



Office of the Gene Technology Regulator

APPLICATION FOR LICENCE FOR INTENTIONAL RELEASE OF A GMO INTO THE ENVIRONMENT:

Application No. DIR 020/2002

SUMMARY INFORMATION

Updated October 2003

Project Title:	General release of Roundup Ready [®] canola (<i>Brassica napus</i>) in Australia
Applicant:	Monsanto Australia Ltd PO Box 6051 St Kilda Rd Central VIC 8008
Common name of the parent organism:	Canola
Scientific name of the parent organism:	<i>Brassica napus</i>
Modified trait(s):	Herbicide tolerance
Identity of the gene(s) responsible for the modified trait(s):	<i>CP4 EPSPS</i> from the bacterium <i>Agrobacterium</i> sp. strain CP4 (herbicide tolerance) <i>goxv247</i> gene from the bacterium <i>Ochrobactrum anthropi</i> (herbicide tolerance)
Proposed Location	Potentially all canola growing regions of Australia
Proposed Release Size:	Phased introduction (see below) through to full commercial release in all canola growing regions
Proposed Date of Release:	2003

The Office of the Gene Technology Regulator (OGTR) has received an application from Monsanto Australia Ltd (Monsanto) for a licence for the intentional release of a genetically modified organism into the environment. Monsanto proposes the commercial release of GM canola under the trade name Roundup Ready[®] canola. Monsanto is seeking regulatory approval of one genetically modified 'line'¹ of canola, GT73 (known as RT73 in the USA).

Roundup Ready[®] canola is tolerant to glyphosate, which is the active constituent of a range of proprietary herbicides (registered by the APVMA), including Roundup[®]. Roundup Ready[®] herbicide is registered for use on Roundup Ready[®] cotton in Australia but is not currently registered for use on Roundup Ready[®] canola.

¹ 'Line' is used to describe a GMO with a specific genetic modification derived from a single transformation event and is inclusive of the introduction of the genetic modification into other conventional (non-GM) genetic backgrounds using conventional breeding.

A parallel application has been made to the APVMA for a variation of the registration to enable the extension of use of glyphosate as Roundup Ready[®] herbicide for use on Roundup Ready[®] canola.

The proposed dealings

Monsanto proposes the commercial cultivation of Roundup Ready[®] canola in all the current and potential future canola growing regions of Australia, which includes New South Wales, Victoria, South Australia, Western Australia, Queensland, Tasmania and the Australian Capital Territory. A number of State and Territory governments have introduced measures to delay the commercial release of certain GM crops until market access and supply chain segregation issues (which by agreement, are outside the scope of the assessment required by the Act) are better understood. Therefore, if the Regulator were to approve the proposed commercial release on human, health, safety and the environment grounds, the applicant would need to obtain the requisite approval, from such jurisdictions where it wishes to grow Roundup Ready[®] canola.

Monsanto proposes a phased introduction of Roundup Ready[®] canola with a limited release of approximately 5000 hectares in the first year in the canola growing regions of south eastern Australia. Monsanto expects a steady increase in the area sown to Roundup Ready[®] canola over a number of years across the canola growing regions of Australia, with the rate of increase being determined by market acceptance, seed and variety availability. Monsanto has indicated it intends to continue to work closely with State and Territory Governments and the grains industry, including the Gene Technology Grains Committee, to manage the introduction of Roundup Ready[®] canola. Monsanto is seeking approval to commence the release as soon as possible.

The canola plants and their by-products, would be used in the same manner as conventional canola, including for human food and animal feed. After harvest of the Roundup Ready[®] canola, the grain will enter the general commerce supply chain in Australia for domestic and export markets. Canola is grown commercially primarily for its seeds that yield about 40% oil and a high protein animal feed. Canola oil is used in the manufacture of a variety of food products. Canola meal is primarily used as a feed for livestock, but it is also used in poultry and fish feed, pet foods and fertilisers.

During the processing of (GM and non-GM) canola oil, DNA and introduced proteins are removed. The use in human food of oil derived from Roundup Ready[®] canola was approved by Food Standards Australia New Zealand (formerly the Australia New Zealand Food Authority) by inclusion in the Food Standards Code in November 2000.

Monsanto proposes a systematic and strategic approach to risk management and product stewardship through the implementation of its Roundup Ready Canola Technology Stewardship Strategy, which includes a Roundup Ready Canola Crop Management Plan. These will be consistent with the Guidelines for Industry Stewardship Programs and Crop Management Plans proposed by the Plant Industries Committee of the Primary Industries Standing Committee (under the Primary Industries Ministerial Council) and the Guidelines for Supply Chain Management of GM Canola that have been developed by the Gene Technology Grains Committee.

Parent organism

The parent organism is canola (*Brassica napus*), which is exotic to Australia and is grown as an agricultural crop in New South Wales, Queensland, Victoria, South Australia, Western Australia and Tasmania. More detailed information on canola can be found in a review document ‘The Biology and Ecology of Canola (*Brassica napus*)’ that was produced in order to inform this risk assessment process. This document is available at the OGTR website <http://www.ogtr.gov.au/pdf/ir/brassica.pdf>.

Genetic modification and its effects

Roundup Ready® canola has been modified to introduce tolerance to the compound glyphosate, the active ingredient in the herbicide Roundup Ready®. Non-GM, herbicide tolerant (triazine and imidazolinone) canola varieties currently comprise approximately 60% of the Australian canola market.

Herbicide tolerance is conferred to Roundup Ready® canola by two mechanisms. The first is through introduction of the *CP4 EPSPS* gene from the soil bacterium *Agrobacterium* sp., which produces a version of an essential plant enzyme that is less sensitive to glyphosate. The second is through the introduction of the *goxv247* gene from the soil bacteria *Ochrobactrum anthropi* that produces glyphosate oxidoreductase, which breaks down glyphosate into non-herbicidal compounds.

Short regulatory sequences that control expression of the genes are also present in Roundup Ready® canola. These sequences are derived from the figwort mosaic virus, *Arabidopsis thaliana*, and *Pisum sativum* (Table 1). Although the first organism is a plant pathogen, the regulatory sequences comprise only a small part of their total genome and are not in themselves capable of causing disease.

Detailed information on the *CP4 EPSPS* and *goxv247* genes, characterisation of the inserted genetic material and the new proteins expressed by Roundup Ready® canola is provided in Appendix 1.

Table 1: Genetic elements and their origin.

Gene	Promoter	Additional Elements	Terminator
<i>CP4 EPSPS</i> <i>Agrobacterium</i> strain CP4	P-CMoVb modified figwort mosaic virus constitutive promoter	AEPSPS/CTP2 <i>Arabidopsis thaliana</i> chloroplast transit peptide	E9 3' <i>Pisum sativum</i>
<i>goxv247</i> <i>Ochrobactrum anthropi</i> strain LBAA	P-CMoVb modified figwort mosaic virus constitutive promoter	Arab-SSU1A/CTP1 <i>Arabidopsis thaliana</i> chloroplast transit peptide	E9 3' <i>Pisum sativum</i>

Method of gene transfer

Roundup Ready® canola GT73 was generated by inserting the genes on a plasmid vector carried by *Agrobacterium tumefaciens* (a bacterium). The vector is ‘disarmed’ since it lacks the genes that encode the tumour-inducing functions of *A. tumefaciens* (see Appendix 1 for details).

Previous releases and international approvals

Previous Australian Releases

Under the former voluntary system overseen by the Genetic Manipulation Advisory Committee (GMAC), Monsanto and Seedex Pty Ltd conducted five limited and controlled releases of Roundup Ready® canola under deliberate release proposals PR-77 (Seedex Pty Ltd, 1997), PR-77X, PR-77X(2), PR-77X(3) and PR-77X(4) (Monsanto, 1998-2001). These trials were carried out in Queensland, New South Wales, Victoria, South Australia, Western Australia, and Tasmania.

The first release in Australia of lines covered by this application was in 1997. All previous releases have been carried out under conditions to limit spread or persistence of the GMO in the environment. Roundup Ready® canola GT73 has been grown in various Australian locations and conditions in New South Wales, Victoria, South Australia, Western Australia, Queensland and Tasmania. In the largest approved trial, the planting area was 150 hectares. No adverse effects on human health and safety or the environment were reported for any of these releases.

On 22 August 2002 the Regulator issued a licence (DIR 011/2001) to Monsanto for a limited and controlled release of Roundup Ready® canola in two consecutive winter seasons. In the winter of 2002 the total trial area was a maximum of 4 hectares on 4 sites in 3 shires in Victoria and South Australia with no one site having an area greater than 1.2 hectares. In the winter of 2003 the total trial area was 32.8 hectares at a maximum of 25 sites in 13 shires in New South Wales, Victoria, Western Australia and South Australia with no one site having a greater area than 5 hectares.

The approvals issued by GMAC and the Regulator included conditions for the management of the trials to minimise the risks posed by the Roundup Ready® canola. Monitoring undertaken by the Interim Office of the Gene Technology Regulator (IOGTR) identified a number of instances of non-compliance with GMAC conditions under deemed licences PR-77X, PR-77X(2), PR-77X(3), and PR-77X(4) as detailed in IOGTR and subsequently OGTR Quarterly Reports (www.ogtr.gov.au/pubform/reports.htm). In some of these instances Monsanto notified the IOGTR of the non-compliance.

Most of the instances of non-compliance related to post-harvest monitoring conditions, in particular the requirement to remove volunteer GM-canola (ie. plants which germinate from fallen seed after the crop has been harvested) from the trial site prior to flowering. In the last of these instances Monsanto elected to destroy the crop when the pollen trap, required by the licence conditions was damaged by herbicide drift. It should be noted that in each instance the IOGTR or the OGTR (in consultation with GMAC or GTTAC respectively) assessed the risks posed to human health and safety and the environment as a result of the non-compliances as negligible. Monsanto undertook additional management actions to minimise any risks, including removal of volunteers and extension of the monitoring period, for example, as a result of an investigation by the OGTR into instances of non-compliance at sites under PR-77X and PR-77X(2) in Tasmania (see www.ogtr.gov.au/pdf/public/tasbreachmonsanto.pdf).

Approvals by Other Australian Government Agencies

The OGTR is responsible for assessing the biosafety risks to human health and the environment associated with development and use of GMOs. Other government regulatory requirements must also be met in respect of the release of the GMOs, and the use of products of the GMO, including the requirements of the Australian Pesticides and Veterinary Medicines Authority (APVMA), formerly National Registration Authority (NRA) and Food Standards Australia New Zealand (FSANZ), formerly Australia New Zealand Food Authority (ANZFA).

Australian Pesticides and Veterinary Medicines Authority (APVMA)

The registration of herbicides is the responsibility of the APVMA. Roundup Ready[®] canola is tolerant to glyphosate, the active constituent of a number of proprietary herbicides including Roundup[®]. The use of Roundup Ready[®] canola will enable glyphosate to be used for the control of weeds that emerge following crop planting. Glyphosate is widely used in a variety of formulations for weed control in broadacre agriculture, horticulture and other situations in Australia.

Glyphosate is not currently registered for 'in crop' use on canola. Monsanto have made a parallel application to the APVMA for a variation of the registration to enable the extension of use of glyphosate under the trade name 'Roundup Ready[®] by Monsanto' for 'over the top' use on Roundup Ready[®] canola. Roundup Ready[®] herbicide is already registered for use on Roundup Ready[®] cotton in Australia. As there is potential for development of herbicide-resistant weeds if the Roundup Ready[®] herbicide is used inappropriately, this issue has been assessed by the APVMA and will be addressed by conditions of registration for the herbicide. Feedback to the Regulator from stakeholders has also raised the issue of inappropriate use of the herbicide leading to resistance. The Regulator strongly supports the APVMA imposing conditions on the application of herbicide to adequately address the possible development of glyphosate resistance associated with any extension of use of the Roundup Ready[®] herbicide to Roundup Ready[®] canola.

Further information about the use and safety of insecticides and herbicides can be obtained from the Australian Pesticides and Veterinary Medicines Authority (APVMA)

PO Box E240 KINGSTON ACT 2604

Phone: (02) 6272 5158

Fax: (02) 6272 4753

Email: contact@apvma.gov.au

<http://www.apvma.gov.au>

Food Standards Australia New Zealand (FSANZ)

The safety and labelling of foods derived from genetically modified plants are the responsibility of FSANZ. Canola is only consumed by humans as oil in Australia. FSANZ have approved the use of oil derived from Roundup Ready[®] canola for use in food in Australia. FSANZ has determined that refined oil derived from Roundup Ready[®] canola is as safe for human consumption as refined oil derived from conventional (non-GM) canola varieties (see Appendix 2). Further details of the risk analysis conducted by FSANZ and information about food labelling are available from Food Standards Australia New Zealand

PO Box 7186 Canberra Mail Centre ACT 2610

Phone: (02) 6271 2222

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E-mail: info@foodstandards.gov.au

<http://www.foodstandards.gov.au>

International Approvals for Roundup Ready® canola

Roundup Ready® canola has been approved for growing and consumption in the US, Canada and Japan and for consumption in Europe. The line GT73 has been approved for food (Table 2), feed (Table 3) and environmental safety (Table 4) are listed below.

Table 2: Food regulatory approvals (oil) obtained for the Roundup Ready® canola

Country	Year Approved
Canada	1994
USA	1995
Japan	1996
European Union	1997
Australia	2000

Table 3: Feed regulatory approvals obtained for Roundup Ready® canola.

Country	Year Approved
USA	1995
Canada	1995
Japan	1996

Table 4: Environmental regulatory approvals obtained for Roundup Ready® canola.

Country	Year Approved
Canada	1995
Japan	1996
USA	1999
Europe*	Pending

* The European Commission has recently revised the relevant legislation see <http://gmo.info.jrc.it>

The National Advisory Commission on Agricultural Biotechnology (Comisión Nacional Asesora de Biotecnología Agropecuaria, CONABIA) in Argentina refused an application for a large field trial (500 hectares) of glyphosate-tolerant canola in 1997. This decision was based on Argentina being the centre of origin of one *Brassica* species and the presence of many other weedy species that are sexually compatible with canola. Additional factors were firstly, concerns regarding the selection of glyphosate-tolerant weeds following the potential increased use of the herbicide, which could only be controlled by less environmentally satisfactory herbicides. Secondly, the apparent intention of the applicant to grow canola off-season to produce bulk seed for export and/or future commercialisation in Argentina. Therefore agronomic and economic factors which are outside the scope of this assessment contributed to this decision in addition to environmental safety. The issues of weediness and gene flow in the Australian environment are considered in detail in Appendices 4 and 5 respectively. The regulation of herbicide usage is the responsibility of the APVMA but is considered briefly in Appendix 6.

No other country is known to have refused an application for the release of Roundup Ready® canola on the basis of risks to human health and safety or the environment. There have been no reports of adverse effects on human health or the environment resulting from the use or release of Roundup Ready® canola in Australia or any other countries in which it has been approved.