



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

1 December 2004

**APPLICATION FOR LICENCE FOR INTENTIONAL RELEASE OF GMOs INTO THE ENVIRONMENT: Application No. DIR 057/2004**

**SUMMARY INFORMATION**

Project Title:	Field trials of genetically modified herbicide tolerant, hybrid <i>Brassica juncea</i>
Applicant:	Bayer CropScience Pty Ltd 391-393 Tooronga Road East Hawthorn VIC 3123
Common name of the parent organism:	Indian mustard (includes Brown and Oriental mustard)
Scientific name of the parent organism:	<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):	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> and a herbicide tolerance gene.  (Details of the herbicide tolerance gene, gene constructs including the plasmid maps, identity and precise arrangements of the regulatory sequences and the molecular characterisation data have been declared as Confidential Commercial Information. However the CCI will be made available to the various prescribed expert authorities that will be consulted on the preparation of the risk assessment and risk management plan.)
Proposed Location(s)	<b><i>Shires for Winter trials (2005-2008):</i></b> <u>New South Wales:</u> Coolamon, Culcairn, Lockhart, Junee, Wagga Wagga and Narrandera <u>South Australia:</u> Naracoorte/Lucindale, Grant, Wattle Range <u>Victoria:</u> Ararat, Hindmarsh, Glenelg, Horsham, Moyne, Northern Grampians, Southern Grampians and Yarriambiack  <b><i>Shires for Summer trials (2005-2008):</i></b> <u>South Australia:</u> Grant, Naracoorte/Lucindale and Wattle Range <u>Victoria:</u> Glenelg, Moyne, Northern Grampians and Southern Grampians
Proposed Release Size:	Maximum area of 4 hectares/site at 4 sites each in the winter and summer growing seasons.
Proposed Release Dates:	May 2005 to May 2008

## 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 licence.

## 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 juncea* (Indian mustard) into the environment on a limited scale and under controlled conditions. The GM *B. juncea* lines proposed for release have been genetically modified by the introduction of genes for herbicide tolerance and hybrid breeding system based upon seed production (male sterility (MS)/fertility restorer (RF) lines see section below on Genetic Modification).

The main aims of the proposed trials are to evaluate the effectiveness of the herbicide tolerance trait in the field, to observe the agronomic performance of the GM *B. juncea* lines and to increase seed.

Herbicide tolerant, hybrid seeds from GM *B. juncea* lines would be collected and used for future developmental work in Australia (subject to further approvals) and shipped to Canada for further trait evaluation. Bayer envisages that seeds from promising lines identified in Canada may be returned for evaluation in subsequent seasons in Australia.

Bayer also proposes to compare the agronomic performance of *B. juncea* with the GM herbicide tolerant, hybrid canola (*B. napus*), approved for a limited and controlled release under Licence No. DIR032/2003 (this would require a variation to the existing licence), GM herbicide tolerant, hybrid InVigor<sup>®</sup> canola approved under Licence No. DIR021/2001 for commercial release, and conventional canola varieties.

Bayer plans to conduct the field trials at 4 sites in the winter and summer growing seasons of 2005-2008 on a maximum of 4 hectares per site. A total of 17 shires in New South Wales, South Australia and Victoria have been chosen as potential locations for these trials.

Since the research is at a preliminary stage and information on the novel gene constructs is still limited, the applicant has proposed a range of containment measures to restrict the spread and persistence of the genetic material for the GM *B. juncea* in the environment.

None of the GM *B. juncea* plants from the 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 *B. juncea* 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 the herbicide in the trial may be required for the proposed field trials.

## Confidential Commercial Information

Bayer has sought and received approval to have details of the herbicide tolerance gene, gene constructs including the plasmid maps, precise arrangements of the regulatory sequences and data on molecular characterisation as Confidential Commercial Information (CCI) under section 185 of the Act. However, the CCI 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 for this application.

## Previous releases of the GMO

There has been no previous release of the proposed GM herbicide tolerant, hybrid *B. juncea* in Australia. However the Regulator issued a licence to Bayer in March 2004 for a limited and controlled release of GM canola (*B. napus*) containing the same herbicide tolerance and hybrid traits (Licence No. DIR032/2002). The Regulator has also approved releases of:

- InVigor<sup>®</sup> GM canola lines that contained the same hybrid breeding system as the GMO proposed for release but modified to be tolerant to a different herbicide (glufosinate ammonium) for trial under limited and controlled conditions (Licence No. DIR 010/2001 on 30 July 2002) and for commercial release under Licence No. DIR021/2001 on 25 July 2003; and
- Roundup Ready<sup>®</sup> GM canola lines tolerant to the herbicide glyphosate for trial under limited and controlled conditions (Licence No. DIR011/2001 on 22 August 2002) and for commercial release under Licence No. DIR020/2001 on 19 December 2003.

Under the former voluntary system that was overseen by the Genetic Manipulation Advisory Committee (GMAC) several field trials of GM *B. napus*, *B. rapa* and *B. juncea* lines were conducted that include the following Planned Releases (PRs) and extensions to them:

- PR60 - GM *B. napus* lines tolerant to herbicide glufosinate ammonium;
- PR62 - GM *B. napus* lines that contained the hybrid breeding system and tolerance to the herbicide glufosinate ammonium;
- PR77 - GM *B. napus* lines tolerant to the herbicide Roundup Ready<sup>®</sup> ;
- PR85 - GM *B. rapa* lines that contained the hybrid breeding system and tolerance to the herbicide glufosinate ammonium; and
- PR90 and PR93 - GM *B. juncea* lines that contained the hybrid breeding system and tolerance to the herbicide glufosinate ammonium.

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

## Parent organism

The parent organism *B. juncea* (L.) Czern. and Coss., commonly known as 'Indian, Oriental or Brown Mustard', belongs to the Cruciferae family (*Brassicaceae*). 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* (canola) and *B. rapa* (rapeseed, turnip) and has a similar growth habit.

India and Canada produce the bulk of the world's mustard seed. India ranks first and accounts for around 80% of the 4-6 million hectares of oilseed production annually. Canada is the second largest producer where it is predominantly used for oilseed production. In Australia, *B. juncea* has been grown for the past 25 years for cold pressed oil and as a condiment for the spice market. *B. juncea* is generally grown as a winter/spring crop, although it is grown as a summer crop in some states, with major centres of production in western Victoria and central New South Wales. However, the scale of cultivation is very small compared to *B. napus*.

*B. juncea* has been found to be more tolerant to heat and water stress than *B. napus*, matures more quickly and produces seed pods that are less prone to shatter. In addition, it exhibits enhanced yield and biofumigation effects when used as a break crop prior to growing wheat due to more effective suppression of cereal root pathogens.

Interest in growing *B. juncea* as an alternative to *B. napus* has recently increased in western Canada and 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" (CQ) *B. juncea* cultivars. These CQ *B. juncea* cultivars are expected to be demonstrated to farmers in 2005 with commercial release anticipated in 2006.

## Genetic modification and its effect

The herbicide tolerant, hybrid GM *B. juncea* lines contain a gene that confers herbicide tolerance, and the *barnase* and *barstar* genes that form the basis of a novel breeding system which emulates the natural phenomenon of hybrid vigour. Both the genes are derived from a common soil bacterium *Bacillus amyloliquefaciens*.

Bayer's system involves crossing male sterile (MS) lines containing the *barnase* gene with the fertility restorer (FS) lines containing the *barstar* gene.

The *barnase* gene encodes for the Barnase enzyme (a ribonuclease) expressed at the early stage of anther development (the pollen-bearing parts of the flower) in a specific cell layer of the anthers, 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 is also restricted to the anthers by the use of an anther-specific promoter. In hybrid plants derived from crosses of MS and RF lines, the protein expressed by the *barstar* gene inhibits the Barnase enzyme enabling normal anther development and pollen production. These hybrids are therefore fully fertile.

The male sterile and fertility restorer lines have also been genetically modified to contain a herbicide tolerance gene. The herbicide tolerance trait may be used for weed management in the GM *B. juncea* crop.

Some regulatory sequences transferred to the GM *B. juncea* plants are derived from plant pathogens. However, they represent only a very small proportion of the pathogen's genome and the sequences are not, in themselves, infectious or pathogenic.

## Method of genetic modification

The herbicide tolerance gene, the MS gene (*barnase*) and the RF gene (*barstar*) were introduced into *B. napus* lines on plasmid vectors carried by *Agrobacterium tumefaciens* (a soil bacterium). The plasmid vector is disarmed since it lacks the oncogenes that encode the tumorigenic functions of *A. tumefaciens*. The *A. tumefaciens* mediated transformation system is a frequently employed plant transformation method used routinely in many laboratories in Australia and overseas for introducing new genes into plants without causing any biosafety problems.

## 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 low risk potential of the GMO, the control measures that will be imposed, and the limited scale and scope of the dealings, **the Regulator has decided that the proposed 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. In the interim, copies of the application are available on request from the OGTR. Please quote application number DIR 057/2004.

In preparing the RARMP, the Regulator will seek input from a wide range of key stakeholders and expert groups including State and Territory Governments, relevant Australian Government agencies, the Minister for the Environment and Heritage, panel of experts and appropriate local councils. The Regulator will again consult with these prescribed agencies and authorities as well as the public in finalising the RARMP, as required by the Act.

At this stage, the consultation version of the RARMP is expected to be released for an extended **six** week consultation period in **late February 2005**. 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. Summaries and copies of the RARMP 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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