



APPLICATION FOR LICENCE FOR INTENTIONAL RELEASE OF GMOs INTO THE ENVIRONMENT: Application No. DIR 069/2006

SUMMARY INFORMATION

Project Title:	Limited and controlled release of GM herbicide tolerant hybrid <i>Brassica napus</i> and hybrid <i>Brassica juncea</i> ¹
Applicant:	Bayer CropScience Pty Ltd
Common name of the parent organisms:	Canola and Indian mustard
Scientific name of the parent organisms:	<i>Brassica napus</i> (L.) oleifera Metzg. <i>Brassica juncea</i> (L.) Czern and Coss.
Modified trait(s):	Herbicide tolerance and hybrid breeding system
Identity of the gene(s) responsible for the modified trait(s):	<ul style="list-style-type: none">• A hybrid breeding system consisting of the <i>barnase</i> (male sterility) and <i>barstar</i> (fertility restorer) genes derived from the bacterium <i>Bacillus amyloliquefaciens</i>• Herbicide tolerance traits²
Proposed Sites:	A maximum total of up to 42 sites (8 sites per winter and 6 sites per summer season) over 6 seasons (2007-10). <i>Shires for Winter trial sites(2007-2009):</i> <u>New South Wales:</u> Coolamon, Greater Hume, Lockhart, Junee, Wagga Wagga and Narrandera <u>South Australia:</u> Kingston, Mount Gambier, Naracoorte/Lucindale, Grant, Robe, Tatiara, and Wattle Range <u>Victoria:</u> Ararat, Corangamite, Hindmarsh, Glenelg, Horsham, Moyne, Northern Grampians, Pyrenees, Southern Grampians, Warrnambool, and Yarriambiack <i>Shires for Summer trial sites (2007-2010):</i> <u>South Australia:</u> Lacedpede, Mount Gambier, Naracoorte/Lucindale, Grant, Robe, Tatiara, and Wattle Range <u>Victoria:</u> Ararat, Glenelg, Moyne, Northern Grampians, Southern Grampians, and Warrnambool
Proposed Release Size:	A maximum total of up to 252 hectares comprising up to 6 hectares per site on up to 42 sites over 6 seasons.
Proposed Release Dates:	April 2007 to May 2010

¹The title of the licence application submitted by Bayer is *Evaluation of herbicide tolerant hybrid Brassica napus and herbicide tolerant hybrid Brassica juncea lines*.

² An application by Bayer to have details of the herbicide tolerance traits declared as CCI by the Regulator is currently under consideration

Introduction

The *Gene Technology Act 2000* (the Act) took effect on 21 June 2001. The Act, supported by the *Gene Technology Regulations 2001*, an inter-governmental agreement and corresponding legislation that is being enacted in each State and Territory, underpins 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 the legislation 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 the requirements for considering applications for licences for dealings with GMOs and the matters that the Regulator must take into account before deciding whether, or not, to issue a licence³.

The application and the proposed dealings

The OGTR has received an application from Bayer CropScience Pty Ltd (Bayer) for a licence for the intentional release of genetically modified (GM) *Brassica napus* (canola) and *B. juncea* (Indian mustard) into the environment on a limited scale and under controlled conditions. The GM canola and Indian mustard lines proposed for release contain introduced genes for herbicide tolerance and a hybrid breeding system comprising male sterile and fertility restoring lines.

The aims of the proposed trial are seed production and the evaluation of agronomic traits such as herbicide tolerance, germination efficiency, and flowering dates in the GM canola and Indian mustard lines, and their respective GM hybrid lines, under Australian cropping systems.

Seeds collected from the GM hybrid canola and Indian mustard lines would be shipped to Canada for further trait evaluation. Bayer envisages that seeds from promising lines may be assessed in subsequent seasons in Australia (subject to further approvals).

Bayer proposes a maximum total area up to 252 hectares spread over up to 42 sites of up to 6 hectares, comprising 8 sites per winter and 6 sites per summer season over the 6 seasons between 2007 and 2010. A total of 24 shires in New South Wales, South Australia and Victoria have been identified as potential sites for the trial.

The applicant has proposed a range of containment measures for the conduct of the field trial that will be considered during the assessment of the application including:

- surrounding the site with a 50m monitoring zone from which related weed species and crop plants would be removed prior to flowering, as well as one of the following measures:
 - *maintaining a 1km isolation zone between the site and any other Brassica crop, or*
 - *surrounding the site with a 15m pollen trap (non-GM canola or Indian mustard) and 400m isolation zone from any other Brassica crop, or*
 - *surrounding the site with a 400m isolation zone from any other Brassica crop if the GMOs at the site are all GM male sterile canola or Indian mustard, or*

³ More information on the assessment of licence applications and copies of the *Risk Analysis Framework* are available from the Office of the Gene Technology Regulator (OGTR). Free call 1800 181 030 or at <http://www.ogtr.gov.au/ir/process.htm> and <http://www.ogtr.gov.au/pdf/public/raffinal2.2.pdf> respectively.

- *surrounding the site with a 400m isolation zone from any other Brassica crop if the GMOs at the site are all covered with selfing bags, minicages or tents*
- cleaning of equipment and destroying all GM plant materials not required for further analysis by methods approved by the Regulator
- monitoring for, and destroying any, volunteer GM *B. napus* and *B. juncea* that may occur in the release area for 3 years on a monthly basis after completion harvest
- specific containment, transport and storage conditions in accordance with OGTR guidelines.

None of the GM canola and Indian mustard plants from the proposed release, or their by-products would be used for stock feed or human food. An approval from FSANZ would be required before oil from the GM lines could be used for human consumption.

The APVMA is responsible for the use and safety of herbicides in Australia. A research permit from the APVMA for use of herbicides in the proposed field trial would be required.

Confidential Commercial Information

Bayer has sought to have certain details declared as Confidential Commercial Information (CCI) under section 185 of the Act. The information requested to be protected includes the herbicide tolerance traits, including gene constructs and plasmid maps, the combination and precise arrangements of these genes with other genetic elements and data on molecular characterisation. The CCI application is currently under consideration, however, the confidential information will be made available to the prescribed expert groups and agencies that will be consulted on the preparation of the risk assessment and risk management plan (RARMP) for this application.

Previous releases of the GMO

GM canola and Indian mustard lines containing the same hybrid breeding system as the GMOs proposed for the current trial have previously been approved for release in Australia. The Regulator issued a licence to Bayer for a limited and controlled release of GM canola and Indian mustard containing the same hybrid breeding system (Licence DIR032/2002 and DIR057/2004, respectively).

InVigor[®] GM canola, which contains the same hybrid breeding system as the GMOs proposed for this trial, was permitted to be trialled under limited and controlled conditions under the former voluntary system that was overseen by the Genetic Manipulation Advisory Committee (GMAC) and by the Regulator (Licence DIR010/2001), and was subsequently approved for commercial release under Licence DIR021/2001.

Several field trials of GM *B. napus*, *B. rapa* and *B. juncea* lines containing the hybrid breeding system were also conducted under the former voluntary system including Planned Release (PR) 62; PR85; and PR90 and extensions to them.

There have been no reports of adverse effects on human health or the environment resulting from any of these previous releases.

Parent organism

The parent organisms are *B. napus* L. oleifera Metzg. and *B. juncea* (L.) Czern. and Coss., commonly known as canola and Indian mustard, respectively. Both species belong to the Cruciferae family (*Brassicaceae*) and are exotic to Australia. In Australia, the generic term 'Indian mustard' is used to include both the Brown and the Oriental mustards. *B. juncea* is closely related botanically to *B. napus* and *B. rapa* (rapeseed, turnip) and has a similar growth

habit. Canola is mainly grown in the NSW, Victoria, SA, and WA, and to a much lesser extent in Tasmania and southern Qld.

Interest in growing Indian mustard as an alternative to canola has recently increased in Australia since higher yielding, enhanced oil content and low erucic acid and glucosinolate varieties are becoming available through conventional breeding programs that aim to develop “canola quality” Indian mustard cultivars.

Genetic modification and its effect

The GM canola and Indian mustard lines proposed for release contain either or both of the *barnase* (male sterile) and *barstar* (fertility restorer) genes derived from the common soil bacterium *Bacillus amyloliquefaceins*.

The BARNASE enzyme encoded by the *barnase* gene, is a ribonuclease, modified to be produced early in the development of the anthers in a specific cell layer, preventing pollen production and thus conferring male sterility. Flower morphology of the selected male sterile line is characterised by the absence of anthers.

Expression of the *barstar* gene (fertility restorer) is also restricted to the anthers by an anther specific promoter. In hybrid plants derived from crosses of male sterile and fertility restorer lines, the BARSTAR protein inhibits the BARNASE enzyme enabling normal anther development and pollen production. These hybrids are therefore fully fertile.

Bayer developed this novel breeding system, based on GM male sterile and fertility restorer lines to emulate the natural phenomenon of hybrid vigour. Traditional plant breeding selects for plants with agronomically valuable characteristics but can also produce highly inbred plants that display lowered fitness or vigour as compared with their non-inbred counterparts. The converse of this, hybrid vigour, can occur when the progeny from crosses of genetically distinct parents outperform the parental lines. Plant breeders have often used male sterile plants to accomplish hybrid seed production on a commercial scale.

The male sterile and fertility restorer lines also contain herbicide tolerance genes that may be used for weed management during the trial.

Some regulatory sequences transferred to the GM canola and Indian mustard plants are derived from plant pathogens. However, these regulatory sequences comprise only a small part of their total respective genome and are not capable of causing diseases.

Method of genetic modification

Herbicide tolerance, male sterility and fertility restorer genes were introduced into non-GM canola plants on six different gene constructs carried by *Agrobacterium tumefaciens* (a soil bacterium) to produce the GM canola lines proposed for release. These constructs are ‘disarmed’ since they lack the genes that encode the tumour-inducing functions of *A. tumefaciens*.

The GM Indian mustard lines were created by crossing plants from the GM canola lines with non-GM Indian mustard plants followed by several generations of backcrossing to the Indian mustard parent.

The GM hybrid canola and GM Indian mustard lines were derived from conventional breeding between selected GM male sterile and GM fertility restorer lines.

Consultation on preparation of the Risk Assessment and Risk Management Plan

The Regulator has made an initial assessment as to whether the proposed release may pose significant risks to human health and safety or the environment, in accordance with section 49 of the Act. Due to the characteristics of the introduced genes, the control measures that have been proposed, and the limited scale and scope of the dealings, **the Regulator has decided that the proposed controlled release does not pose a significant risk to human health and safety or the environment.**

This means that the Regulator is **not required to seek public comment** on the assessment of this proposal until after a risk assessment and risk management plan (RARMP) has been prepared for consultation. In the interim, copies of the application are available on request from the OGTR. Please quote application number DIR 069/2006.

In preparing the RARMP, the Regulator will seek input from a wide range of key stakeholders and expert groups including State and Territory Governments, Australian Government agencies, the Minister for the Environment and Heritage, the Gene Technology Technical Advisory Committee and the relevant local councils. The Regulator will consult again with these prescribed agencies and authorities, as well as the public, in finalising the RARMP, which then forms the basis of her decision whether or not to issue a licence.

At this stage, the consultation version of the RARMP is expected to be released for a six week consultation period in **late January 2007**. 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 from the OGTR, or on the OGTR website.

If you have any questions about the application or the assessment process, please contact the OGTR at:

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