seed yield, of the GM canola lines under field conditions. Some seed will be retained for seed increase or further experimentation (subject to additional approvals).

The applicant proposes to limit the release to two sites at Victorian government research stations in the local government areas of Horsham and Southern Grampians, on a maximum area of 0.8 ha per year between May 2010 and May 2012.

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:

- locating the trial sites at least 50 m away from natural waterways
- surrounding the GM canola with a 15 m pollen trap of non-GM canola and a 50 m monitoring zone that is free of canola and related species
- locating the trial sites at least 400 m away from any Brassica crop
- harvesting all GM canola plants in a manner to reduce the loss of seed
- destroying all GM plant material not required for testing or future trials
- incorporating any plant material remaining at the site after harvest into the soil and allowing it to decompose
- cleaning all equipment on site
- promoting the germination of any residual seed following harvest through light tillage, irrigation, and other agronomic practices
- post harvest monitoring of the trial site on a monthly basis for 24 months and destroying any volunteer canola plants
- not permitting any GM canola plant material to be used in human food or animal feed
- transporting and storing GM plant materials in accordance with Regulator's guidelines.

Confidential Commercial Information

Some details, including unpublished data from glasshouse experiments, are the subject of an application for declaration of Confidential Commercial Information (CCI) under section 185 of the Act, which is currently under consideration. The confidential information will be made available to

³ The term 'line' is used to denote plants derived from a single plant containing a specific genetic modification(s) made by one transformation event.

the prescribed experts and agencies that will be consulted on the Risk Assessment and Risk Management Plan (RARMP) for this application.

Parent organism

The parent organism is canola (*Brassica napus* L.), which is exotic to Australia. Commercial canola cultivation occurs mainly in New South Wales, Victoria, South Australia and Western Australia, and to a much lesser extent in Tasmania and southern Queensland.

The cultivar used to produce the GMOs is the advanced breeding line RR014. RR014 is not grown commercially but has been used for crossing and transformation purposes.

The genetic modifications and their effect

The GM canola lines contain the *ipt* gene under the control of a functionally active fragment of the *Arabidopsis thaliana* MYB32 promoter. The *ipt* gene encodes the enzyme isopentenyl transferase, 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 a marker gene (*hph*) derived from bacteria that confers resistance to the antibiotic hygromycin. This was used as a selectable marker during early stages of development of the GM plants in the laboratory.

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 *A. tumefaciens* and Cauliflower mosaic virus.

Method of genetic modification

The *ipt* and *hph* genes 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 using the expression of the antibiotic resistance marker gene. The GM canola lines proposed for release were obtained by self pollination of these primary transformants.

Previous releases of the same or similar GMOs

There has been no previous release of these GM canola lines in Australia.

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 020/2002: Roundup Ready[®] canola and DIR 021/2002: InVigor[®] canola).

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.

The Regulator has determined that DPI Victoria 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 GMOs and their 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 103.

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, Heritage and the Arts. 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 June 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:

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