28 March 2007

Technical Summary of the Risk Assessment and Risk Management Plan for Application No. DIR 069/2006 from Bayer CropScience Pty Ltd

INTRODUCTION

The Gene Technology Regulator (the Regulator) has decided to issue a licence (DIR 069/2006) to Bayer CropScience Pty Ltd (Bayer) for dealings involving the intentional release of genetically modified (GM) canola and Indian mustard lines into the environment, on a limited scale and under controlled conditions.

The *Gene Technology Act 2000* (the Act), the *Gene Technology Regulations 2001* (the Regulations) and corresponding State and Territory law govern the comprehensive and highly consultative process undertaken by the Regulator before making a decision whether to issue a licence to deal with a GMO.

The Regulator's *Risk Analysis Framework* explains the approach used to evaluate licence applications and to develop the Risk Assessment and Risk Management Plans (RARMPs) that form the basis of her decisions[1].

This RARMP for DIR 069/2006 has been finalised in accordance with the gene technology legislation. Matters raised in the consultation process regarding risks to the health and safety of people or the environment from the proposed dealings were taken into account by the Regulator in deciding to issue a licence and the licence conditions that have been imposed.

Application

Project Title:	Limited and controlled release of GM herbicide tolerant hybrid *Brassica napus* and *Brassica juncea*[2]
Applicant:	Bayer CropScience Pty Ltd
Common name of the parent organisms:	Canola and Indian mustard
Scientific name of the parent organisms:	*Brassica napus* (L.) oleifera Metzg. *Brassica juncea* (L.) Czern and Coss.
Modified trait(s):	Herbicide tolerance and hybrid breeding system
Identity of the gene(s) responsible for the modified trait(s):	• Hybrid breeding system - *barnase* (male sterility) and *barstar* (fertility restorer) genes derived from the bacterium *Bacillus amyloliquefaciens* • Herbicide tolerance trait - *Details declared Commercial Confidential Information (CCI)*

[1] 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/> and <http://www.ogtr.gov.au/pdf/public/raffinal2.2.pdf>, respectively.

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

Proposed Sites:	A maximum of 42 sites (up to 8 sites per winter and 6 sites per summer season) between 2007 and 2010. ***Shires for Winter trial sites (2007-2009):*** New South Wales: Coolamon, Greater Hume, Lockhart, Junee, Wagga Wagga and Narrandera South Australia: Kingston, Mount Gambier, Naracoorte/Lucindale, Grant, Robe, Tatiara, and Wattle Range Victoria: Ararat, Corangamite, Hindmarsh, Glenelg, Horsham, Moyne, Northern Grampians, Pyrenees, Southern Grampians, Warrnambool, and Yarriambiack ***Shires for Summer trial sites (2007-2010):*** South Australia: Kingston, Mount Gambier, Naracoorte/Lucindale, Grant, Robe, Tatiara, and Wattle Range Victoria: Ararat, Glenelg, Moyne, Northern Grampians, Southern Grampians, and Warrnambool
Proposed Release Size:	A maximum of 252 hectares comprising up to 42 sites of no more than 6 ha.
Proposed Release Dates:	April 2007 to May 2010

Bayer applied for a licence to release GM canola and Indian mustard lines containing introduced genes for herbicide tolerance and a hybrid breeding system into the environment, on a limited scale and under controlled conditions. The trial will take place on a maximum of 252 hectares, comprising up to 42 sites of no more than 6 ha, over 6 seasons between 2007 and 2010. Up to 8 sites per winter and 6 sites per summer season may be used. Potential sites have been identified in 24 shires in New South Wales, South Australia and Victoria.

The GM canola and Indian mustard lines contain either the *barnase* gene or *barstar* gene which confer male sterility (MS) or restore fertility (Rf), respectively, and comprise Bayer's novel hybrid breeding system. Conventional breeding between genetically modified MS and Rf lines results in GM hybrid lines with restored fertility. Bayer intends to release genetically modified MS, Rf and hybrid lines of canola and Indian mustard. All GM canola and Indian mustard lines are herbicide tolerant.

In accordance with the provisions of section 185 of the *Gene Technology Act 2000*, Bayer sought and received approval for details of the trait for herbicide tolerance, including gene constructs and plasmid maps, precise arrangement of the regulatory sequences and data on molecular characterisation to be declared Confidential Commercial Information (CCI). The CCI was made available to the various prescribed experts and agencies that are consulted on the preparation of all RARMPs for DIR applications.

The purpose of the trial is to evaluate agronomic traits such as herbicide tolerance, germination efficiency, and flowering times in the GM canola and Indian mustard lines compared to conventional non-GM canola and Indian mustard, as well as previously approved GM InVigor® canola lines.

Seed of the GM canola and Indian mustard lines will be imported from Canada. Seeds collected during the trial may be shipped back to Canada for further trait evaluation. Bayer envisages that seeds from promising lines may be further assessed in future seasons in Australia (subject to further approvals).

Bayer proposed a number of measures to limit the spread and persistence of the GMO and the introduced genetic materials that have been considered during the evaluation of the application. None of the GM plant materials, or their by-products, will be used for stock feed or human food.

Risk assessment

The risk assessment considered information contained in the application, previous GM canola and Indian mustard assessments, current scientific knowledge, and issues relating to risks to human health and safety and the environment raised in submissions received from consultation with a wide range of prescribed experts, agencies and authorities on the application (summarised in Appendix B of the RARMP). No new risks to people or the environment were identified from the advice received on the consultation RARMP. However, feedback on the consideration of previously raised issues enabled their clarification in the final RARMP.

Two submissions were received from the public on both the application and the consultation RARMP. Summaries of this advice and how it was considered are provided in Appendices C and D of the RARMP, respectively.

A reference document, *The Biology and Ecology of Canola* (Brassica napus) was produced to inform the risk assessment process for licence applications involving GM canola plants. The document is available from the OGTR or from the website <http://www.ogtr.gov.au>.

The hazard identification process considered the circumstances or events by which people or the environment may be exposed to the GMOs, GM plant materials, GM plant by-products, the introduced genes, or products of the introduced genes.

A hazard (source of potential harm) may be an event, substance or organism. A risk is identified when a hazard is considered to have some chance of causing harm. Those events that do not lead to an adverse outcome, or could not reasonably occur, do not advance in the risk assessment process

Nineteen events were identified and assessed whereby the proposed release of the GM canola and Indian mustard lines might give rise to harm to people or the environment.

These 19 events included consideration of whether expression of the introduced genes could result in products that are toxic or allergenic to people or other organisms, alter characteristics that may impact on the spread and persistence of the GM plants, or produce unintended changes in their biochemistry or physiology. In addition, consideration was given to the opportunity for gene flow to other organisms, and its effects if this occurred.

All events were characterised in relation to both the magnitude and probability of harm in the context of the controls proposed by the applicant to limit the spread and persistence of the GMOs in both time and space. This detailed consideration concluded that none of the 19 events gave rise to an identified risk that requires further assessment. The principal reasons comprise:

- the scale of the trial is limited in both area and duration
- containment, monitoring and disposal measures proposed by the applicant to limit the spread and persistence of GM canola and Indian mustard plants
- none of the GM plant materials or products from the GM plants will be used in human food or animal feed

- widespread presence of the same or similar proteins encoded by the introduced genes in the environment and lack of known toxicity or allergenicity from these proteins
- limited capacity of the GM canola and Indian mustard lines to spread and persist in natural ecosystems or undisturbed areas
- limited ability and opportunity for the GM canola and Indian mustard lines to transfer the introduced genes to sexually compatible species or other organisms.

Therefore, as no risks to the health and safety of people, or the environment were identified from the limited and controlled release of the GM canola and Indian mustard lines, the level of risk is considered to be **negligible**.

Risk management

A risk management plan builds upon the risk assessment to consider whether any action is required to mitigate the identified risks, and what can be done to protect the health and safety of people and the environment.

As none of the 19 events that were characterised in the risk assessment process are considered to give rise to an identified risk that requires further assessment, the level of risk to human health and safety and the environment from the release of the GM canola and Indian mustard lines is considered to be **negligible.**

The Regulator's *Risk Analysis Framework* defines negligible risks as insubstantial with no present need to invoke actions for their mitigation. However, containment measures have been imposed to restrict the release to the locations, size and duration requested by the applicant, as these were important parameters in establishing the context for assessing the risks.

Licence conditions to manage this limited and controlled release

A number of licence conditions have been imposed to limit and control the release, including requirements to:

- surround each site with a 50 m monitoring zone from which related weed species and crop plants would be removed prior to flowering, as well as one of the following measures:
  - *maintain a 1 km isolation zone between the site and any other Brassica crop,* ***or***
  - *surround the site with a 15 m pollen trap (non-GM canola or Indian mustard) and 400m isolation zone from any other Brassica crop,* ***or***
  - *surround the site with a 400 m isolation zone from any other Brassica crop if the GMOs at the site are all GM male sterile canola or Indian mustard,* ***or***
  - *surround the site with a 400m isolation zone from any other Brassica crop if all GMOs at the site are covered with cages, tents or selfing bags*[3]
- harvest and store canola and Indian mustard seed from the release separately from commercial Brassica crops
- not permit canola or Indian mustard seed or other materials from the release to be used in human food or animal feed

[3] The purpose of using insect proof cages, tents or selfing bags is to maximise seed purity but as they also reduce pollen flow, the spread and persistence of the introduced genes will also be limited.

- treat all pollen trap plants as if they are GM plants
- destroy all GM plant materials not required for further analysis by methods approved by the Regulator
- following harvest, clean each site, monitoring zone and equipment to remove all GM plant materials
- following cleaning, encourage germination of GM seed through the use of 'light' tillage of each site
- monitor for, and destroy any, volunteer GM *B. napus* and *B. juncea* that may occur at each site for 24 months after harvest and thereafter until the site is free of volunteers for a continuous 12 month period.

The Regulator has issued guidelines and policies for the transport, supply and storage of GMOs (*Guidelines for the transport of GMOs, June 2001; Policy on transport and supply of GMOs, July 2005*). Licence conditions based on these guidelines and policies have also been imposed to control possession, use or disposal of the GMOs for the purposes of, or in the course of, the authorised dealings.

Other regulatory considerations

Australia's gene technology regulatory system operates as part of an integrated legislative framework. The Regulator sought input on the preparation of the RARMP from other agencies that also regulate GMOs or GM products including Food Standards Australia New Zealand (FSANZ), Australian Pesticides and Veterinary Medicines Authority (APVMA), Therapeutic Goods Administration (TGA), National Industrial Chemicals Notification and Assessment Scheme (NICNAS), National Health and Medical Research Council (NHMRC) and Australian Quarantine Inspection Service (AQIS). Dealings conducted under a licence issued by the Regulator may also be subject to regulation by one or more of these agencies[4].

FSANZ is responsible for human food safety assessment, including GM food. The applicant does not intend any material from the GM canola and Indian mustard lines proposed for release to be used in human food. Accordingly the applicant has not applied to FSANZ to evaluate any materials from the trial for use in human food. FSANZ approval would need to be obtained before such materials could be used in human food.

The APVMA is responsible for the use and safety of herbicides in Australia. The canola and Indian mustard lines proposed for release have been genetically modified for herbicide tolerance. Bayer states that the extent of herbicide application to herbicide tolerant GM lines would not exceed 5 ha nationally per annum. Hence it would be authorised under the APVMA's general, small scale trial permit (APVMA Permit 7250).

Bayer has indicated they intend to obtain a permit from AQIS to import seed of the GM canola and Indian mustard lines.

Approval may also be required from the State and Territory Governments that have introduced legislation to delay the commercial introduction of GM canola due to concerns regarding possible market impacts.

[4] More information on Australia's integrated regulatory framework for gene technology is contained in the *Risk Analysis Framework* available from the Office of the Gene Technology Regulator (OGTR). Free call 1800 181 030 or at <http://www.ogtr.gov.au/pdf/public/raffinal2.2.pdf>.

Identification of issues to be addressed for future releases

The risk assessment identified additional information that may be required to assess an application for a larger scale trial, reduced containment measures, or a commercial release of any of these GM canola and Indian mustard lines. These would include:

- molecular characterisation of the introduced genetic materials, genotypic stability, and expression levels of the introduced genes in the GM canola and Indian mustard lines
- data on the potential toxicity of plant material from the GM canola and Indian mustard lines including levels of known endogenous toxins
- data on the viability of Indian mustard pollen
- the level of pollen mediated gene flow between both canola and Indian mustard and closely related plants in Australia
- biochemical, physiological and agronomic characteristics of the GM canola and Indian mustard lines indicative of weediness including measurement of germination, seed dormancy, tolerance to environmental stresses (eg heat, drought or disease) and reproductive capacity (eg growth rate and window of flowering) compared to the non-GM parent lines.

Conclusions of the RARMP

The risk assessment concludes that the limited and controlled release of GM canola and Indian mustard lines containing genes for herbicide tolerance and a hybrid breeding system poses **negligible** risks to the health and safety of people and the environment posed by, or as a result of, gene technology.

The risk management plan concludes that these **negligible** risks do not require specific risk treatment measures. However, licence conditions have been imposed to contain the release to the size, duration and locations requested by the applicant, as these were important parameters in establishing the context for assessing the risks.