Risk Assessment and Risk Management Plan

Application for licence for dealings involving an intentional release into the environment

DIR 032/2002

Title: Field trial - Seed increase and field evaluation of herbicide tolerant genetically modified canola incorporating a hybrid breeding system

Applicant: Bayer CropScience Pty Ltd

March 2004
Abbreviations

AAFC  Agriculture and Agri-Food Canada
APHIS  Animal and Plant Health Inspection Service
APVMA  Australian Pesticides and Veterinary Medicines Authority (formerly NRA)
DIR  dealing involving intentional release
dna  deoxyribonucleic acid
FAO  Food and Agriculture Organisation of the United Nations
FDA  Food and Drug Administration (USA)
FSANZ  Food Standards Australia New Zealand (formerly ANZFA- Australia New Zealand Food Authority)
g  gram
GM  genetically modified
GMAC  Genetic Manipulation Advisory Committee
GMO  genetically modified organism
GTTAC  Gene Technology Technical Advisory Committee
ha  hectare
KD  kiloDaltons
km  kilometre
m  metre
mg  milligram
mRNA  messenger ribonucleic acid
Ms  Male sterile gene
MS  Male sterile line
NRA  National Registration Authority for Agricultural and Veterinary Chemicals
OECD  Organisation for Economic Cooperation and Development
OGTR  Office of the Gene Technology Regulator
PR  planned release
RF  Restoration of fertility gene
RF  Fertility restorer line
RNA  ribonucleic acid
T-DNA  transfer deoxyribonucleic acid
US EPA  United States Environmental Protection Agency
WHO  World Health Organisation
µg  micrograms
µm  micromoles
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EXECUTIVE SUMMARY

INTRODUCTION

The Gene Technology Act 2000 (the Act) and the Gene Technology Regulations 2001 (the Regulations) set out requirements which the Gene Technology Regulator (the Regulator) must follow when considering an application for a licence to intentionally release a genetically modified organism (GMO) into the environment.

For a licence to be issued, the Regulator must be satisfied that the release will not pose any risks to human health and safety or the environment that can not be managed. As part of the evaluation process, section 51 of the Act requires the Regulator to prepare a risk assessment and risk management plan (RARMP) for each licence application, in consultation with a wide range of expert groups and stakeholders.

Under section 52 of the Act, the Regulator is required to seek comment on the RARMP from those consulted in its preparation and to invite submissions from the public. Matters raised relating to the protection of human health and safety or the environment are taken into account in finalising the RARMP, which then forms the basis of the Regulator’s decision on whether, or not, to issue a licence.

The Gene Technology Act 2000 is designed to operate in a cooperative legislative framework with other regulatory authorities that have complementary responsibilities and specialist expertise. As well as enhancing coordinated decision making, this arrangement avoids duplication. The OGTR liaises closely with other regulators to ensure the identification, evaluation and management of risks that may be associated with development and use of gene technology.

The Regulator has made a decision to issue a licence in respect of application DIR 032/2002 from Bayer CropScience Pty Ltd (Bayer).

THE APPLICATION

Bayer has applied for a licence (application DIR 032/2002) for the intentional release, under limited and controlled conditions, of genetically modified (GM) herbicide tolerant canola incorporating a hybrid breeding system into the environment. Bayer proposes to conduct field trials in the three winter and summer seasons during 2004 to 2007 on up to 18 sites covering maximum area of 66 ha. The release is proposed for 17 shires in the canola growing areas of New South Wales, South Australia and Victoria.

In accordance with the provisions of section 185 of the Act, Bayer sought and received approval for details of the gene constructs including the plasmid maps, the identity of the herbicide tolerance gene, regulatory sequences and preliminary analysis data to be declared as confidential commercial information (CCI). While the Regulator was satisfied that the public interest in the release as proposed did not outweigh the prejudice that disclosure would cause the applicant, the CCI was made available to the various prescribed expert groups that were consulted on the preparation of the risk assessment and risk management plan.

The GM canola lines\(^1\) have been modified to introduce a herbicide tolerance gene and a hybrid breeding system based on male sterile (MS: \textit{barnase} gene) and fertility restorer (RF: \textit{barstar}

\(^1\) The term ‘line’ has been used throughout this risk assessment. ‘Line’ is used to denote canola containing a specific genetic modification derived from a single transformation event.
The release will involve up to 70 individual GM canola lines and their progeny derived from conventional crossings. The main aims of the release are to evaluate the agronomic performance of the GM canola lines and their progeny and produce seed of specific crosses. The release is part of early stage research to identify the most promising lines suitable for further development.

Bayer has advised that glasshouse trials of this GM canola have been conducted in Europe and North America and field trials have been conducted in North America. The herbicide tolerance gene contained in this GM canola has not previously been approved for field release in Australia.

However, the Regulator has previously assessed and approved another GM canola (InVigor® canola) containing the barnase and barstar genes and a different herbicide tolerance gene for field trials and commercial release under licence applications DIR 010/2001 and DIR 021/2002, respectively.

There have been no reports of adverse effects on human health or the environment resulting from the field releases of InVigor® canola.

Bayer has advised that the herbicide to which the GM canola lines are tolerant has previously been assessed and registered by the Australian Pesticides and Veterinary Medicines Authority (APVMA) as a proprietary herbicide.

To minimise dissemination of the GMOs and the introduced genetic material, Bayer proposes isolation and containment measures similar to those imposed by the Regulator as licence conditions for previous limited and controlled releases of GM canola. To ensure purity of seed produced from specific crosses and selfings, Bayer also proposes to enclose some experimental plots with minicages and minitents.

None of the GM plants or their by products, would be used for animal feed or human food. However, seed derived from the GM canola trials can be collected and stored for future release in Australia or overseas subject to further approvals.

EVALUATION PROCESS

A risk assessment and risk management plan (RARMP) has been prepared in relation to licence application DIR 032/2002 from Bayer in accordance with the Act and the Regulations, using a Risk Analysis Framework. This framework was developed as part of the establishment of the new regulatory arrangements in consultation with the public, State, Territory and Australian governments, key stakeholders and the Gene Technology Technical Advisory Committee and is available at www.ogtr.gov.au/pdf/public/raffinal.pdf.

Details of the process that the Regulator must follow, including the prescribed consultation process on the application and the matters that she must consider in preparing a RARMP, are set out in Appendix 6 of the RARMP. The complete RARMP can be obtained from the OGTR’s web site at www.ogtr.gov.au or by contacting the Office on 1800 181 030.

The risk assessment considered information relevant to the evaluation of potential impacts on human health and safety and the environment contained in the application (including information required by the Act and the regulations on the GMO, the parent organism, the proposed dealings and containment measures, submissions received during consultation with expert groups and authorities, and current scientific knowledge.
Through this process, potential hazards to human health and safety and the environment that may be posed by the release of the GM canola were identified. These have been evaluated on the basis of the likelihood of each hazard occurring and their likely impact of each hazard would this be realised.

The identified potential hazards relate to:

- **toxicity and allergenicity to humans**: could the GM canola be more toxic or allergenic to humans than non-GM canola as a result of the novel gene products or because of unintended effects?
- **toxicity for other organisms**: could the GM canola be more toxic to other organisms than non-GM canola, as a result of the novel gene products or because of unintended effects?
- **weediness**: could the genetic modification of the GM canola be harmful to the environment by increasing the potential of GM canola to establish as a problem weed?
- **transfer of introduced genes to other organisms**: could the new genes introduced into the GM canola transfer to non GM canola crops, closely related *Brassica* crops, related brassicaceous weeds or other organisms, with any adverse consequences?
- **herbicide resistance**: could weeds develop resistance to the herbicide if the herbicide tolerant GM canola crop-herbicide combination is used inappropriately?

**CONCLUSION OF THE RISK ASSESSMENT**

It is concluded the proposed release of the GM canola lines does not pose significant risks to human health and safety and the environment as a result of the genetic modification. The Regulator has imposed licence conditions to minimise the potential exposure of humans and other organisms and to limit the spread and persistence of the GMOs or the introduced genes in the environment (detailed in Risk Management Section). The assessment of each potential hazard identified above is summarised under a separate heading below.

**Toxicity or allergenicity to humans and other organisms**

The risk that the GM canola will be more toxic or allergenic than non-GM canola is very low. None of the introduced proteins, including the herbicide tolerance protein, have any known toxicity or allergenicity and they do not share amino acid sequence homology with known allergens or toxins.

The release is limited in scale and conditions are imposed to limit the spread of the GMOs and the introduced genes. None of the material from the release will be permitted to be used in human food or animal feed. Therefore, the potential for humans or other organisms to be exposed to the GM canola is very low.

The novel proteins expressed in the GM canola are identical or very similar to these produced by organisms that are naturally widespread in the environment. The level of expression of the introduced proteins is expected to be very low. Toxicity and allergenicity of the BARNASE and BARSTAR proteins have been comprehensively assessed by the Regulator for Bayer’s licence application DIR 021/2002 to commercially release *InVigor®* canola.

Food Standards Australia New Zealand (FSANZ), is responsible for human food safety assessment and FSANZ approval would be needed before products of the GMOs could be used in human food.
**Weediness**

The risk of this GM canola establishing as a weed in the environment is very low and not likely to be greater than that of non-GM canola. Although canola has some traits which are common in weed species, such as pod shattering and induced seed dormancy, canola is a poor competitor outside the agricultural environment and is not considered as a weed of natural undisturbed habitats. The genetic modifications are not expected to change these characteristics and in previous greenhouse and field experiments on this GM canola conducted overseas, no such effects were observed. Although the growth characteristics and agronomic performance of the GM hybrid lines are expected to be within the range of conventional canola hybrids, the licence conditions contain a requirement to collect data that there is no unintended increase in weediness.

The presence of the herbicide tolerant gene in the GM canola lines only confers a selective advantage in the presence of the herbicide. The GM canola lines remain susceptible to all other herbicides and non-chemical methods used to control conventional canola. Management measures to manage any potential weediness include the removal of all volunteers from the release sites after harvest.

**Gene transfer**

Canola is 70% self-pollinating, but it can exchange pollen or out-cross with other canola plants, particularly those in close proximity. However, the overall frequency of out-crossing is very low, decreasing significantly at distances over 5-10m and decreasing further to less than 0.01% at greater distance from the pollen source.

The hybrid vigour of the GM canola in this release is not a direct function of the genetic modification but results from the breeding of the two genetically distinct parent lines, hence it cannot be transferred.

However, under uncontrolled conditions, transfer of the herbicide tolerance gene to other canola crops growing nearby would be likely to occur at very low frequencies. Transfer of the introduced genes would not confer selective advantage in the absence of the herbicide to which the GM canola is tolerant. If these recipient canola crops were also herbicide tolerant, this could result in offspring tolerant to multiple herbicides (gene stacking).

The limited size of the trial sites would only comprise small pollen sources and containment measures are imposed to minimise the likelihood of gene transfer. In addition, as part of the OGTR’s commitment to ongoing review of data, research conditions are also imposed to confirm previous research on out-crossing rates.

The likelihood of gene transfer between the GM canola and other compatible species is lower than to other canola. Interspecific hybrids occur rarely, display reduced fitness and there is limited evidence of successful gene introgression (ie incorporation of the genes into subsequent generations).

The risk of transfer of genes from GM canola to other organisms other than sexually compatible species is considered to be negligible, as there are no reports of this occurring in nature and because of sexual incompatibility.

**Herbicide resistance**

Bayer does not plan to apply the herbicide to which the GM canola is tolerant in total areas greater than 1 ha/jurisdiction/annum and more than 5 ha/annum nationally. Therefore, Bayer does not require a specific permit to use the herbicide on this GM canola field trial from the Australian Pesticides and Veterinary Medicines Authority (APVMA) which regulates...
agricultural chemical use, including herbicides under the Agricultural and Veterinary Chemical (the Code) Act 1994. The limited scale of herbicide application would be covered by the general small-scale trial permit TMP0001A issued by the APVMA.

The likelihood of herbicide resistant weeds developing as a result of the trial is negligible, given their overall small scale and the limited application of the herbicide.

**THE RISK MANAGEMENT PLAN**

As part of the evaluation process for this licence application, a risk management plan has been developed to address the risk identified (refer to Conclusions of the Risk Assessment, above). This plan will be given effect by the licence conditions imposed. The key licence conditions are outlined below.

**Toxicity or allergenicity to humans**

Licence conditions have been imposed which require the applicant to:

- limit the scale of the release;
- prevent the GMOs and their products being used for human food;
- ensure secure transport and storage of the GMOs; and
- destroy all GM material not required for this or subsequent releases (which would be subject to separate applications and assessments) after harvest.

**Toxicity to other organisms**

Licence conditions have been imposed which require the applicant to:

- limit scale of the release;
- prevent the GMOs and their products being used as animal feed;
- destroy all GM material not required for this or subsequent releases (which would be subject to separate applications and assessments) after harvest; and
- require secure transport and storage of the GMOs.

**Weediness**

Licence conditions have been imposed which require the applicant to:

- limit the scale of the release;
- conduct research to detect changes to phenotypic characteristics associated with weediness;
- ensure secure transport and storage of the GMOs;
- clean equipment used at release sites; and
- clean and monitor the release sites after harvest and destroy all volunteers.

**Transfer of introduced genes to other organisms**

Licence conditions have been imposed which require the applicant to:

- limit the scale of the release;
- surround the GM canola by a pollen trap, and an isolation zone (including the monitoring zone);
conduct studies on out-crossing to confirm previous research;

- destroy sexually compatible *Brassica* plants including canola and brassicaceous weeds in the monitoring zone surrounding the trial site during the release;

- ensure secure transport and storage of the GMOs;

- clean equipment used at release sites; and

- monitor release sites after harvest and destroy all volunteers.

**Herbicide resistance**

No conditions have been imposed in relation to managing herbicide resistance development, as the risk was assessed as negligible.

**General conditions**

The licence issued by the Regulator also contains a number of general conditions, which are relevant to risk management. These include, for example:

- identification of the persons or classes of person covered by the licence;

- a requirement that the applicant allow access to the release sites by the Regulator, or persons authorised by the Regulator, for the purposes of monitoring or auditing; and

- a requirement to inform the Regulator if the applicant becomes aware of any additional information about the risks to human health and safety or to the environment.

**Additional data**

The release represents the early stages of a breeding program to identify promising lines for further development and many of the lines for this release will be screened out on the basis of the research results. The limited data available on expression and molecular characterisation of the introduced genes for these lines was collected in glasshouse and field trials overseas. Although these showed no unintended effects on plant properties, genes inserted by genetic modification can have an influence on multiple, sometimes unrelated plant traits. Unintended effects of the inserted genes may result in changes to characteristics that affect toxicity or allergenicity to humans, toxicity to other organisms, or weediness. Accordingly, further information will be collected during the trialling process to ascertain that there are no unintended effects in lines selected for further development.

While not necessary for managing the risks posed by this particular release, further data would also be required before any future application for significantly larger scale trials or requests for reduced containment conditions could be evaluated. Further relevant data that will be required includes:

- molecular characterisation of the introduced genetic material and insertion in the genome;

- the levels of expression of the introduced genes in various tissues and seasonal variation under Australian field conditions;

- potential toxicity and allergenicity of the herbicide tolerance protein to humans and other organisms; in addition to

- unintended effects of the genetic modification on toxicity or weediness.
Monitoring and enforcement of compliance by the OGTR

As well as legislative capacity to enforce compliance with licence conditions, the Regulator has additional options for risk management. The Regulator can direct a licence holder to take any steps the Regulator deems necessary to protect the health and safety of people and the environment. The OGTR also independently monitors releases that the Regulator has authorised. At least 20% of all field trial sites will be inspected each year, in accordance with a monitoring and compliance strategy based on risk profiling (which takes into account biological seasonal, geographical and ecological risk factors) to determine whether licence holders are complying with the licence conditions, or whether there are any unforseen problems.
CHAPTER 1 BACKGROUND

1 This chapter provides background information about the application and previous releases of relevant genetically modified organisms (GMOs) into the environment.

SECTION 1 THE APPLICATION

2 The OGTR has received an application (licence application number DIR 032/2002) from Bayer CropScience Pty Ltd (Bayer) for the intentional release of genetically modified (GM) herbicide tolerant canola incorporating a hybrid breeding system into the environment, on a limited scale and under controlled conditions. Key information on the application is given below.

Project Title: Field trial - Seed increase and field evaluation of herbicide tolerant genetically modified canola incorporating a hybrid breeding system
Applicant: Bayer CropScience Pty Ltd
391-393 Tooronga Rd
East Hawthorn VIC 3123

Common name of the parent organism: Canola
Scientific name of the parent organism: Brassica napus L.
Modified traits: Hybrid breeding system and herbicide tolerance

Identity of the genes responsible for the modified traits:

- barnase gene: from the bacterium Bacillus amyloliquefaciens (male sterility, hybrid breeding system)
- barstar gene: also derived from B. amyloliquefaciens (fertility restorer, hybrid breeding system)
- A herbicide tolerance gene

Proposed Location

Shires for Winter trials:
Victoria: Ararat, Hindmarsh, Glenelg, Horsham, Moyne, Northern Grampians, Southern Grampians and Yarrambiaek
New South Wales: Coolamon, Culcairn, Lockhart, Junee, Wagga Wagga and Narrandera
South Australia: Naracoorte/Lucindale

Shires for Summer trials:
Victoria: Glenelg
South Australia: Grant, Naracoorte/Lucindale and Wattle Range

Proposed Size of Release: A maximum of 66 ha comprising 12 sites in winter and 6 sites in summer over 3 years (details in Table 1)

3 In accordance with section 185 of the Act, Bayer sought and received approval for details of the gene constructs including the plasmid maps, the identity of the herbicide tolerance gene, regulatory sequences and preliminary analysis data to be declared as Confidential Commercial Information (CCI). However, the CCI was made available to the various prescribed expert groups that were consulted on the preparation of the risk assessment and risk management plan.

Section 1.1 The proposed dealings

4 The main aim of the release is to evaluate the agronomic performance of up to 70 canola lines and their progeny to identify the most promising lines for future development and to produce seed for future releases, (which would require further licence applications and separate assessment). None of the canola plants from the release or their by-products, will be used for human food or animal feed.

5 Field trials for the release will occur in the winter seasons 2004, 2005, 2006 and summer seasons 2004/5, 2005/6, 2006/7 on a maximum of 18 sites selected from 17 shires in New South Wales, Victoria and South Australia, covering a maximum total area of 66 ha (see Table 1, below)

Table 1 Maximum release areas and seasons

<table>
<thead>
<tr>
<th>Season</th>
<th>Site no./year</th>
<th>Area (ha)/site</th>
<th>Total area (ha)/year</th>
<th>Planting seasons (no.)</th>
<th>Total area (ha)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Winter</td>
<td>4</td>
<td>4</td>
<td>16</td>
<td>3</td>
<td>48</td>
</tr>
<tr>
<td>Summer</td>
<td>2</td>
<td>3</td>
<td>6</td>
<td>3</td>
<td>18</td>
</tr>
<tr>
<td>Total</td>
<td>6</td>
<td>-</td>
<td>22</td>
<td>6</td>
<td>66</td>
</tr>
</tbody>
</table>

6 As the research is at a preliminary stage and information on the GM canola lines is still limited, the applicant has proposed a range of containment measures to restrict the spread and persistence of the genetic material from the GM canola in the environment.

Section 1.2 Parent organism

7 The parent organism is cultivated canola (*Brassica napus* L.). This species is exotic to Australia but is currently grown commercially, as an agricultural crop, in the winter production cereal belt of southern Australia. More detailed information on canola can be found in a review document ‘The Biology and Ecology of Canola (*Brassica napus*)’ (OGTR 2002) that was produced in order to inform the risk assessment processes for licence applications involving GM canola. This document is available at www.ogtr.gov.au.

Section 1.3 Genetic modifications and their effects

8 The GM canola has been modified to incorporate a hybrid breeding system based on the introduction of the *barnase* (male sterile) and the *barstar* (fertility restorer) genes derived from *Bacillus amyloliquefaceins* and a herbicide tolerance gene.

9 Bayer has developed a novel breeding system, based on genetically modified male sterile (MS) and fertility restorer (RF) lines to emulate the natural phenomenon of hybrid vigour. Crosses of the male sterile line with the fertility restorer line ensure the production of fertile hybrids. It is this resultant hybrid seed that is employed in agricultural production.

10 The MS lines express the *barnase* gene encoding the BARNASE enzyme that prevents pollen production and thus confers male sterility by resulting in production of flowers without anthers.
The RF lines express the barstar gene encoding the BARSTAR protein, which is a specific inhibitor of BARNASE. 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.

In each of the MS and RF plasmid constructs, the barnase or barstar gene is linked to a gene which confers tolerance to a proprietary herbicide. The herbicide tolerance trait was used for selection of transformed plants, for ensuring purity of hybrid seed production and to eventually enable post emergent weed control in canola crops.

The MS and RF plasmid constructs also contain short regulatory sequences and other genetic elements that control, maximise and stabilise the expression of the introduced genes but are not translated into proteins. One of the regulatory sequences is derived from the plant pathogen Agrobacterium tumefaciens. However, the regulatory sequence comprises only a small part of the total genome and is not capable of causing disease.

Further information on the introduced genetic material and the new proteins expressed by the GM canola is provided in Appendix 1.

Method of gene transfer

The herbicide tolerance gene, the male sterility (barnase) gene and the fertility restorer (barstar) gene were introduced into the canola lines on plasmid vectors carried by Agrobacterium tumefaciens (a bacterium). The vector is ‘disarmed’ since it lacks the genes that encode the tumorigenic functions of A. tumefaciens. This type of vector has been used frequently in Australia and overseas, without causing any biosafety problems, for introducing new genes into plants (see Appendix 1 Section 4 for details).

Previous releases and international approval

Previous Australian release of similar GM canola

There have been no previous releases of this GM canola in Australia. The herbicide tolerance gene has not been assessed by the Regulator before, however, the Regulator has previously assessed InVigor® canola which incorporates the barnase and barstar genes but is tolerant to a different herbicide (glufosinate ammonium) under licence applications DIR 010/2001 and DIR 021/2002.

The Regulator recently approved the commercial release of InVigor® canola (DIR 021/2002) concluding that it was as safe to humans and the environment as conventional canola. However, full-scale introduction has been delayed by measures imposed by various State Governments pending the resolution of market impact and segregation issues. Limited and controlled releases of InVigor® canola have occurred in Australia during 2001-2003 under licence DIR 010/2001 and during 1996-2001 under the former voluntary system overseen by the Genetic Manipulation Advisory Committee (GMAC) (PR 62 and PR-63 and extensions).

Approvals by other Australian government agencies

The OGTR is responsible for assessing the risks to human health and the environment associated with development and use of gene technology. Other government regulatory requirements must also be met in respect of the release of the GMOs, and the use of products of the GMOs, in this instance the requirements of Food Standards Australia New Zealand (FSANZ) and the Australian Pesticides and Veterinary Medicines Authority (APVMA) are relevant.
Section 2.2.2 Food Standards Australia New Zealand

19 FSANZ is responsible for human food safety assessment and labelling. FSANZ approval would need to be obtained before any material from the GM canola for this release under this application could be used for human food. Given the early stage of this research, the applicant has not submitted an application to FSANZ and the licence conditions prohibit the entry of the GMOs into the human food.

20 Further information about FSANZ’s assessment is available from FSANZ:

Food Standards Australia New Zealand
PO Box 7186
Canberra Mail Centre ACT 2610
Phone (02) 6271 2222
Fax (02) 6271 2278
E-mail info@foodstandards.gov.au
http://www.foodstandards.gov.au

Section 2.2.3 Australian Pesticides and Veterinary Medicines Authority

21 The APVMA is responsible for regulating agricultural chemical use, including herbicides, in Australia under the Agricultural and Veterinary Chemicals (the Code) Act 1994. For commercial products, the normal form of approval for use on a commercial scale is through registration, but the APVMA may also issue research permits allowing restricted use of an agricultural chemical, for example for a limited period of time or on a limited area.

22 The current registration for the proprietary herbicide to which the GM canola is tolerant does not include its use on these GMOs. A specific permit is not required from the APVMA during these trials as the rate of application will not exceed 1 ha/jurisdiction/annum and more than 5 ha/annum nationally. This limited use is covered by the general small-scale trial permit: TMP0001A issued by the APVMA (NRA 1999). If further applications proposed herbicide use in excess of this limit, the APVMA and the OGTR would work closely together to ensure thorough coordinated assessments are undertaken and, wherever possible, that timing of assessments and decisions by both agencies coincide.

23 In considering applications for registrations or permits, the APVMA also considers a number of issues that are outside the scope of the Gene Technology Regulator’s assessment, such as occupational exposure and the efficacy of herbicides and insecticides and resistance development. The APVMA can impose conditions on the use of herbicides and insecticides for both registrations and permits.

24 Further information about the APVMA’s assessment is available from the APVMA:

Australian Pesticides and Veterinary Medicines Authority
PO Box E240
KINGSTON ACT 2604
Phone: (02) 6272 5158
Fax: (02) 6272 4753
Email: contact@apvma.gov.au
http://www.apvma.gov.au
Section 2.3 International approval

25 The GM canola for this release has not been commercially released elsewhere. However, some glasshouse trials have been conducted in North America and Europe and field trials have been conducted in North America.

26 A number of InVigor® GM canola lines containing the barnase and barstar genes and herbicide tolerance genes which detoxify glufosinate ammonium have been approved for growing and consumption in Canada, Japan and the USA (further detail is provided in the RARMP for DIR 021/2002 available at www.ogtr.gov.au or from the OGTR).
CHAPTER 2  SUMMARY OF THE RISK ASSESSMENT AND RISK MANAGEMENT PLAN

27  The Act and the Regulations require that risks associated with dealings with GMOs are identified and assessed as to whether they can be managed to protect human health and safety and the environment (see Appendix 6).

SECTION 1  ISSUES RAISED IN SUBMISSIONS ON THE APPLICATION AND THE RISK ASSESSMENT AND RISK MANAGEMENT PLAN

28  Comments received in response to the consultation with expert groups and authorities on the preparation of the risk assessment and risk management plan (RARMP) under section 50 of the Act, and with the same stakeholder and the public on the RARMP, under section 52 of the Act (see Appendix 6) were very important in finalising the plan, which formed the basis of the Regulator’s final decision on the application.

29  Written submissions in relation to DIR 032/2002 received from the agencies and authorities raised the following issues relating to human health and safety to the environment, which have been addressed in the RARMP:

- the potential toxicity and allergenicity of the GM canola (Appendix 2, Section 2.2 refers);
- the potential for increased weediness of the GM canola (Appendix 3, Section 2.2 refers);
- possible adverse environmental impact from possible agronomical characteristic changes by the gene modification (Appendix 3, Section 2.2 refers);
- potential for transfer of the introduced genes to other canola crops, related crops and weedy relatives (Appendix 4, Section 2.2 refers);
- potential for adverse impacts arising from gene transfer to other organisms (Appendix 4 refers);
- the efficacy of the containment measures imposed under the licence conditions (Appendices 3, 4 and 5 refer);
- the adequacy of post harvest monitoring and volunteer management strategy (Appendices 3, 4 and 5 refer);
- data requirements under the current licence conditions and for the future development of the GMOs (Chapter 2 and Appendix 5 refer).

30  Submissions from agencies also raised other issues such as environmental impact of the herbicide used with the GM canola. Although the regulation of herbicides is the responsibility of the APVMA, the OGTR and the APVMA liaise extensively during the evaluation of applications. However, in this instance, the small amount of herbicide that will be applied during the trials does not require specific APVMA approval and the potential for adverse environmental impacts is considered negligible.

31  In total the Regulator received 7 submissions from the public on this risk assessment and risk management plan. A summary of these written submissions is provided in Appendix 7. The key issues raised by the public that related to human health and safety or the environment were:

- environmental impact from the release of the GMOs (Appendices 2, 3 and 4 refer)
- potential for adverse impacts arising from gene transfer (Appendix 4 refers);
➢ the efficacy of the containment measures imposed under the licence conditions (Appendix 5 refers); and

➢ the adequacy of post harvest monitoring and volunteer management strategy (Appendix 5 refers).

32 Public submissions also raised issues such as responsibility and liability for GM canola contamination, ensuring co-existence of GM and non-GM canola, marketability of produce both locally and overseas, a moratorium of the GM crops, ethical concerns and pesticides/herbicide residue in GM products which are outside the scope of evaluation conducted under the Act and therefore have not been considered as a part of the risk assessment process.

33 In accordance with section 56 of the Act, the Regulator has taken into account all issues raised in written submissions that related to the protection of human health and safety and to the environment in finalising the risk assessment and the risk management plan. These issues were considered carefully and weighed against the body of current scientific information in reaching the conclusions set out in this document.

SECTION 2 FINALISATION OF THE RISK ASSESSMENT AND THE RISK MANAGEMENT PLAN

34 The Regulator has conducted a risk assessment in relation to the proposed dealings and prepared a risk management plan in accordance with the Act and the Regulations. The risk assessment process used a Risk Analysis Framework developed in consultation with the public and key stakeholders (available from the OGTR website www.ogtr.gov.au). A number of hazards were identified that may be posed by the proposed dealings. The risks posed by these hazards were assessed as being either ‘negligible’, ‘very low’, ‘low’, ‘moderate’, ‘high’ or ‘very high’ by considering:

➢ the likelihood of the hazard occurring; and

➢ the likely consequences (impact) of the hazard, were it to be realised.

35 The following table (Table 2) lists each of the hazards that were considered during the risk assessment process in the Hazard Identification column and summarises the assessment of each hazard under the column headed Risk. A comprehensive assessment of each identified hazard is provided in Appendices 2-5, as cross-referenced in the column headed Summary of Risk Assessment.

36 Where it is considered that risk management is required to protect the health and safety of humans and/or the environment, the Risk management column identifies the selected methods and the reasons they were chosen. The risk management plan for the proposed dealing is given effect by specific conditions within the licence. These conditions are summarised in the final column, headed Licence Conditions, and detailed in Appendix 5.

SECTION 3 RESEARCH REQUIREMENTS

37 During the proposed release, the licence conditions include the requirement that the applicant collect and provide to the Regulator further information regarding:

➢ stability of the inserted genes over generations under Australian field conditions; and
potential weediness of the GM canola including pod shattering, susceptibility to pests, seed dormancy, early seedling establishment, flowering period and yield components of the most promising lines.

38 As part of the OGTR’s ongoing commitment to the review of data, research conditions are also imposed under the licence conditions to confirm previous research on gene flow.

SECTION 4 FUTURE RESEARCH REQUIREMENTS

39 This limited and controlled release is a limited scale release (maximum 4 ha/site). Bayer’s trials are at an early stage of research with the aim of selecting lines for further development by breeding and selecting the GM canola lines most suitable for Australian agriculture and producing seed for future trials in Australia and overseas. Many of the lines in this release will be screened out by the trialling process. If the applicant makes any applications for future larger scale or commercial releases of GM canola lines selected from these trials, more data will be required on:

- molecular characterisation of the introduced genetic material and insertion in the genome;
- the levels of expression of the introduced genes in various tissues and with seasonal variation under Australian field conditions;
- the potential toxicity and allergenicity of the introduced proteins to humans and other organisms; and
- other unintended effects of the genetic modification.

40 It should be noted that the collection of the above data during the release is not required to ensure the management of risks to human health and safety and the environment from the release. The risk management measures summarised in the Table 2 below and given effect by the licence conditions, will achieve this purpose.

41 It should also be noted that the use of the GM canola in food would require approval from FSANZ.

SECTION 5 DECISION ON THE APPLICATION

42 Details of the matters that the Regulator must consider in making a decision are provided in Appendix 6. It is important to note that the legislation requires the Regulator to base the licence decision on whether risk posed by the dealings are able to be managed so as to protect human health and safety and the environment.

43 It is concluded the proposed release of the GM canola lines does not pose significant risks to human health and safety and the environment as a result of the genetic modification. The Regulator has imposed licence conditions to minimise potential exposure of humans and other organisms, and to limit the spread and persistence of the GMOs or the introduced genetic materials while additional data is collected on the behaviour of the GMOs in the Australian environment. Detailed risk analyses based on the available scientific information are provided in Appendices 2-5 in support of this conclusion.

44 Therefore the Regulator has issued licence DIR 032/2002 in respect of this application.
### Table 2  Summary of the risk assessment and the risk management plan (including licence conditions)

GMOs, GM canola: the genetically modified canola proposed for release
BARNASE: an enzyme expressed in tapetum cells that confers male sterility in the GM canola lines
BARSTAR: an enzyme expressed in tapetum cells that restores fertility in the GM canola lines
N/A: not applicable

<table>
<thead>
<tr>
<th>Hazard identification</th>
<th>Risk (combines likelihood &amp; impact)</th>
<th>Summary of Risk Assessment (Refer to appendices for details)</th>
<th>Does risk require management?</th>
<th>Risk management (RM) Method(s) and Reason(s) for Selection</th>
<th>Is risk managed?</th>
<th>Licence conditions (see Appendix 5 for details)</th>
</tr>
</thead>
</table>
| Toxicity or allergenicity for humans: Food | Very low | **See Appendix 2**
- introduced proteins are not known to be toxic or allergenic to humans and there are no indications of structural homology to any known toxins or allergens;
- humans are commonly exposed to identical, or very similar proteins, that are naturally widespread in the environment;
- proteins are expected to be expressed at very low levels;
- BARNASE and BARSTAR are both rapidly degraded in simulated gastric conditions;
- exposure of humans to the GM canola will be minimal as the release is small in scale and none of the GM materials will be used for human food. | Yes | • **limit scale of release**: decreases likelihood of exposure;
• **prevent the GMOs and its products from entering the human food supply**: prevents exposure through food;
• **ensure secure transport and storage of the GMOs**: prevents unintended exposure;
• **destroy all seed not required for future trials**: prevents unintended exposure. | Yes | • **Limit scale**: restrict area to no more than 4 ha/site on maximum 6 individual sites per year;
• **Prevent entry into human food supply**: the licence holder must ensure that the GMOs, material from the GMOs and pollen trap plants are not consumed by humans.
• **Secure transport and storage**: GMOs must not be transported unless contained within a primary sealed container packed into a secondary unbreakable container; only transport to the extent necessary; store in sealed container within a lock facility that is signed to indicate GM canola is stored within.
• **Destroy seed**: destroy all seed not required for future trials. |
<table>
<thead>
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</tr>
</thead>
</table>
| Toxicity or allergenicity for humans: Occupational exposure | Very low | See Appendix 2  
• introduced proteins are not known to be toxic or allergenic to humans;  
• though some individuals may be allergic to conventional canola pollen, the introduced proteins are unlikely to increase the allergenic effect;  
• humans are commonly exposed to identical, or very similar proteins that are naturally widespread in the environment;  
• introduced proteins are expected to be expressed at very low levels;  
• no known report of allergenicity caused by exposure to the GM canola in trials conducted overseas;  
• exposure to the GM canola will be limited due to the small scale of the release. | Yes | As for Toxicity and Allergenicity to Humans – food (see above).  
• report any adverse impacts on human health and safety: ensure identification of unexpected adverse impacts | Yes | As for Toxicity and Allergenicity to Humans – food (see above).  
• Report adverse impacts: any adverse impacts on human health and safety must be reported to the Regulator. |
<table>
<thead>
<tr>
<th>Hazard identification</th>
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<th>Summary of Risk Assessment (Refer to appendices for details)</th>
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<th>Licence conditions (see Appendix 5 for details)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Toxity for Other Organisms: Mammals (including wildlife) Invertebrates and Micro-organisms</td>
<td>Very low</td>
<td>See Appendix 2</td>
<td>Yes</td>
<td>limit scale of the release decreases likelihood of exposure; prevent the GMOs and their products from entering the animal feed: prevents exposure through feed; ensure secure transportation and storage: prevents unintended exposure; destroy all seed not required for future trials: prevents unintended exposure; clean equipment and release sites including pollen trap: decreases likelihood of exposure.</td>
<td>Yes</td>
<td>Limit scale: restrict area to no more than 4 ha/site on maximum 6 individual sites per year; Prevent entry into animal feed supply: the licence holder must ensure that the GMOs, material from the GMOs and pollen trap plants must not be consumed by animals. Secure transport and storage: GMOs must not be transported unless contained within a primary sealed container packed into a secondary unbreakable container; only transport to the extent necessary; store in sealed container within a lock facility that is signed to indicate GM canola is stored within. Destroy seed: destroy all seed not required for future trials. Clean equipment and release sites and pollen trap: clean equipment used in the release and destroy the GMOs from the release site when no longer required.</td>
</tr>
</tbody>
</table>

**Summary of Risk Assessment**

- introduced proteins show no sequence homology to any known toxins;
- proteins are expected to be expressed at very low levels;
- identical or very similar proteins are already widespread in the environment;
- none of the GM canola or its by-products will be used for animal feed;
- exposure is limited by small scale of the release.

**Risk management (RM)**

- limit scale of the release decreases likelihood of exposure;
- prevent the GMOs and their products from entering the animal feed: prevents exposure through feed;
- ensure secure transportation and storage: prevents unintended exposure;
- destroy all seed not required for future trials: prevents unintended exposure;
- clean equipment and release sites including pollen trap: decreases likelihood of exposure.

**Licence conditions**

- Limit scale: restrict area to no more than 4 ha/site on maximum 6 individual sites per year;
- Prevent entry into animal feed supply: the licence holder must ensure that the GMOs, material from the GMOs and pollen trap plants must not be consumed by animals.
- Secure transport and storage: GMOs must not be transported unless contained within a primary sealed container packed into a secondary unbreakable container; only transport to the extent necessary; store in sealed container within a lock facility that is signed to indicate GM canola is stored within.
- Destroy seed: destroy all seed not required for future trials.
- Clean equipment and release sites and pollen trap: clean equipment used in the release and destroy the GMOs from the release site when no longer required.
### Summary of Risk Assessment

<table>
<thead>
<tr>
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</thead>
<tbody>
<tr>
<td>Weediness Potential:</td>
<td>Very Low</td>
<td>See Appendix 3</td>
<td>Yes</td>
<td>limit scale of release site: decreases likelihood of spread and persistence;</td>
<td>Yes</td>
<td>Limit scale: restrict area to be no more than 4 ha/site on maximum 6 individual sites per year;</td>
</tr>
<tr>
<td>Spread and persistence in the environment</td>
<td></td>
<td></td>
<td></td>
<td>light tillage: reduces soil seed bank and limits development of secondary dormancy;</td>
<td></td>
<td>Light tillage: Location and pollen trap must be lightly tilled twice after harvest;</td>
</tr>
<tr>
<td></td>
<td></td>
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<td></td>
<td>ensure secure transport and storage of the GMOs: prevents spread of the GMOs;</td>
<td></td>
<td>Secure transport and storage: GMOs must not be transported unless contained within a primary sealed container packed into a secondary unbreakable container; only transport to the extent necessary to store; store in sealed container within a lock facility that is signed to indicate GM canola is stored within;</td>
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<tr>
<td></td>
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<td></td>
<td>destroy all seed not required for future trials: prevents spread of the GMOs;</td>
<td></td>
<td>Destroy GMOs: any GMOs or material from GMOs not required for analysis or future planting must be destroyed after harvest;</td>
</tr>
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<td></td>
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<td></td>
<td></td>
<td>clean equipment and release sites: minimises the spread and persistence of the GMOs;</td>
<td></td>
<td>Clean equipment used at the release site: equipment must be cleaned before it is used for any other purpose;</td>
</tr>
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<td></td>
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<td></td>
<td>post-harvest inspection: minimises persistence and spread of the GMOs;</td>
<td></td>
<td>Post-harvest inspection: release sites must be monitored after harvest at least once every 35 days for a period of at least 3 years and any volunteers identified must be destroyed before flowering; and ensure that crops sown after the trial would allow ready detection of the GMOs;</td>
</tr>
<tr>
<td></td>
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<td></td>
<td></td>
<td>require data collection on weediness potential: collect data on phenotypic characters to ascertain whether there is any unintended effect which may lead to weediness potential;</td>
<td></td>
<td>Data collection: Collect data on phenotypic characteristic which may enhance weediness potential during this release.</td>
</tr>
<tr>
<td>Hazard identification</td>
<td>Risk (combines likelihood &amp; impact)</td>
<td>Summary of Risk Assessment (Refer to appendices for details)</td>
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</tbody>
</table>
| Gene Transfer: To other canola | Very low | • See Appendix 4  
  
  - canola is 70% self-pollinating but outcrossing does occur;  
  - the highest rate of outcrossing occurs between adjacent plants (less than 5m), and the rate decreases significantly at distances of over 5-10m;  
  - extremely low level of outcrossing can be detected at greater distances (up to 2.6km under Australian conditions);  
  - hybrid vigor is not a direct result of the genetic modification and cannot be transferred;  
  - if transfer of the herbicide tolerance gene from the GM canola to other canola did occur as a result of outcrossing, the hazards will be the same as those for the GM canola;  
  - the resultant progeny would only have a selective advantage in the presence of the herbicide;  
  - the herbicide tolerant plants and volunteers can be readily controlled by alternative herbicide and non-chemical management practices currently used to control conventional and herbicide tolerant (non-GM or GM) canola volunteers;  
  - the development of multiple herbicide tolerance canola is likely to occur at very low levels through outcrossing between the GM canola and other canola crops if no management measures taken;  
  - the release is small in size. | Yes | • limit scale of the release decreases the likelihood of pollen dispersal and hence gene transfer;  
  - limit pollen transfer minimises pollen movement and hence gene transfer;  
  - secure transport and storage: minimises spread of the GMOs and hence decreases the likelihood of gene transfer;  
  - clean equipment and release sites: minimises spread of GMOs and hence minimises the likelihood of gene transfer;  
  - post-harvest inspection: minimises spread and persistence and spread of the GMOs; destroys pollen source and hence decreases likelihood of gene transfer;  
  - destroy all seed not required for future trials: minimises spread of the GMOs and hence decreases the likelihood of gene transfer. | Yes | • Limit scale: restrict area to be no more than 4 ha/site on maximum 6 individual sites per year;  
  - Limit pollen transfer: surround the release site with pollen trap/monitoring/isolation zones, remove canola from monitoring zone, ensure isolation from cultivated canola (isolation zone);  
  - Secure transport and storage: GMOs must not be transported unless contained within a primary sealed container packed into a secondary unbreakable container; only transport to the extent necessary; store in sealed container within a lock facility that is signed to indicate GM canola is stored within.  
  - Clean equipment used at the release site: equipment must be cleaned before it is used for any other purpose;  
  - Post-harvest inspection: release sites must be monitored after harvest at least once every 35 days for a period of at least 3 years and any volunteers identified must be destroyed before flowering; and ensure that crops sown after the trial would allow ready detection of the GMOs.  
  - Conduct studies to confirm previous research on gene flow. |
<table>
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</thead>
<tbody>
<tr>
<td>Gene Transfer:</td>
<td>Very low</td>
<td>See Appendix 4</td>
<td>Yes</td>
<td>As for Gene transfer to other canola (see above)</td>
<td>Yes</td>
<td>As for Gene transfer to other canola (see above)</td>
</tr>
</tbody>
</table>
| To sexually compatible species B. rapa B. juncea                                    |                                   | • in the absence of containment and isolation measures, canola can outcross with B. rapa and B. juncea to form interspecific hybrids;  
• the gene transfer to these species is likely to occur at very low frequency if they are in close proximity and were flowering in synchrony, but out-crossing frequency decreases rapidly with distance;  
• inter-specific hybrids have reduced fertility, seed set and fitness relative to their parents, therefore, introgression of the introduced genes is unlikely to occur;  
• the hybrids would only have selective advantage over B. rapa or B. juncea in the presence of the herbicide;  
• the herbicide tolerant hybrids can be effectively controlled using a range of alternative herbicides and other non-chemical management techniques currently used for the control of Brassica spp.;  
• the release is small in size. |                      |                                                                                                                                                                                                                                                                                                                                                                           |                | • Surround the GM canola with monitoring zone and conduct inspection; ensure no B. rapa and B. juncea are present in or adjacent to GM canola site;  
• Surround the GM canola with isolation zone; ensure isolation from cultivated B. rapa and B. juncea (isolation zone). |
<table>
<thead>
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</thead>
<tbody>
<tr>
<td>Gene Transfer:</td>
<td>Very low</td>
<td>See Appendix 4</td>
<td>Yes</td>
<td>As for Gene transfer to other canola (see above)</td>
<td>Yes</td>
<td>As for Gene transfer to other canola (see above).</td>
</tr>
<tr>
<td>To other weedy relatives ie Raphanus raphanistrum Hirschfeldia incana Sinapis arvensis</td>
<td></td>
<td>- interspecific hybrids between canola and the sexually compatible brassicaceous weeds R. raphanistrum, H. incana, S. arvensis can occur in the absence of containment/isolation measures. However, out-crossing occurs at very low rates and requires physical proximity and flowering synchrony; - the interspecific hybrids tend to have significantly reduced fitness and are unlikely to persist in the environment; - the inter-specific hybrids only have selective advantage in the presence of the herbicide; - the hybrids can be effectively controlled using a range of alternative herbicides and other non-chemical management techniques currently used for the control of brassicaceous weeds; - the release is small in size.</td>
<td></td>
<td></td>
<td></td>
<td>- Surround the GM canola with monitoring zone and conduct inspection; ensure no R. raphanistrum, H. incana are present in or adjacent to GM canola site; - Surround the GM canola with isolation zone; ensure isolation from R. raphanistrum, H. incana.</td>
</tr>
<tr>
<td>Gene Transfer:</td>
<td>negligible</td>
<td>See appendix 4</td>
<td>No</td>
<td>N/A</td>
<td>N/A</td>
<td>None required</td>
</tr>
<tr>
<td>Humans and other animals</td>
<td></td>
<td>- the risk of the introduced gene transferring from GM canola to humans and other animals is negligible due to the limited probability of occurrence of uptake and functional integration of the DNA; - natural events of horizontal gene transfer from plants to distantly related organisms are negligible; - the likelihood of transfer is negligible and the introduced gene would not present a hazard to the health and safety of humans or animals.</td>
<td></td>
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</tbody>
</table>
### Gene Transfer: Microorganisms

**Hazard identification:** Gene Transfer: Microorganisms  
**Risk (combines likelihood & impact):** negligible  
**Summary of Risk Assessment (Refer to appendices for details):** See Appendix 4  
- horizontal gene transfer is the only possible mechanism for such transfer. This has not been demonstrated from plants to microbes under natural conditions;  
- the genes are already present and widespread in the environment;  
- gene transfer from these natural sources of the gene is much more likely than is transfer from the GM canola.

<table>
<thead>
<tr>
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<th>Is risk managed?</th>
<th>Licence conditions (see Appendix 5 for details)</th>
</tr>
</thead>
<tbody>
<tr>
<td>No</td>
<td>N/A</td>
<td>N/A</td>
<td>None required</td>
</tr>
</tbody>
</table>

**Herbicide tolerance**  
**Risk (combines likelihood & impact):** negligible  
**Summary of Risk Assessment (Refer to appendices for details):** negligible due to small scale of the trial and limited application of the herbicide (less than 1 ha/jurisdiction/annum and more than 5 ha/annum nationally- the APVMA threshold for trial permits).

<table>
<thead>
<tr>
<th>Does risk require management?</th>
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<th>Licence conditions (see Appendix 5 for details)</th>
</tr>
</thead>
<tbody>
<tr>
<td>N/A</td>
<td>• not required because the risk is negligible.</td>
<td>N/A</td>
<td>None required</td>
</tr>
</tbody>
</table>
APPENDIX 1  INFORMATION ABOUT THE GMOS

45 In preparing the risk assessment and risk management plan, the Regulator is required under section 49 (2) of the Act to consider the properties of the parent organism and the effects of the genetic modification.

46 This Appendix addresses these matters and provides detailed information about the GMOs for this release, the parent organism, the genetic modification process, the genes that have been introduced and the new proteins that are expressed in the GM canola as a result of the genetic modification.

47 It should be noted that some details of the gene constructs including the identity of herbicide tolerance gene, the plasmid maps, the regulatory sequences and preliminary protein expression data have been declared as Confidential Commercial Information (CCI) under section 185 of the Act. However, the CCI was made available to the prescribed expert groups, that were consulted in the preparation of the risk assessment and risk management plan.

SECTION 1  SUMMARY INFORMATION ABOUT THE GMOS

48 The GMOs to be released include 70 GM canola parental lines and their progeny. The parental lines are either male sterile (MS) or fertility restorer (RF) and all these lines also contain a gene conferring tolerance to a herbicide. The MS and RF lines form the basis of Bayer’s novel hybrid breeding system. The release would also include hybrid plants derived from crosses between RF and MS lines or offspring derived from crossing between these lines and Australian commercial varieties.

Section 1.1  Hybrid breeding

49 Traditional plant breeding selects for plants with agronomically valuable characteristics but repetitive selfing can produce inbred plants that may 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 in yield, increased resistance to disease and enhanced agronomic performance.

50 The production of hybrids presents a challenge for plant breeders in crop plants that have both male (stamen which produces pollen) and female (stigma which produces the ovule or egg) reproductive parts on the same plant or in the same flower and are self-fertile. Canola is self-fertile and its flowers normally contain both stamen and stigma.

51 This problem may be overcome by the selection of ‘male sterile’ plants that cannot produce pollen and therefore can only function as the female parent. Fertilisation of male sterile plants by pollen from other genetically distinct plants will therefore result in controlled crossing and the production of hybrid seed.

52 Bayer has utilised gene technology techniques to develop hybrid seed from two distinct parents. The hybridisation system ensures the female lines are pollinated by the desired male lines. It is based on:

---

1 The term ‘line’ has been used throughout this risk assessment. ‘Line’ is used to denote canola with a specific genetic modification derived from a single transformation event.
A female line or male sterile (MS) line obtained by the introduction of the barnase gene which produces BARNASE, a ribonuclease (RNase), which is expressed only in the tapetum cells (layer of cells rich in reserve food supporting the development of pollen) that surround the pollen sacs during anther development. BARNASE destroys the tapetum cells thereby blocking pollen production. Consequently the flowers only contain a fertile female reproductive organ (stigma);

A male parental line or a fertility restorer (RF) line obtained by the introduction of the barstar gene, which produces BARSTAR, a specific RNase inhibitor, which is expressed only in tapetum cells during anther development and breaks down the product of the barnase gene.

Full fertility restoration is obtained by crossing the MS line and the RF line enabling the co-expression of both barnase and barstar in tapetum cells.

53 Further details on these genes and the proteins they encode are provided in Section 3 of this Appendix.

54 The GM canola lines for this release are similar to InVigor® canola (which was recently approved for commercial release under DIR 021/2002) in that both contain the barnase and barstar genes. However, the MS and RF gene constructs in InVigor® contain genes that detoxify the herbicide glufosinate ammonium.

55 The MS and RF plasmid constructs for this release are linked to a different herbicide tolerance gene. In addition, these plasmids contain different regulatory sequences and other genetic elements that have been introduced to control, maximise and stabilise the expression level of the introduced genes but are not translated to proteins. The confidential status of the identity of the herbicide tolerance gene and other genetic elements incorporated into the GM canola has in no way compromised the rigour of the assessment of risks to human health and the environment. The CCI was made available to the various prescribed expert groups that were consulted on the preparation of the risk assessment and risk management plan.

56 The GMOs for this release have not been previously approved for field trials in Australia.

SECTION 2 THE PARENT ORGANISM

57 A comprehensive review of the parent organism, Brassica napus L (cultivated canola) is provided in the document, “The Biology and Ecology of Canola (Brassica napus)” (OGTR 2002), that was produced in order to inform the risk assessment process for licence applications involving GM canola. This document can be accessed at www.ogtr.gov.au/pdf/ir/brassica.pdf.

SECTION 3 THE INTRODUCED GENES AND THEIR PRODUCTS

Section 3.1 The barnase gene

58 The barnase gene in the GM canola is derived from Bacillus amyloliquefaciens, a commonly occurring soil bacterium that is frequently used as a source for industrial enzymes such as alpha amylase. The barnase gene encodes a ribonuclease (RNase) (Hartley 1988). RNases are enzymes that degrade ribonucleic acid (RNA), the biochemical intermediate between the gene and the protein it encodes (RNases are ubiquitous in nature and serve many biological functions.) The BARNASE protein is secreted and serves a protective function by degrading the RNA of potential enemies (Hartley 1988).
Plasmid constructs containing the barnase gene were used to produce the MS GM canola giving rise to 44 MS lines (derived from discrete transformation events) that will be released. Expression of barnase in the GM canola lines is controlled by an anther specific promoter. Specific expression of the barnase gene in the tapetum cell layer results in production of the cytotoxic RNase only in the tapetum cell layer of the pollen sac during anther development, destroying those cells, preventing pollen formation and resulting in male sterility (Mariani et al. 1990). The anther tapetum plays a key role as reserve food during microspore and pollen grain development (Esau 1961).

The origin and identity of the promoter, terminator and other genetic elements controlling the expression of the barnase gene have been declared CCI under section 185 of the Act.

Section 3.2 The barstar gene

The barstar gene in the GM canola is also derived from B. amyloliquefaciens and encodes a ribonuclease inhibitor protein, BARSTAR, that binds specifically to the BARNASE RNase, forming a stable complex that suppresses the ribonuclease activity (Hartley 1988; Hartley 1989). In B. amyloliquefaciens the expression of the barstar gene to produce the inhibitor protein protects the cell from being destroyed by the BARNASE activity.

A plasmid construct containing the barstar gene was used to produce RF GM canola lines, giving rise to 26 RF lines (derived from discrete transformation events) that will be released. Expression of the barstar in RF lines is controlled by an anther specific promoter.

The origin and identity of the promoter and terminator controlling the expression of the barstar gene have been declared CCI under section 185 of the Act.

Section 3.3 Herbicide tolerance gene

In each of the MS and RF plasmid constructs, the barnase or barstar gene is linked to the herbicide tolerance gene. The herbicide tolerance trait may be used for selection of transformed plants, for ensuring purity of hybrid seed production and eventually enable post emergence weed control.

The origin and identity of the herbicide tolerance gene, the promoter, terminator and other genetic elements controlling the expression of the herbicide tolerance gene have been declared Confidential Commercial Information (CCI) under section 185 of the Act.

Section 3.4 Regulatory sequences

Some regulatory sequences introduced to MS and RF lines are derived from plant pathogens, including Agrobacterium tumefaciens. However, they represent only a very small proportion of the pathogen genome and the sequences are not, in themselves, infectious or pathogenic. The identity and precise arrangement of the genetic elements in the plasmids used to generate the MS and RF GM canola lines, including the regulatory sequences have been declared CCI under section 185 of the Act.

The GM canola lines do not contain any antibiotic resistance genes.

SECTION 4 METHOD OF GENE TRANSFER

Section 4.1 Agrobacterium mediated transformation

Agrobacterium tumefaciens is a gram-negative soil bacterium belonging to the family Rhizobiaceae. This pathogen is known as a plant pathogen causing crown gall disease mainly...
on stone fruits, ornamental and grapevine. The soil phytopathogen has been extensively
studied since it was identified as the causative agent of crown gall disease. *A. tumefaciens*
and *A. rhizogenes* are the two well-known prokaryotic organisms capable of transferring
DNA to the eukaryotic cell (Bundock & Hooykaas 1998). *Agrobacterium*’s gene transfer
ability may have evolved from bacterial conjugal transfer systems, which mobilise plasmids
for transfer between bacterial cells (Stachel & Zambryski 1986).

69 Normally when using *Agrobacterium* vectors, only the Transfer DNA (T-DNA), a
specific segment of the plasmid is transferred and integrated into the plant genome (Chilton et
al. 1977); (Zupan et al. 2000), although flanking vector sequences can also be transferred.
The transfer of the T-DNA (located between specific border sequences on a resident plasmid)
from *A. tumefaciens* occurs through the mediation of genes from the *vir* (virulence) region of
*Ti* (tumour inducing) plasmids (Christie 1997); (Zupan et al. 2000). It is generally accepted
that T-DNA transfer into plant cell by *Agrobacterium* is irreversible (Hutter 1997) and cannot
be re-mobilised to transfer elsewhere in the genome or to other organisms.

70 Disarmed *Agrobacterium* strains have been constructed specifically for plant
transformation. The disarmed strains do not contain the genes (*iaaM, iaaH* and *ipt*)
responsible for the overproduction of auxin and cytokinin, which are required for tumour
induction and rapid callus growth (Klee & Rogers 1989). A useful feature of the *Ti* plasmid is
the flexibility of the *vir* region to act in either *cis* or *trans* configurations to the T-DNA. This
has allowed the development of two types of transformation systems:

- co-integration vectors that join the T-DNA that is to be inserted into the plant and the *vir*
  region in a single plasmid (Stachel & Zambryski 1986); and

- binary vectors that have the T-DNA and *vir* regions segregated on two plasmids (Bevan
  1984).

71 Both provide functionally equivalent transformation systems. Transformation
efficiencies have been increased further by the use of ‘superbinary vectors’, which contain
increase expression of *vir* G gene (which boosts the expression of other *vir* genes) (Sheng &
Citovsky 1996). *Agrobacterium*-mediated transformation has been widely used in Australia
and overseas for introducing new genes into plants without causing any biosafety problems.

72 The GM canola was produced using, a conventional, disarmed plasmid vector to
introduce the genes of interest into conventional canola using standard *Agrobacterium*
transformation protocols (De Block et al. 1989). Details of the plasmid map are declared as
CCI. Genetically modified plants were screened for tolerance to a herbicide, which is used as
a selective marker gene in the laboratory and under field conditions. The herbicide tolerance
gene is also used as a quality assurance/selectivity tool in seed production.

73 Following co-cultivation with *A. tumefaciens*, canola cells were cultured in the media
containing the herbicide to which they were tolerant, to select for lines containing the inserted
DNA. The lines to be released in this trial were derived from canola plants that were
regenerated from the GM cells that survived.

74 During the proposed field release herbicide tolerant hybrid canola will be produced by
conventional crossing between MS lines and RF lines of the GM canola.

**SECTION 5 CHARACTERISATION OF THE INSERTED GENETIC MATERIAL AND
STABILITY OF THE GENETIC MODIFICATION**

75 The field release represents an early stage of the research program to develop this GM
canola and therefore information on characterisation of the lines is still limited. Results from
preliminary analyses indicated that the inserted genetic elements have been incorporated into the plant genome. Segregation analysis by selfing the GM canola progenies in glasshouses in Europe and North America indicated the inserted genes remain structurally stable through meiosis and are inherited in a normal Mendelian manner. The applicant stated that for all 70 individual GM canola lines for this release, a single copy of the T-DNA is present.

Experience from previous releases of the GM canola containing the genes for the hybrid breeding system has indicated that the MS and RF traits are stably inherited over multiple generations and that the traits exhibit dominant Mendelian inheritance.

The stability of introduced traits has been established for four generations in the glasshouse and two generations in the field trials conducted overseas (information provided by Bayer).

Further detailed information on the molecular characterisation of the introduced genetic material and its insertion in the genome would be required for any future application for a larger scale or commercial release of the GM canola in Australia. And the licence conditions require the collection of data on the stability of the introduced genes.

SECTION 6  EXPRESSION OF THE INTRODUCED PROTEINS

The expression of the \textit{barnase} gene in the MS lines of the GM canola was confirmed by the male sterile phenotype. The expression of the \textit{barstar} gene in the RF GM canola was confirmed by the phenotype of the F1 progeny of RF x MS crosses that are fully fertile with normal anther development –as a result of the co-expression of BARNASE and BARSTAR proteins.

The expression of the herbicide tolerance gene was confirmed by selected plants exhibiting tolerance to the herbicide.

Preliminary data on expression levels of the introduced gene products have been declared CCI. Detailed information on the expression of the introduced genes would be required for any future application for a larger scale release of the GM canola.

SECTION 7  PLEIOTROPIC EFFECTS OF THE GENETIC MODIFICATION

A single plant gene, including genes inserted by genetic modification, can have an influence on multiple, sometimes unrelated, plant traits by disrupting the function of the existing genes. This phenomenon is known as pleiotropy. Therefore it is necessary to evaluate genetically modified plants for unintended, pleiotropic effects of the inserted genes.

Section 7.1 Male sterility and restored fertility

Bayer indicated that comparison of initial individual transformed MS lines showed a large phenotypic variation in the flower morphology and pollen production ranging from large amounts of non-viable pollen to total absence of pollen. In addition, in field trials conducted overseas, some agronomically undesirable pleiotropic effects such as growth delay, flowering retardation and smaller petals were observed in field trials. These undesirable pleiotropic effects also occur in other male sterile systems (cytoplasmic male sterility) and reflect the physiological similarity between conventionally bred plants and the new system.

However, Bayer proposes to release only MS lines that have been selected for reliable expression of MS trait, absence of anthers and absence of any undesired pleiotropic effects.
Introduction of the *barstar* gene expressed in tapetum cells has no influence on the plant phenotype (Mariani et al. 1992). The effect of expression of the *barstar* gene is only manifested after crossing the MS line with the RF line which results in first generation progeny that are fully fertile.

**Section 7.2 Herbicide tolerance gene**

Bayer stated that no pleiotropic effects have been observed in the glasshouse trials completed overseas to date. During the glasshouse trials, transgenic lines that expressed unintended adverse effects related to agronomic performance were not selected for further field-testing. The applicant is required under the licence conditions to collect agronomic characteristic of the GM canola during the proposed release. More extensive data to confirm this would also be required for future larger scale releases.

**SECTION 8 SUMMARY OF FUTURE RESEARCH REQUIREMENTS**

If the applicant makes any applications for future large scale releases of the GM canola, more data would be required to collected on:

- further detailed information on molecular characterisation of the insertion;
- the levels of expression of the inserted genes under Australian conditions; and
- unintended effects of the genetic modification.
APPENDIX 2  TOXICITY AND ALLERGENICITY TO HUMANS AND TOXICITY TO OTHER ORGANISMS

88  Under section 51 of the Act, the Regulator is required to consider risks to human health and safety and the environment in preparing the risk assessment and the risk management plan. This Appendix considers potential hazards that may be posed as a result of any toxicity or allergenicity of the GM canola or its novel proteins to human health and safety.

89  This Appendix also considers potential hazards that may be pose as a result of any toxicity of the GM canola or its novel proteins to other organisms.

SECTION 1  NATURE OF THE POTENTIAL TOXICITY OR ALLERGENICITY HAZARD

90  A toxic response to a chemical is shown by the cascade of reactions resulting from exposure to a dose of chemical sufficient to cause direct cellular or tissue injury or otherwise inhibit normal physiological processes (Felsot 2000). Allergic responses are immune system reactions, resulting from stimulation of a specific group of antibodies known as IgE, or sensitisation of specific tissue bound lymphocytes (Taylor & Lehrer 1996; FAO & WHO 2000; Taylor 2000). Allergic responses have well-defined aetiologies (ie. biochemical cause) that is quite different from toxicity. Anaphylaxis is a shock syndrome caused by a massive release of histamine and other allergic mediators from even minute exposures to an antigen. Food proteins are common causes of anaphylaxis, especially peanut and shell fish (Frick 1995).

91  An allergic response can have severe consequences for an individual and is mediated through the immune system by IgE antibodies, resulting in the release of histamine and other allergic mediators. Predicting allergenicity is difficult and has been based on sequence, structural and biochemical comparisons with known allergens. Protein allergens usually share a number of characteristics (Davies 1986; Flavell et al. 1992; Fuchs et al. 1993a; Fuchs et al. 1993b; Fuchs et al. 1993c; Taylor 1995; Fuchs & Astwood 1996; Metcalfe et al. 1996; ANZFA 2001a), including the following:

- molecular weight ranges between 15-70 kD;
- typically glycosylated;
- stable in the mammalian digestive system;
- stable during the high temperatures involved in cooking or processing; and
- present as the major protein component in the specific food.

92  Current scientific knowledge suggests that common food allergens tend to be resistant to degradation by heat, acid, and proteases (Astwood et al. 1996). This is because it is necessary that a protein is sufficiently stable to reach and cross the mucosal membrane for it to stimulate an allergenic response following oral ingestion (Kimber et al. 1999).

93  The GM canola lines differs from conventional canola in the expression of BARNASE and BARSTAR and a herbicide tolerance protein. The potential of GM canola lines to be toxic or allergenic to humans and other organisms due to either expression of the novel gene products or because of unintended effects of the genetic modification is considered in this Appendix.
SECTION 2 LIKELIHOOD OF THE TOXICITY OR ALLERGENICITY HAZARDS OCCURRING

94 In assessing the likelihood of adverse impacts due to toxicity or allergenicity of GM canola on human health and safety, or toxicity to other organisms a number of factors were considered including:

- the inherent toxicity or allergenicity of conventional canola;
- the potential toxicity or allergenicity of the introduced proteins;
- the potential toxicity and allergenicity of the GM canola lines; and
- the potential for exposure to the GM canola.

Section 2.1 The potential toxicity or allergenicity of conventional canola

95 *Brassica napus* seed naturally contains erucic acid and glucosinolate as toxicants. However, the term canola refers to those varieties of *B. napus* that meet specific standards on the level of erucic acid and glucosinolates. These cultivars must yield oil low in erucic acid and meal low in glucosinolates and are often referred to as double low varieties.

96 Canola meal is produced as a by-product during the extraction of oil from canola seed and is widely used as a high protein feed source in animal nutrition (Canola Council of Canada 2001, Queensland Department of Primary Industries 2002). Full fat canola seed may also be used directly as animal feed (Roth-Maier 1999). Industry standards require canola meal to be low in glucosinolates (total glucosinolates of 30 micro moles/g) in toasted oil free meal (Organisation for Economic Co-operation and Development (OECD) 2001). The maximum level for erucic acid is 2% in the oil fraction (CODEX 2001). Further details can be obtained from the OGTR document on the Biology and Ecology of Canola (*Brassica napus*) (OGTR 2002).

97 No allergic reaction to fats (including canola oil) has been reported in humans. Occupational exposure to canola pollen (Chardin et al 2001; OGTR 2002a), canola dust (Suh et al. 1998) and canola flour (Monsalve et al 1997; Alvarez et al 2001) have been implicated in allergic reactions in humans and a number of putative allergens have been characterised, including seed storage proteins (Monsalve et al 1997). It is important to note that these findings relate to conventional, non-transgenic canola, and that canola seed meal or flour is not considered suitable for human food. Canola oil is the only fraction used for human food. As a quality control measure, no protein is allowed to be present in canola oil.

Section 2.2 Potential toxicity and allergenicity of the introduced proteins in the GM canola

98 Up to three novel proteins are expressed in the GM canola lines or their offspring – BARNASE, BARSTAR and a herbicide tolerant protein.

Section 2.2.1 BARNASE and BARSTAR proteins

99 The BARNASE and BARSTAR proteins are not known allergens. Both genes are derived from a commonly occurring soil bacterium (*Bacillus amyloliquefaciens*) which is not a known source of allergens. *B. amyloliquefaciens* is used extensively in the food industry as a source for industrial enzymes such as alpha amylase (ANZFA 2001).

100 Examination of potential toxicity and allergenicity of BARNASE and BARSTAR were conducted by comparing the amino acid sequences of the novel proteins with known toxins and allergens. Results indicated that BARNASE and BARSTAR do not possess...
characteristics typical of known protein allergens and have no structural similarity to known food allergens or toxins (Van den Bulcke 1997). The BARNASE and BARSTAR proteins are both rapidly degraded in simulated gastric conditions (0.32% pepsin and acidic pH), with all proteins completely degraded within five minutes (Van den Bulcke 1997).

101 Identified epitopes of allergenic proteins tend to have an optimal length of between 8 and 12 amino acids for binding to T-cells and it has been proposed that an immunologically significant sequence identity requires a match of at least eight contiguous amino acids (Metcalf et al 1996). A search for homology with known allergens of BARNASE and BARSTAR was therefore conducted, based on detecting identities of eight continuous amino acids and no sequence homologies were detected (Van den Bulcke 1997).

102 A more refined method for detecting possible allergenic epitopes has recently been published (Kleter & Kuiper 2002). The method is based on detecting identities of six amino acids with known IgE epitopes. The method was applied to the amino acid sequences of proteins introduced into GM plants, including the BARNASE and BARSTAR proteins. No identities with known IgE epitopes were found confirming the previous results.

103 Neither the GMOs nor any of their products from this trial will be used in human food or animal feed. However, other GM canola lines containing BARNASE and BARSTAR have been assessed by FSANZ (formerly ANZFA) with regard to toxicity. FSANZ concluded that oil derived from the GM canola (containing BARNASE and BARSTAR proteins) is as safe and wholesome as oil from other commercial canola varieties (ANZFA 2001a; ANZFA 2001b).

104 In conclusion, it is considered that the BARNASE and BARSTAR proteins expressed in the GM canola are not likely to be toxic or allergenic to humans or toxic to animals.

Section 2.2.2 Herbicide tolerance protein

105 The GM canola to be released contains a herbicide tolerance gene (details declared CCI). Bayer has not supplied any data relating to the acute toxicity of the herbicide tolerance protein. However, they have indicated that the herbicide tolerance protein belongs to a family of modified proteins that has been tested in other GM crops in Australia and overseas. Similar gene products that confer tolerance to the same herbicide have been studied extensively in mammals and have not been found to be toxic to tested animals (information supplied by Bayer). The applicant stated that the family of proteins to which the herbicide tolerance protein belongs to have no structural similarity to known food allergens, and that, GM plants containing the herbicide tolerance trait has been assessed by FSANZ.

106 The Regulator’s assessment of the characteristics of the herbicide tolerance protein also supports the conclusion that it is commonly encountered in the environment and is unlikely to be toxic or allergic. The applicant stated that results on feeding studies for this particular GM canola would be submitted with any application for commercial release. Data on the potential toxicity or allergenicity of the herbicide tolerance protein introduced into the GM canola and molecular characterisation of the insertion would also need to be provided before any application for larger scale release is considered.

Section 2.3 Potential toxicity and allergenicity of the GM canola lines

107 An important consideration for assessing the GM plants is whether the toxicity or allergenicity of the parent plant has been altered. For canola, an investigation on whether the levels of the natural toxicants ie erucic acid and alkyl glucosinolates have been altered in the GM canola lines would need to be considered. Composition analysis can provide evidence of whether the genetic modifications have resulted in any unintended effects being introduced.
into the GM canola- for example whether there are any significant changes with respect to processing characteristics, oil content, oil composition, oil quality (physical properties) or protein content.

108 However, the GM canola lines for this release represent early stage research. No data have been obtained on the level of erucic acid or alkyl glucosinolates, or on the compositional profile of the GM canola lines. Data addressing these questions would be required before larger scale or commercial release of these GM canola lines would be considered.

109 On the basis of the characteristics of the introduced proteins, and the assessment of analogous GMOs modified by the introduction of a herbicide tolerance trait or the hybrid breeding systems, both in Australia and overseas, it would not be expected that the GM canola lines would be more toxic or allergenic than conventional canola. However, data on other unintended effects of the genetic modification would be needed before an application for any larger scale release is considered.

110 None of the GM canola plants from this release or their by-products will be used for food and animal feed. FSANZ approval would need to be obtained before the GMOs or any parts of the GMOs could be used as food. However, no application has been made as yet in view of the early stage of the research.

Section 2.4 Potential for exposure to novel proteins

111 The expressions of BARNASE in MS lines and BARSTAR in RF lines are specific to tapetum cells during anther development because they are under the control tapetum specific promoter. The tapetum cell layer makes up only a small fraction of the total biomass of the plant. Therefore the likelihood of any exposure to humans is very low.

112 Preliminary data supplied by Bayer indicated that the herbicide protein is expressed at a low level in the GM canola lines. From the nature of the promoter controlling the herbicide tolerance gene, it would be expected that the herbicide tolerance protein would be expressed at a low level in plant tissues. However, further information on levels of expression of the introduced genes in various tissues under Australian field conditions would be required before an application for any future larger scale release is considered.

113 The scale of the release is limited and Bayer proposes measures to contain the GM canola lines and the GM material, thereby limiting exposure to humans and other organisms.

Section 2.4.1 Occupational exposure

114 Exposure may occur for workers handling or working with the GM canola. This may include exposure to canola pollen (as noted previously conventional canola pollen is implicated in allergic reactions).

115 Humans are commonly exposed to the introduced proteins or very similar proteins, as the genes which express them were derived from organisms that are naturally ubiquitous in the environment.

116 The introduced genes do not encode known toxins or allergens and they are expected to be expressed at very low level and the introduced proteins are commonly encountered in the environment without any record of adverse consequences.

117 No empirical data are available on the level of expression of the introduced proteins in pollen of the GM canola lines. The expression of the barnase and barstar genes in the similar InVigor® canola is not detected in pollen (ANZFA 2001a; DIR 021/2002: www.ogtr.gov.au).
It is considered that the GM canola would not be more toxic or allergenic to workers than non-GM canola. However, as a condition of the licence, the applicant is required to report to the Regulator any adverse effects on human health and safety that arise as a consequence of release.

Section 2.4.2 Exposure to wildlife including animals, fish and birds

Both the level and pattern of expression of the introduced proteins are important factors when considering the potential exposure.

Limited data are available on the expression of the herbicide tolerance gene, the *barnase* and the *barstar* genes in the GM canola lines. However, the available data and knowledge of the levels of expression provided by the promoters controlling these genes, suggest that they would all be expressed at low levels. Expression of the *barnase* and *barstar* genes in the hybrid breeding system will be restricted to the tapetum cells of developing flowers by a tapetum specific promoter. The level of expression of these genes in the similar *InVigor*® canola is very low (DIR 021/2002, (OGTR 2003b) available at www.ogtr.gov.au).

As described above, the introduced genes do not encode known toxins or allergens they are expected to be expressed at very low level and the introduced proteins are commonly encountered in the environment.

Other GM crops containing the same or very similar herbicide tolerant proteins have been tested or grown commercially overseas or used as feed without any adverse effect to animals.

None of the material from the GM canola lines would be used for animal feed. As the scale of the release is relatively limited, with no site being greater than 4 ha hence, the level of exposure to wildlife such as marsupials or birds would be low.

Section 2.4.3 Exposure to invertebrates and soil microbes

The levels of expression of the introduced proteins are expected to be low. In *InVigor*® canola, where the *barnase* and *barstar* genes are controlled by a tapetum specific promoter, no expression could be detected in pollen. The level of exposure to pollinating insects, such as bees is therefore likely to be minimal. In addition, no adverse effects on bees from canola or other plants expressing herbicidal proteins has been observed (Malone 2002).

The *barnase* and *barstar* genes are derived from a common soil bacterium, *B. amyloliquefaciens* and hence the soil microorganisms are likely to be exposed to the introduced proteins in the environment naturally. Organisms are also commonly exposed to very similar proteins to the herbicide tolerance protein as these proteins are widespread in the environment. In conclusion, it is considered that the GM canola would not be toxic to invertebrates and soil microbes than non-GM canola.

SECTION 3 Conclusions regarding toxicity and allergenicity

It is considered that the risk of toxicity or allergenicity of GM canola to humans or toxicity to other organisms is very low due to the following:

- available scientific information indicates that the products from the introduced genes are not toxic to humans or animals as BARNASE, BARSTAR and the herbicide tolerance proteins:
  - are not known to be toxic to humans;
  - show no sequence homology to any known toxins or allergens;
  - are rapidly degraded in simulated gastric conditions;
human and other organisms are commonly exposed to the proteins produced by the introduced barnase and barstar genes as these are derived from organisms prevalent in the environment;

- humans and organisms are also commonly exposed to proteins very similar to the herbicide tolerance protein that are naturally widespread in the environment;

- potential exposure to the GM canola is very low because introduced proteins are expected to be expressed at very low levels and none of the GM material from the release will be used for human food or animal feed and the scale of the release is small.

127 Licence conditions (Appendix 5) have been imposed to limit the spread and persistence of the GMOs and ensure that none of the GM canola plants from the release or their by-products would enter the food supply.

128 The licence holder would also be required to report any adverse effects on human health and safety (for example allergic reactions as a result of occupational exposure to the GM canola) or to the environment.

SECTION 4 SUMMARY OF RESEARCH REQUIREMENTS FOR FUTURE RELEASE

129 If the applicant makes any applications for future large scale releases of the GM canola, more data would be required to be collected on:

- potential toxicity and allergenicity of the introduced proteins to humans and other organisms;

- the level of expression of the introduced genes in various tissues and with seasonal variation under Australian conditions; and

- other unintended effects of the genetic modification.
APPENDIX 3 WEEDINESS

130 Under section 51 of the Act, the Regulator is required to consider the risks to human health and safety and the environment in preparing the risk assessment and the risk management plan. In this Appendix, risks posed by the dealing to the environment are considered in relation to the potential for GMOs to become a weed.

131 There are numerous definitions of weeds (Richardson et al. 2000) including ‘a plant growing where it should not be’. Richardson et al (2000) recommended terminology describing weeds as plants (not necessarily alien) that grow in sites where they are not wanted and which usually have detectable economic or environmental effects (synonyms: plant pests, harmful species; problem plants). According to Richardson et al (2000), ‘environmental weeds’ are alien plant taxa that invade natural vegetation, usually adversely affecting native biodiversity and/or ecosystem functioning. From analysis of global data sets, Daehler (Daehler 1998) found that ‘agricultural weeds’ tend to be herbaceous, rapidly reproducing, abiotically dispersed species, whereas plants that are most likely to become invaders of native ecosystems tend to be primarily aquatic or semi-aquatic, grasses, nitrogen-fixers, climbers, and clonal trees.

132 Weeds become a problem to the community when their brief presence or abundance interferes with the intended use of the land they occupy. Weeds may also represent a source of food to various organisms hence the introduction of weeds to an environment may also bring about ecological change by altering the structure of food webs. Weeds generally have a number of life history characters that enable them to rapidly colonise and persist in ecosystems, particularly those that are regularly disturbed. These characteristics include:

- ability to germinate, survive, and reproduce under a wide range of environmental conditions;
- long-lived seed with extended dormancy periods;
- rapid seedling growth;
- rapid growth to reproductive stage;
- long continuous seed production;
- ability to self pollinate but are not exclusively autogamous;
- use of unspecialised pollinators or wind when out-crossing;
- high seed output under favourable conditions;
- special adaptations for long distance and short distance dispersal; and
- being good competitors (Baker 1965).

133 It is generally accepted that most crop plants, including canola, have undergone selective breeding and domestication, resulting in reduced competitiveness. Crop plants tend to function optimally only under controlled agricultural conditions.

SECTION 1 NATURE OF THE WEEDINESS HAZARD

134 The possibility was considered that the GM canola lines might have the potential to be harmful to the environment because of inherent weediness either due to expression of the novel gene products or as a result of unintended effects of the genetic modification.
This could occur if the GM canola displayed altered characteristics such as increased fitness or increased fecundity. This could result in an increased likelihood of GM canola being able to survive in the environment compared to that of conventional canola. If GM canola were to persist and spread in the environment, it could have an impact on native biodiversity.

**SECTION 2 LIKELIHOOD OF WEEDINESS HAZARD OCCURRING**

In assessing the likelihood of adverse impacts due to the GM canola, a number of factors were considered including:

- the inherent weediness of conventional canola in Australia;
- the potential weediness of the GM canola lines;
- persistence and spread of the GM canola lines.

**Section 2.1 Inherent weediness of conventional canola**


In summary, although canola has a number of ‘weedy traits’ such as pod shattering, induced seed dormancy, self and cross pollination and unspecialised pollinators, it is a poor competitor and does not establish well in unmanaged areas (Salisbury 2002b). Canola is not considered a major weed, nor invasive of natural undisturbed habitats (Canadian Food Inspection Agency 1994); (Crawley et al. 1993; Warwick et al. 1999; Beckie et al. 2001; Dignam 2001).

Canola occurs in disturbed habitats along roadsides, railway lines, field margins and wastelands in all countries where it is grown. It is not considered invasive and dissemination normally results from seed spillage during harvest and transport operations. In Australia, feral populations rarely persist (J Baker per comm, Norton 2003, Salisbury, 2002b).

**Section 2.2 Weediness potential of the GM canola**

The GM canola lines differ from conventional canola in the expression of BARNASE and/or BARSTAR and tolerance to a herbicide. These traits would not be expected to result in changes to the intrinsic weediness of the GM canola lines.

However, the possibility that these new proteins/enzymes produced in the GM canola lines may alter plant characteristics and functions and have an impact on weediness of the GM canola should be considered.

**Section 2.2.1 Effect of BARNASE and BARSTAR on weediness**

The male sterility (BARNASE) and fertility restoration (BARSTAR) traits would not be expected to increase the weediness potential in canola. In fact, male sterile GM canola lines rely on other pollen to produce seed. Therefore, ability to establish itself as a weed species would be less likely than that of conventional canola. The phenotype of RF lines was reported to be similar to that of conventional canola.

The RF and MS lines provide a mechanism to allow controlled production of hybrid seeds, which exhibit hybrid vigour. Cytoplasmic male sterility is used widely in the...
conventional breeding of hybrid canola cultivars. The male sterility in the GM canola is unlikely to increase the weediness potential any more so than would cytoplasmic male sterility. It is important to note that the hybrid vigour displayed in F1 hybrids is not a function of the genetic modification, but is a result of the breeding of the two genetically distinct parents. The RF and MS genetic modifications provide a mechanism to allow controlled production of hybrid seeds, which exhibit the natural phenomenon of hybrid vigour or heterosis. Hybrid vigour has the benefits of the production of a healthier plant, less influenced by disease and environmental conditions such as drought stress, and is most often measured in agronomic terms as increased yield. The degree of hybrid vigour achieved is related to the genetic background of the parental lines (eg Starmer et al. 1998). In general, hybrid vigour manifested in the F1 generation declines in subsequent generations (Falconer & Mackay 1996).

Although data on hybrid vigour of these GMOs is not available, it is expected to be very similar to that of InVigor® and within the range of vigour displayed by other hybrid canola.

Hybrid canola was found to produce higher yield than parents because of increase pod number, larger seeds and later maturity (Starmer et al. 1998). Provided that plentiful of resources are available in agricultural fields, hybrids may have higher competitive ability than their parental lines due to their early crop establishment. However, these hybrid vigour characteristics are unlikely to confer such an advantage outside agricultural fields where resources are limited.

Therefore, it is expected that hybrids derived from MS and RF lines would perform better in the field than the parental lines but they would not be more invasive or persistent than conventional canola off farm. Licence conditions are imposed to require the collection of data on agronomic traits that might influence the potential weediness of the GM canola lines during the release.

Section 2.2.2 Effect of herbicide tolerance trait on weediness

The herbicide tolerance trait of the GM canola is the most important trait when considering whether the genetic modification will have any impact on weediness of the GM canola lines because this trait provides for a possible selective advantage over non-herbicide tolerant non-GM canola.

Currently, there is no evidence that transgenic herbicide tolerant crops are more invasive than their conventional counterparts (Crawley et al. 1993; Crawley et al. 2001). As discussed earlier, traits that lead to weediness in plants tend to be polygenic traits and would not be easily conferred by adding a single herbicide tolerance gene. It is considered that the herbicide tolerance gene would not significantly enhance the weediness potential of GM canola over that of non-GM canola in the absence of the herbicide.

The GM canola lines would only have a selective advantage in situation where the herbicide to which they are tolerant is applied. In the absence of any other management measures, application of the herbicide might facilitate the persistence of the GM canola lines by enabling them to reach maturity and set seed (Knezevic & Cassman 2003). The GM canola lines are as susceptible to other herbicides as non-GM canola, therefore they can be controlled using other herbicides and non-chemical management techniques. However, Bayer has proposed management measures for this release that include removing all canola volunteers from the release sites and the Regulator has imposed these measures in the licence conditions (details in Appendix 5).
Section 2.2.3 Development of herbicide resistance weeds

150 Bayer does not plan to apply the herbicide to which the GM canola is tolerant in areas greater than 1 ha/jurisdiction/annum or more than 5 ha/annum nationally. Therefore Bayer does not require a specific permit to use the herbicide on the GM canola from the Australian Pesticides and Veterinary Medicines Authority (APVMA) which regulates agricultural chemical use, including herbicide under the Agricultural and Veterinary Chemical (the Code) Act 1994. The limited scale of herbicide application would be covered by the general small-scale trial permit TMP0001A issued by the APVMA.

151 The likelihood of herbicide resistant weeds developing as a result of the proposed trial is negligible, given the overall small scale of the proposed trial and the limited application of the herbicide.

Section 2.3 Persistence and spread of the GMOs in the environment

152 The genetic modifications introduced to the GM canola lines are unlikely to make them more persistent. The herbicide tolerance trait is unlikely to confer any advantage to the GM canola lines in the absence of that herbicide.

153 Canola can persist in the agricultural environment, particularly as volunteer plants in subsequent seasons. As described previously, it can also establish in disturbed environments, normally as a result of human activities such as seed spillage during transport.

154 Bayer proposes release of the GM canola lines in both winter and summer growing seasons. Analysis of monitoring reports from Australian GM trial sites indicate that at the majority (82.5%) of winter sown GM trial sites, no volunteers were recorded in the third year (Salisbury 2002b).

155 If the GM canola lines were released without any containment or post-harvest management actions the likelihood that they would persist at the release sites would be high. However, Bayer proposes to harvest the seed by hand which would reduce spillage and the likelihood of soil seed bank accumulation caused by machine harvesters.

156 Similarly, if no measures were taken to ensure that seed is transported in a secure manner before and after harvest, the likelihood of some dissemination into the environment would be high. If seed from the GM canola lines were to persist at the release site or were disseminated into the environment, they would not be expected to have an adverse impact on the environment except as a minor weed in the following crops. Volunteers could be easily controlled by application of registered selective herbicides recommended for use in the following crops.

157 The scale of the release is relatively small, with a small number of sites of limited area (no site greater than 4 ha). Bayer has a range of management procedures, including transport arrangements to limit the possibility of persistence or spread of the GMOs during and after the release. These procedures have been incorporated in the licence conditions (detailed in Appendix 5 and summarised in Chapter 2).

Section 2.3.1 Likelihood of seed dispersal

158 The GM canola lines for this release are not proposed to be used for animal feed but there could be incidental grazing by wildlife or domestic animals while growing in the field. It is conceivable that small amounts of seed could disperse in the faeces of grazing animals. An Australian study found that germinable canola seed was excreted from sheep for 5 days after it was last included in the diet (Stanton et al. 2003). Only 1-1.5% of canola seed
ingested by sheep was excreted whole and the germination rate of this seed was found to be 10-40% (Stanton et al. 2003).

159 The possibility of dissemination of canola seed by wild birds consuming seed directly from the crop has been raised. Birds such as cockatoos and sparrows can shred or remove pods during development and at maturity (Stanley & MacCormick 1999). Canola is soft seeded and is very unlikely to survive passage through the gut of a bird. However, even if the seed survived, the likelihood of adverse consequence from gene escape through seed is very low to negligible. The scale of the release is small and would be conducted under controlled conditions.

SECTION 3 CONCLUSIONS REGARDING WEEDINESS

160 It is considered that the risk of the GM canola lines establishing as weeds as a result of the limited and controlled release is very low because:

- the scale of the proposed release is small and herbicide application will be limited;
- canola is not considered a weed of undisturbed habitats but can be minor weed of agricultural and disturbed habitats;
- the genetic modifications are unlikely to enhance the weediness of the GM canola lines as compared to non-GM canola;
- the presence of the herbicide tolerance gene will only have a selective advantage in the presence of the herbicide; and
- the GM canola lines are susceptible to other herbicide and can be controlled using all other alternative herbicides and non-chemical management methods currently used to control conventional canola.

161 It is considered that the risks of the GM canola lines from this release establishing as weeds will be managed by implementing various strategies to minimise their spread and persistence from the release sites. Refer to Chapter 2 and Appendix 5 for risk management conditions.

162 The licence conditions (detailed in Appendix 5 and summarised in Chapter 2) include the requirement that the applicant collects data on the growth characteristics that might contribute to weediness potential of the GM canola lines (eg pod shattering, seed dormancy, yield components etc) to ascertain if there have been any unintended effects of the genetic modifications.

SECTION 4 SUMMARY OF RESEARCH REQUIREMENTS FOR PROPOSED RELEASE

163 The licence conditions include a requirement to collect data on agronomic traits that might influence the potential weediness of the most promising lines of the GM canola during the release. These agronomic traits to be collected include pod shattering, susceptibility to major pests, seed dormancy, early seedling establishment, flowering period and yield components.
APPENDIX 4 TRANSFER OF INTRODUCED GENES TO OTHER ORGANISMS

164 Under section 51 of the Act, the Regulator is required to consider risks to human health and safety and the environment in preparing the risk assessment and risk management plan. This Appendix contains information on the risk assessment of potential gene transfer to other organisms.

165 Gene transfer is the movement of genes between individuals. When analysing this risk, a distinction needs to be made between hybridisation and introgression. Hybridisation is the crossing between two different organisms, either of the same or different species, resulting in the production of hybrid progeny in which gene transfer (or flow) may have occurred. Introgression is the incorporation of a gene or genes into successive generations of the population after a hybridisation event.

166 Within a species genes are routinely exchanged between individuals of successive generations through sexual reproduction in animals, cross pollination in plants and conjugation in bacteria. Hybrids can be produced between closely related species through sexual reproduction. For example, in plants cross-pollination of wheat and rye produces triticale, in animals fertilisation of a mare by a donkey produces a mule. Hybrid progeny may be fertile or sterile, meaning hybridisation may or may not lead to the introgression of a gene or genes into a population.

167 Without the application of gene technology, gene transfer is not readily observed between distantly related species, except among bacteria. However, to a limited extent, gene transfer between sexually incompatible organisms can occur. Reconstruction of family trees based on DNA sequence similarities over millions of years reveals that ancestral plants have occasionally exchanged small DNA fragments with distantly related organisms (Lawrence & Ochman 1998; Ochman et al. 2000; Worobey & Holmes 1999). In general, there seems to have been only very limited transfer of genes from plants to other types of organisms (Mayo & Jolly 1991).

168 A number of factors influence the likelihood of gene flow occurring within plants. Pre-fertilisation considerations include physical proximity and pollen movement, synchrony of flowering, breeding system and floral characteristics and competitiveness of pollen. Post-fertilisation considerations include sexual compatibility, hybrid viability and fertility, and successful gene transfer to occur, all pre- and post- fertilisation requirements must be met. Failure to meet any one requirement will mean that gene transfer and introgression cannot occur.

169 For ease of reference, the assessment of potential gene transfer hazards to other organisms is being considered in the following three sections:

- other canola plants (Section 1 of this Appendix);
- other plants (Section 2 of this Appendix); and
- other organisms (Section 3 of this Appendix).

SECTION 1 TRANSFER OF INTRODUCED GENES TO OTHER CANOLA PLANTS

Section 1.1 Nature of the gene transfer hazard

170 The field trial is a limited and controlled release of GM canola comprising up to 70 parental lines and their progeny (refer to Appendix 1 for details). These lines include either
male sterile lines (MS) due to the tapetum specific expression of the *barnase* gene or fertility restorer gene lines due to the tapetum specific expression of *barstar* gene. The MS, RF and their hybrid lines also contain a herbicide tolerance gene.

171 For further information on gene transfer from GM canola to other organisms, please refer to the document “The Biology and Ecology of Canola (*Brassica napus*)” (OGTR 2002) and RARMPs of DIR 020/2002 (Roundup Ready® canola, OGTR 2003a) and DIR 021/2002 (InVigor® canola, OGTR 2003b), which contained extensive discussion on this topic (these documents are available at www.ogtr.gov.au).

172 Transfer of the introduced genes into other plant species, in particular to weedy relatives, might produce weeds that are more competitive or invasive and have adverse effects on biodiversity. The potential hazards specific to the transferred gene sequences are as follows:

- **Herbicide tolerance gene**: Plants could become tolerant to the herbicide. This would have an impact in situations where the herbicide is used for volunteer or weed control.
- **Male sterility gene (*barnase* gene)**: Male sterile plants are unable to produce pollen and can only reproduce by receiving foreign pollen. Transfer of the *barnase* gene from the GM canola plants to other compatible species would result in male sterility in a proportion of interspecific hybrids;
- **Fertility restorer gene (*barstar* gene)**: The acquisition of the fertility restorer gene by the plants which were already fertile would have no effect. The fertility restorer trait would not express if the fertility restorer gene is transferred to plants which do not have *barnase* gene expressed at tapetum cells.
- **Promoters and other regulatory sequences**: If gene transfer did occur, there could be unintended or unexpected effects if the introduced regulatory sequences altered the expression of endogenous plant genes.

Section 1.2 Likelihood of the gene transfer to other canola crops

**Section 1.2.1 Out-crossing rate within canola**

173 For further details on pollination of canola refer to the “Biology and Ecology of Canola (*Brassica napus*)” (OGTR 2002), and the final risk assessment and risk management plan for the commercial release of InVigor® canola DIR 021/2002 (OGTR 2003b) and the consultation RARMP for the commercial release of Roundup Ready® canola DIR 020/2002 (OGTR 2003a). These documents are available at www.ogtr.gov.au.

174 Canola is mainly self-pollinating, though it is estimated that out-crossing occurs at a rate of approximately 30% (ranging between 12 and 47 %) in adjacent plants (Williams et al. 1986; Becker et al. 1992). The highest rate of cross-pollination requires close proximity and occurs in situations where there is physical contact with neighbouring plants, although pollen can be transferred over longer distances by insects and wind. In general, wind-transport is considered to play a minor role in long distance transfer compared to insect-transport (Salisbury 2002b).

175 Pollen viability varies with environmental conditions, particularly temperature and humidity. Under controlled conditions in the laboratory, canola pollen can remain viable for between 24 hours and one week (Mesquida & Renard 1982). Under natural conditions pollen viability gradually decreases over 4-5 days (Ranito-Lehtimäki 1995). In Australia, canola crops flower in spring when temperature increases and humidity declines. Under these conditions, pollen may remain viable only for 24-48 hours (M. Rieger, pers. comm.).
Canola pollen distribution from pollen counts shows a steep decline with distance, with a tail containing rare long distance events. While most pollen travels less than 10 m, on rare occasions it can be transferred up to 1.5 km by wind and 3 km by insects (Salisbury 2002b). In Australia, honeybees (Apis mellifera) are believed to be the main insect responsible for transfer of canola pollen over long distances. The majority of pollen collected by A. mellifera has been measured at distances of 1 to 2 km, and even up to 4 km.

In Europe, out-crossing rates below 0.4 % have been measured at distances up to 50 m (eg Beckie et al. 2001; (Champolivier et al. 1999; Downey 1999a). Out-crossing rates of 0.02-0.5% have been measured up to 100 m (Staniland et al. 2000); Beckie et al. 2001; (Downey 1999b); (Downey 1999a); Norris unpublished, cited in (Eastham & Sweet 2002). Out-crossing rates below 0.1 % were measured up to 250 m from the source field (Norris unpublished, cited in Eastham & Sweet 2002).

An Australian study determined out-crossing rates between commercial fields of non-GM canola (Clearfield®) with tolerance to the herbicide OnDuty® (an imidazolinone herbicide) (Rieger et al 2002). Results indicated that in Australia, between adjacent fields, maximum gene flow was found to be very low (less than 0.2%). Gene flow was not detected in commercial fields further than 2.6 km from the pollen source (Rieger et al 2002).

Section 1.2.2 Likelihood of gene transfer through pollen

Herbicide tolerance

The most important trait when considering possible impacts on the environment is the herbicide tolerance trait, as it is the only one, which would be predicted to provide any selective advantage.

If gene transfer did occur it would probably be manifested as volunteers tolerant to the herbicide. The GM canola lines are susceptible to all other herbicides and non-chemical methods currently used to control conventional canola. However, as this release is limited and controlled, the licence conditions (detailed in Appendix 5 and summarised in Chapter 2) include measures, which would ensure that the likelihood of gene flow is minimised.

barnase and barstar

Any transfer of the barnase gene to other canola plants will not have any negative environmental impacts because it will only result in male sterility and not confer any selective advantage in terms of weediness or persistence. However, since male sterility increases the likelihood of being pollinated by external sources (Lefol et al. 1991); (Thompson et al. 1999), male sterile plants would have a marginally higher probability of acquiring genes from other plants. However, 50% of the progeny of such crosses would be male sterile which, unless pollinated, cannot reproduce and so are unlikely to persist in the environment. The remaining 50% of the progeny will be non-transgenic. The barstar gene would not confer any discernible phenotype or selective advantage trait.

Volunteer canola may also represent a potential pollen source for out-crossing. In the absence of effective post harvest management, volunteers from the GM canola lines could provide a source of gene transfer. Bayer proposes to isolate the GM canola lines from all other canola crops. When the trials are completed, Bayer proposes to inspect the sites and remove volunteers prior to flowering. These management measures have been incorporated into the licence conditions (detailed in Appendix 5 and summarised in Chapter 2).
Hybrid vigour

183 As discussed in Appendix 3, hybrid vigour in the GM canola lines is not a direct result of the genetic modification, ie it is not encoded by a ‘gene construct’ that can be transferred to other plants as a single locus in the same way as the herbicide tolerance gene. Therefore, outcrossing from RFx MS hybrids would not result in transfer of the hybrid vigour.

Section 1.2.3 Multiple herbicide resistance

184 There are two conventionally bred herbicide-tolerant canola varieties currently being grown throughout Australia –triazine tolerant and imidazolinone tolerant (Table 3). The Regulator recently approved the commercial release of glufosinate ammonium tolerant InVigor® canola and glyphosate tolerant Roundup Ready® canola. No commercial planting of InVigor® canola or Roundup Ready® canola has occurred to date.

Table 3: Areas planted to conventionally bred herbicide susceptible and herbicide tolerant (Clearfield® and triazine tolerant –TT) canola varieties in 2002 (‘000 ha) in each state. Values in parentheses are percentage of area sown. Figures are a guide only

<table>
<thead>
<tr>
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<th>NSW</th>
<th>VIC</th>
<th>SA</th>
<th>WA</th>
<th>TOTAL</th>
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<tr>
<td>Susceptible</td>
<td>120</td>
<td>48</td>
<td>13</td>
<td>7.2</td>
<td>188.2</td>
</tr>
<tr>
<td>Clearfield</td>
<td>40</td>
<td>48</td>
<td>26</td>
<td>10.8</td>
<td>124.8</td>
</tr>
<tr>
<td>TT</td>
<td>240</td>
<td>144</td>
<td>91</td>
<td>342</td>
<td>817</td>
</tr>
<tr>
<td>Total</td>
<td>400</td>
<td>240</td>
<td>130</td>
<td>360</td>
<td>1130</td>
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</tbody>
</table>

185 Hybridisation between the GM canola for this release and other GM canola or conventional herbicide tolerant varieties of canola would result in the accumulation or ‘stacking’ of genes for tolerance to multiple herbicides within the same plant. Senior and Dale (Senior & Dale 2002) found that stacking together of glyphosate and glufosinate ammonium tolerance traits into both winter and spring lines of canola did not alter their susceptibility to other, unrelated herbicides.

186 Development of tolerance to multiple herbicides (gene stacking) in canola volunteers has been observed in commercial situations in Canada (Downey 1999a; (Lefol et al. 1991; Hall et al. 2000); Beckie et al. 2001). In 1999, 11 fields in Canada were confirmed as containing multiple herbicide tolerant volunteers (Beckie et al. 2001). The frequency of gene stacking between adjoining glyphosate and glufosinate ammonium-tolerant crops was greatest on the field edge (closest to neighbouring GM crop) at approximately 1%, but within the crop was 0.2 % or less for distances between 50m and 800m, from the edge (Beckie et al. 2001).

187 The data on herbicide tolerance gene stacking from Canada, together with what is known about gene flow between canola support the conclusion that the likelihood of stacking of the herbicide tolerance trait from these GM canola lines with other herbicide tolerant canola would be dependent on proximity.

188 The likelihood of multiple herbicide tolerant canola having adverse impacts on natural undisturbed habitat is very low. As previously stated, canola is not considered a weed of undisturbed habitats and plants with multiple herbicide tolerance will not be more weedy or invasive than single herbicide tolerant or non-herbicide tolerant canola types and would be unlikely to have an impact on agricultural practices except the choice of herbicides for weed management (Orson 2002).
189 As this release is small and would be conducted under limited and controlled conditions, the risk of gene stacking would be managed. The licence conditions (detailed in Appendix 5 and summarised in Chapter 2) include measures that limit the dissemination and persistence of the GMOs and minimise the likelihood of gene transfer to other herbicide tolerant canola.

Section 1.3 Reproductive isolation from other canola crops

190 Measures to effect reproductive isolation of GM canola from non-GM canola during field trials are routinely imposed by other regulatory agencies (eg. Canadian Food Inspection Agency; Animal and Plant Health Inspection Service, United States Department of Agriculture; Ministry of Agriculture, Fisheries and Food, U.K.) and similar strategies were used under the previous voluntary regulatory system in Australia. These measures included minimum isolation distances from non-GM crops (Scheffler et al. 1993b); (Timmons et al. 1995); (Thompson et al. 1999) and the use of pollen traps, to reduce the amount of GM pollen leaving the GM crop (Morris et al. 1994); (Staniland et al. 2000); (Canadian Food Inspection Agency 2001).

191 Surrounding the GM plants with a pollen trap of conventional or male sterile canola will reduce the amount of GM pollen that can be transferred to other canola. To determine the threshold distance that would provide barrier to acceptable gene dispersal, scientists studied the influence of trap crop and gap (barren or isolation zone) on gene flow (Morris et al, 1994; Reboud 2002).

192 Reboud (2003) reported that a pollen trap of only 1 m afforded the same reduction on out-crossing as a gap of 3-4 m. Morris et al (1994) demonstrated that the rate of out-crossing between GM and non-GM canola can be reduced by a pollen trap. Staniland et al (2000) reported that surrounding GM canola with non-GM pollen trap of between 10-30 m significantly reduced the amount of out-crossing, with average out-crossing rate of 0.7% at the GM-non-GM interface and declined to 0.02% at 30m. The majority of out-crossing (80%) occurred in the first 10m.

193 In a GM field surrounded by a non GM pollen trap, out-crossing frequency at distance beyond 12 m was found to be less than 0.016 % in Europe (Scheffler et al. 1993a). When surrounded by a pollen trap, no out-crossing was detected beyond 70 m in UK and 32 m in Belgium and France (Scheffler et al. 1993b); (Stanton et al. 2003).

194 Licence conditions are imposed (see Appendix 5) that require reproductive isolation of the GM canola lines from other canola crops or sexually compatible species by 400 m minimum isolation distance and a 15 m pollen trap, or 1000 m isolation zone without a pollen trap which would significantly reduce the likelihood of gene transfer. Bayer proposes to establish a monitoring zone within the isolation zone where any canola and sexually compatible species within 50 m of the release sites will be removed. This has also been incorporated into the licence conditions. Consistent with the OGTR policy to consistently review data, the conditions also include a requirement to conduct outcrossing studies for GM canola under Australian field conditions to confirm previous research results.

Section 1.4 Conclusions regarding gene transfer to other canola crops

195 The risk of gene transfer from the release to other canola is very low. In summary:

- gene transfer through pollen to other canola crops in adjacent fields is likely to occur at very low rate but the rate of gene transfer decreases significantly at distances of over 5–10 m and decrease further to less than 0.01% at greater distance from the pollen source;
- hybrid vigour is not a direct result of the genetic modification and cannot be transferred;
- transfer of the herbicide tolerance gene would only confer selective advantage in the presence of the herbicide. The GM canola lines could be controlled by other herbicides and non-chemical management measures;
- the overall risk of gene transfer from this GM canola would be very low because of the small scale of the release and the licence conditions.

196 In addition, licence conditions (detailed in Appendix 5 and summarised in Chapter 2) have been imposed to further minimise the likelihood of gene transfer between GM canola and other canola crops.

SECTION 2 TRANSFER OF INTRODUCED GENES TO OTHER PLANTS

197 The likelihood of genes transferring from canola to other plants has been considered in detail in the document “The Biology and Ecology of canola (Brassica napus)” (OGTR 2002) that was produced in order to inform the risk assessment processes for licence applications involving GM canola. This document can be accessed at www.ogtr.gov.au.

Section 2.1 Other sexually compatible Brassica species

Section 2.1.1 Nature of gene transfer hazard

198 Transfer of the introduced genes or regulatory sequences to other Brassica species ie B. rapa, B. juncea and B. oleracea would present the same hazards and have the same potential impacts as the presence of the genes in the GM canola for this release (see Appendices 2 and 3).

199 Field hybrids and introgression of foreign genes has been demonstrated for B. rapa and B. juncea (Metz et al. 1997). But the rate of hybridisation and introgression will be influenced by the distribution, proximity and genetic compatibility of each species. The commercial production of B. rapa as an oil seed in Australia is limited due to the availability of higher yielding, better-adapted B. napus cultivars (Salisbury 2002b). There are small commercial growing areas of B. juncea, often spring-sown in the high rainfall regions (Salisbury 2002b). B. napus (AACC) shares a common set of chromosomes with B. rapa (AA), B juncea (AABB) and B. oleracea (CC).

Section 2.1.2 Likelihood of the gene transfer to other compatible Brassica spp.

Brassica rapa

200 Naturally occurring B. rapa is found throughout Australia and sometimes occurs as a minor weed of agriculture and non disturbed areas (Auld & Medd 1987). While not regarded as a problem in South Australia, it is a minor problem in Queensland, New South Wales and Victoria and a major problem in cereals and vegetables in Tasmania (Hyde-Wyatt & Morris 1989; Groves et al. 2000). None of the release sites are located in Tasmania. B. rapa has seed dormancy and seed longevity and seed may persist in the soil for many years (Canadian Food Inspection Agency 1999). B. rapa is self incompatible and an obligate outcrosser (Jorgensen et al. 1999); Salisbury 2002b).

201 The reported rates of out-crossing between B. rapa and B. napus were discussed in detail in the RARMP for DIR 021/2002.

202 In summary, out-crossing between canola and B. rapa can occur particularly if they are in close proximity, and the rate is mainly influenced by distance. Gene introgression into
*B. rapa* populations is extremely low because F1 hybrids tend to be less fit than parental species.

**Brassica juncea**

203 *Brassica juncea* occurs throughout Australia (Queensland, New South Wales, South Australia, Western Australia and Victoria) (Groves et al. 2000) and is regarded as a minor weed in agricultural areas (Salisbury 2002b). *Brassica juncea* is grown on a small scale in Australia for the condiment and cold pressed oil markets.

204 As discussed in detail in the RARMP for DIR 021/2002, spontaneous occurrence of interspecific hybrids between canola and *B. juncea* has been reported (Bing & Lewis 1991; Frello et al. 1995; Bing et al. 1996; Jorgensen et al. 1996). Hybrids were mostly sterile but some survived and could be backcrossed with parental species (Jorgensen et al 1998). The results indicate that subsequent gene introgression into *B. juncea* populations is possible but very unlikely to occur because of the low fitness of the F1 hybrids.

205 The introduced genes would be unlikely to increase the weediness of *B. rapa* or *B. juncea* and would only confer a selective advantage in the presence of the herbicide. If gene transfer did occur, the hybrid progenies containing the herbicide tolerance gene could be easily controlled by alternative herbicides and non-chemical management measures.

206 Bayer has proposed to implement management measures imposed by the Regulator for the previous limited and controlled releases of GM canola to ensure reproductive isolation between the GM canola lines and sexually compatible species.

**Brassica oleracea**

207 Although *B. napus* and *B. oleracea* share a common set of chromosomes, which makes hybridisation potentially possible, successful crosses have been difficult to achieve even in laboratory conditions (Eastham & Sweet 2002; Salisbury 2002b). No hybrids have been reported in the field for *B. napus* and *B. oleracea* vegetables such as cauliflowers, brussel sprouts, broccoli, etc (Scheffler & Dale 1994; Scheffler et al. 1995). Unless used as a seed production crop, *B. oleracea* is generally harvested before flowering, thereby limiting the potential for gene transfer from canola (Salisbury 2002b). Furthermore, these plants are not recognised as weeds in agricultural environments in Australia.

**Section 2.1.3 Conclusion regarding gene transfer to other compatible Brassica species**

208 In summary:

- the risk from gene transfer to other compatible *Brassica* species is considered to be very low due to:
  - reduced fitness of any progeny;
  - these species are not commonly found in canola fields;
  - their distribution in the released areas is limited;
- the release is small and would be conducted under conditions that would minimise gene flow from the GM canola to compatible *Brassica* species; and
- if gene transfer did occur, the hybrid progeny containing the herbicide tolerance gene could be easily controlled by alternative herbicides and non-chemical management measures.
Section 2.2  Sexually compatible weedy relatives

Section 2.2.1  Nature of gene transfer hazard

209 Only three related brassicaceous species in Australia are considered as possible candidates for spontaneous hybridisation and introgression – *Raphanus raphanistrum*, *Hirschfeldia incana* and *Sinapis arvensis* (Salisbury 2002a) although some other species can be crossed with *B. napus* through hand pollination (Table 4). Spontaneous cross-pollinations with related brassicaceous weeds have been recorded either in Australia or overseas (Salisbury 2002b). The crossability between *B. napus* to these species is dependent on the relatedness to *B. napus*, the density of weedy species, flowering synchronisation and environmental conditions (Rieger 2002). Interspecific crossing between canola and *R. raphanistrum*, *H. incana* and *S. arvensis* occurs at very low levels, particularly when canola is the male parent (Chevre et al. 1999).

210 Transfer of the herbicide tolerance gene from the GM canola into other plant species, in particular to weedy and wild relatives such as *R. raphanistrum*, *H. incana* and *S. arvensis* (Salisbury 2002a) could result in a herbicide tolerant biotype that would have a selective advantage in situations where the herbicide is used to control them.

Section 2.2.2  Likelihood of gene transfer to other weedy relatives

211 This risk was assessed in detail in the RARMP for DIR 021/2002. In view of the limited and controlled nature of this release, the assessment is summarised here.

*Raphanus raphanistrum*

212 Of these weed species, *R. raphanistrum* is the most widespread in the Australian cropping zone (Blackshaw 2001). *R. raphanistrum* occurs as a weed in Queensland, New South Wales, Victoria, Tasmania, South Australia and Western Australia (Groves et al 2000). Large number of *R. raphanistrum* can occur along roadsides and railway lines in and around canola growing areas in Australia (Agrisearch 2001; Dignam 2001).

213 Out-crossing and gene introgression from *B. napus* to *R. raphanistrum* is possible but only at a very low rate and would require physical proximity. The hybrids were found to be less fit than the weedy parent.

*Hirschfeldia incana*

214 *Hirschfeldia incana* (Buchan weed) occurs in Queensland, New South Wales, Victoria, Tasmania, South Australia and Western Australia and is characteristically a weed of disturbed soils in eastern Australia (Salisbury 2002a). It is listed by Groves et al (2000) as a minor problem in agricultural areas of Queensland and New South Wales. *H. incana* is also capable of invading disturbed native vegetation. It can also occur in large numbers along railways and roadsides in canola growing regions in Australia (Dignam 2001).

215 Introgression of genes from GM canola into *H. incana* is unlikely for two main reasons: firstly, hybrids have low fertility and fitness relative to their parents; secondly, because of very low sexual compatibility between canola and *H. incana* (Lefol et al 1996b; Chevre et al 1999a).

*Sinapis arvensis*

216 *Sinapis arvensis* (charlock) occurs in Queensland, New South Wales, Victoria, Tasmania, South Australia and Western Australia. For the most part, charlock is a problem in agriculture areas and is a particularly serious weed in cropping regions of New South Wales
(Groves et al 2000). It can also occur in disturbed sites along roadsides and railways in canola growing regions of Australia (Dignam 2001).

217 Scientific evidence indicates that the likelihood of introgression of genes from the GM canola into S. arvensis is extremely remote.

**Other weed species in Brassicaceae family**

218 No natural hybrids between B. napus and other weedy species in the Brassicaceae family have been reported eg B. tournefortii, B. fruticulosa, B. oxyrrhina, Diplotaxis muralis, D. tenuiflia, Rapistrum rugosum (Salisbury 1991) (Table 4). Even with the use of hand pollination and embryo rescue techniques, no hybrids have been obtained with weedy crucifer species tribes (eg Myagrum perfoliatum, Capsella bursa-pastoris, Sisymbrium spp., Cardaria draba) (Salisbury 1991, Salisbury 2002a).

219 The likelihood of gene transfer from B. napus to other non-compatible brassicaceous species via an intermediate species is considered to be extremely low. Such a transfer necessitates the occurrence of hybrid progeny, stable introgression, followed by another successful hybridisation between the interspecific hybrid or introgressed population and the third species, with the attendant prerequisites of proximity and flowering synchrony.

**Section 2.2.3 Conclusion regarding gene transfer to weedy relatives**

220 The risk of gene transfer from the limited and controlled release of GM canola lines to related brassicaceous weeds is considered to be very low. In summary:

- hybridisation between the GM canola lines and R. raphanistrum, H. incana and S. arvensis is possible but at very low rates and requires physical proximity and flowering synchrony;
- interspecific hybrids have significantly reduced fitness and significant barriers to introgression of gene from canola; and
- the herbicide tolerance gene would only confer a selective advantage in the presence of the herbicide. Hybrids could be controlled by alternative herbicides and non-chemical management measures.

221 Licence conditions are imposed (detailed in Appendix 5 and summarised in Chapter 2) to require reproductive isolation from these species during the release to further limit the possibility of out-crossing.
<table>
<thead>
<tr>
<th>Category</th>
<th>I</th>
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<th>III</th>
<th>IV</th>
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<td>Brassiceae</td>
<td>Brassiceae</td>
<td>Brassiceae</td>
<td>Brassiceae</td>
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<td>Raphanus raphanistrum</td>
<td>Brassica fruticulosa</td>
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<td>Conringia orientalis</td>
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<td>Brassica juncea(^1)</td>
<td>Hirschfeldia incana</td>
<td>Brassica nigra</td>
<td>Diplotaxis tenuisiliqua</td>
<td>Carrichtera annua</td>
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<td></td>
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<td>Brassica tournefortii</td>
<td>Diplotaxis muralis</td>
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<td>Cakile maritima</td>
<td>Lepidium sp.</td>
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<td>Myagrum perfoliatum</td>
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<td></td>
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<td>Rapistrum rugosum</td>
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<td>Sisymbrium orientale</td>
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<td></td>
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<td></td>
<td></td>
<td>Sisymbrium officinale</td>
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<tr>
<td>Condiment, fodder &amp; vegetable species</td>
<td>Forage B. napus(^1)</td>
<td>Brassica albo glabra(^3)</td>
<td>Brassica chinensis(^4)</td>
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</tr>
<tr>
<td></td>
<td>B. napus vegetables(^1)</td>
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<td>Brassica oleracea</td>
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</tr>
<tr>
<td></td>
<td>B. rapa vegetables(^1)</td>
<td>Brassica pekinensis(^4)</td>
<td>Raphanus sativus</td>
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<tr>
<td></td>
<td>Condiment B. juncea(^1)</td>
<td>Sinapis alba</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

DECREASING SEXUAL COMPATIBILITY →
\(^1\) Considered likely to happen over a period of time if the species are in physical proximity and have flowering synchrony.
\(^2\) Frequency of interspecific hybrids approx. $10^{-4}$ to $10^{-8}$. Likelihood of subsequent introgression or formation of fertile amphidiploids significantly less again.
\(^3\) This species is sometimes considered to be a subspecies of *B. oleracea*.
\(^4\) These species have sometimes been considered to be subspecies of *B. rapa*. 

Table 4. Potential gene flow between canola (*B. napus*) & Australian Brassicaceae species (Salisbury 2002)
SECTION 3 TRANSFER OF INTRODUCED GENES TO OTHER ORGANISMS  
(ANIMALS & MICROORGANISMS)

222 The likelihood of genes transferring from canola to other organisms has been 
considered in detail in the document “The Biology and Ecology of canola (Brassica napus)” 
(OGTR 2002) that was produced in order to inform the risk assessment processes for licence 
applications involving GM canola. This document can be accessed at www.ogtr.gov.au. In 
summary, the transfer of the introduced genes from GM canola to humans or other animals is 
extremely unlikely.

Section 3.1 Nature of the gene transfer hazard

223 The transfer of genes from plants to other types of organisms cannot occur through 
cross-pollination. Horizontal gene transfer is defined as the transfer of genetic material from 
one organism (the donor) to another organism (the recipient) which is not sexually 
compatible with the donor (Conner et al. 2003). There is growing evidence that horizontal 
gene transfer has been a principal force in the evolution of bacteria (Ochman et al. 2000; 

224 The potential hazards associated with the introduced genes of GM herbicide tolerant 
canola transferring to microorganisms could be highly varied, broadly depending upon the 
phenotype of the recipient and any changes to its survival or reproductive capacity.

225 The likelihood of gene transfer creating a hazard for human health and safety or the 
environment depends on the characteristics of introduced gene sequences, as well as on the 
likelihood of transfer itself.

Section 3.1.2 Potential hazards of transfer of the genes from the GM canola

Male sterility gene (barnase) and the fertility restorer gene (barstar)

226 These genes are derived from Bacillus amyloliquefaciens and the barnase gene encodes 
an RNase and the barstar gene encodes its inhibitor (see Appendix 1 for details). RNases are 
ubiquitous in nature and serve many biological functions. B. amyloliquefaciens is a 
commonly occurring soil bacterium and is frequently used as a source for industrial enzymes 
such as alpha amylase (ANZFA 2001).

Herbicide tolerance gene

227 The transfer of herbicide-tolerance genes to animals or other organisms is unlikely to 
present a hazard to human health or the environment.

Promoters and other regulatory sequences

228 If gene transfer occurred, there could be unintended or unexpected effects if the 
introduced regulatory sequences alter the expression of endogenous genes. If such 
perturbation of normal gene expression occurred, the impact would depend on the resultant 
phenotype.

229 The regulatory sequences present in the GM canola lines are derived from organisms 
prevalent in the environment. All of these sequences and the organisms they were derived 
from are frequently encountered in the environment. While some of these sequences are 
derived from plant pathogens (including Agrobacterium tumefaciens) the regulatory 
sequences only represent a very small proportion of the pathogen genome and are not, in 
themselves, infectious or pathogenic.
All of the introduced regulatory sequences operate in the same manner as do endogenous plant regulatory elements. The transfer of endogenous regulatory elements to a new genetic context could also result in unpredictable effects. Thus the hazard arising due to transfer of the introduced sequences would be no different to that of sequence transfer from non-GM plants.

**Section 3.2   Likelihood of hazard arising through gene transfer from GM canola to other organisms**

The likelihood of gene transfer creating a hazard for human health and safety or the environment depends on the characteristics of the introduced gene sequences, as well as on the likelihood of the transfer itself and on the likelihood of transfer from other sources of these genes in the environment.

Most gene transfers have been identified through analyses of gene sequences (Ochman et al. 2000; Worobey & Holmes 1999). In general, gene transfers are detected over evolutionary time scales of millions of years (Lawrence & Ochman 1998). Most gene transfers have been from virus to virus (Lai 1992), or between bacteria (Ochman et al. 2000). In contrast, transfers of plant genes to other organisms such as bacteria, fungi or viruses are exceedingly rare (Mayo & Jolly 1991; Nielsen et al. 1998; Nielsen et al. 2000; Harper et al. 1999; Schoelz & Wintermantel 1993; Greene & Allison 1994; Pittard 1997; Aoki & Syono 1999; Worobey & Holmes 1999). The transfer of plant genes to bacteria and viruses has been observed in laboratory and glasshouse experiments (Nielsen et al. 1998; Nielsen et al. 2000; Schoelz & Wintermantel 1993; Greene & Allison 1994; Pittard 1997; Worobey & Holmes 1999). However, in all cases this was achieved only under controlled conditions with the presence of related gene sequences (homologous recombination), and using powerful selection methods to detect extremely rare gene transfer events.

**Section 3.2.1   Likelihood of transfer to animals (including humans)**

Theoretically, the introduced genes in the GM canola could be transferred to other animals including humans, via horizontal gene transfer. However, no mechanism has been identified by which plant genes could directly transfer to humans or animals. The most frequently postulated route is via ingestion of plant material, where the introduced gene is transferred into a gut bacterium and then into a cell in the gut lining.

The horizontal transfer of genes from transgenic plants to micro-organisms, to animals or humans would require a series of steps to occur, each of which has a very low probability (Pittard 1997). An intact copy of the gene would need to:

- Survive degradation during processing of food in the gut, and by acid and nucleases in the stomach and intestines;
- Be taken up by a bacterium;
- Survive efficient bacterial defence mechanisms for degrading foreign DNA; and
- Become stably integrated into the bacterial genome or on a plasmid, in precise alignment with a bacterial promoter (if this were not co-transferred intact from the plant).

Thus the risk of gene transfer leading to hazardous consequences is extremely low, and greatly exceeded by the likelihood of transfer from other sources of these genes and regulatory sequences.
Section 3.2.2  Likelihood of transfer to micro-organisms

Bacteria

237 Three different mechanisms of horizontal gene transfer (HGT) in bacteria have been described: transduction, conjugation, and transformation (Nielsen 1998).

238 Transduction is a bacterial cell-virus interaction that can mediate gene transfer between bacteria in the environment (e.g. on plant leaf surfaces, in soil or water). Viruses that function in more than one species are known, but viruses that function in both plants and bacteria, and thereby facilitate HGT from plants to bacteria have not been identified (Nielsen et al. 1998).

239 Conjugation is a mechanism of cell-to-cell interaction that can mediate gene transfer between bacteria in the environment (e.g. in soil, on plant surfaces, in water etc).

240 Conjugation is known to occur frequently between compatible bacteria with the transferable genes usually residing on plasmids. Transfer of chromosomal genes is much less frequent, except for some high frequency recombination strains. Conjugative gene transfer has been regarded as the most frequently occurring mechanism of HGT between bacteria (Sprague 1991; Amabile-Cuevas & Chicurel 1993). However, mechanisms that support conjugative gene transfer from higher plants to bacteria (e.g. transposons that function in both plants and prokaryotes) are not known (Nielsen 1998).

241 Gene transfer by transformation results in the uptake of naked DNA by bacteria, and has been shown to occur in environments such as in soil, on plants, and in water. Most studies describing natural transformation have been conducted in vitro (Streips 1991; Lorenz & Wackernagel 1994) but often are of little relevance to most natural terrestrial environments.

242 Natural transformation is a mechanism by which transfer of DNA from plants to microorganisms could have occurred during evolution (Bertolla & Simonet 1999) and is the mechanism that is most likely to contribute to a horizontal gene transfer from transgenic plants to bacteria (Smalla et al. 2000). Natural transformation enables competent bacteria to generate genetic variability by taking up and integrating free DNA that is present in their surroundings. This uptake of DNA does not necessarily depend on DNA sequence, thus indicating the potential of gene transfer from divergent donor organisms (Nielsen 1998).

243 A number of steps and conditions would need to be fulfilled for functional natural transformation to occur (Bertolla & Simonet 1999), many of which are highly unlikely, making the overall likelihood of gene transfer, and of resulting hazard, extremely low:

- release of the DNA molecules from plant cells into the environment and persistence of the free DNA in the environment;
- presence of bacterial genotypes capable of developing competence for natural transformation and uptake of DNA fragments;
- chromosomal integration via recombination or autonomous replication of the transforming DNA;
- expression of the genes by the recipient bacterium and selective advantage to fix the transformation into the gene pool.

244 The likelihood of each of these events occurring is extremely low, and the combined probability of forming an unbroken chain of events resulting in a hazard is negligible.
Thus horizontal gene transfer from plants to bacteria has not been demonstrated under natural conditions (Syvanen 1999) and deliberate attempts to induce such transfers have so far failed (e.g. (Coghlan 2000). Transfer of plant DNA to bacteria has been demonstrated only under highly artificial laboratory conditions, between homologous sequences and under conditions of selective pressure (Mercer et al. 1999; Gebhard & Smalla 1998; De Vries & Wackernagel 1998; De Vries et al. 2001) and even then only, at a very low frequency.

**Viruses**

There is a theoretical possibility of recombination between sequences that have been introduced into the genome of GM plants and the genome of viruses that infect the plants (Hodgson 2000a; Ho et al. 2000; Hodgson 2000b). Recombination between viral genomes and plant DNA has only been observed at very low levels, and only between homologous sequences under conditions of selective pressure, e.g. regeneration of infectious virus by complementation of a defective virus by viral sequences introduced into a GM plant genome (Greene & Allison 1994; Teycheney & Tepfer 1999). With homologous sequences the consequent risk of adverse effects arising from gene transfer is reduced because with highly similar sequences the likelihood of any recombinants expressing novel properties is low.

Thus the risk of gene transfer leading to hazardous consequences is extremely low, and greatly exceeded by the likelihood of transfer from other sources of these genes and regulatory sequences.

**Fungi**

Fungi are known to be transformable, and horizontal gene transfer from plants to plant-associated fungi has been claimed. Uptake of DNA from the host plant by *Plasmodiophora brassicae* (Bryngelsson et al. 1988; Buhariwalla & Mithen 1995) and uptake of the hygromycin gene from a GM plant by *Aspergillus niger* (Hoffman et al. 1994) have been reported. However, stable integration and inheritance of the plant DNA in the genome of these fungi has not been substantiated by experimental evidence (Nielsen 1998).

Thus the risk of gene transfer leading to hazardous consequences is extremely low, and greatly exceeded by the likelihood of transfer from other sources of these genes and regulatory sequences.

### SECTION 4 CONCLUSIONS REGARDING GENE TRANSFER TO OTHER ORGANISMS

A series of events are necessary for successful horizontal gene transfer to occur. It is considered that there is negligible risk of transferring the introduced genes in canola to other sexually incompatible organisms such as humans, other animals, fungi, bacteria, viruses and other micro-organisms. This is because:

- the chance of interaction, uptake and integration of intact plant DNA by other organisms is extremely low, especially if it involves unrelated sequences (non-homologous recombination) leading to a limited probability of occurrence;
- horizontal gene transfer has generally been achieved (*in vitro*) only with related gene sequences (homologous recombination) using high selective pressure and sensitive detection systems to identify very rare events;
- the chance that any novel organism that may arise from gene transfer will survive, reproduce and have a selective advantage (competitiveness or fitness) is extremely low and there is a limited probability of persistence;
natural events of horizontal gene flow from plants to distantly related organisms are extremely rare;
the introduced genes are already widespread in the environment and gene transfer from these natural sources is more likely than gene transfer from the GM canola; and
any organism that acquires the novel genes is unlikely to pose any additional risks to human health and safety, or the environment.

250 The most significant route of entry of foreign DNA into animals and humans is through food. However, products from the GM canola will not be allowed to be fed to animals or enter the human food supply. Thus the likelihood of gene transfer to animals or humans is negligible. In the extremely unlikely event of such a transfer occurring, human health and safety and the environment are unlikely to be adversely affected.

SECTION 4 SUMMARY OF RESEARCH REQUIREMENTS FOR PROPOSED RELEASE

251 The licence conditions include a requirement to conduct outcrossing studies for GM canola under Australian field conditions to confirm previous research results.
APPENDIX 5 LICENCE CONDITIONS

Gene Technology Regulation in Australia
The Gene Technology Act (2000) and corresponding state and territory legislation is designed to complement other regulatory functions relevant to controlling GMOs and their use.

The Gene Technology Regulator is required to consult with, and take into account advice from a range of regulatory authorities on risks to human health and safety and to the environment in assessing applications for dealings involving the intentional release of GMOs into the Australian environment.

Note in relation to the approval of genetically modified foods for human consumption
Food Standards Australia New Zealand (FSANZ), is responsible for human food safety assessment. Due to the early stage of this research, Bayer has not applied to FSANZ for evaluation of material from the GM canola for use in human food. FSANZ approval would need to be obtained before any parts of the GM canola such as oil derived from GM canola seed could be used as human food. Therefore, the licence contains a condition prohibiting the use of material from this release for human food.

Note in relation to herbicide usage and herbicide resistance management
The GMOs referred to in this licence have been modified to be tolerant to a herbicide. The Australian Pesticide and Veterinary Medicines Authority, (APVMA) has responsibility for setting registration conditions for the use of herbicides in Australia, including implementation of herbicide resistance management programs.

The small amounts of herbicide intended to be used during the trials do not require a specific permit from the APVMA and would be covered by the general small scale trial permit allowed by the APVMA.
SECTION 1  INTERPRETATION AND DEFINITIONS

This licence does not authorise dealings with GMOs that are otherwise prohibited as a result of the operation of State legislation declaring areas to be GM, GM free, or both, for marketing purposes.

In this licence:

Words and phrases used in this licence have the same meaning as they do in the Act and the Regulations;

Words importing a gender include any other gender;

Words in the singular include the plural and words in the plural include the singular;

Words importing persons include a partnership and a body whether corporate or otherwise;

References to any statute or other legislation (whether primary or subordinate) are a reference to a statute or other legislation of the Commonwealth of Australia as amended or replaced from time to time and equivalent provisions, if any, in corresponding State law, unless the contrary intention appears;

Where any word or phrase is given a defined meaning, any other part of speech or other grammatical form in respect of that word has a corresponding meaning;

Specific conditions prevail over standard conditions to the extent of any inconsistency.

In this licence:

‘Act’ means the Gene Technology Act 2000 (Cth) and equivalent provisions in corresponding State law;

‘Brassica plants’ means the following species:

(a) Brassica napus;
(b) B. rapa; and
(c) B. juncea

‘Brassica crops’ means any crop of Brassica plants or Canola (and includes commercial Brassica crops)

‘Brassicaceous weeds’ means the following species:

(a) Hirschfeldia incana;
(b) Raphanus raphanistrum;
(c) Sinapis arvensis.

‘Burial site’ means a place where the GMOs or Material from the GMOs is Destroyed by burial under at least 1 metre of soil
‘Canola’ means plants of the species Brassica napus containing less than 2% erucic acid and 30 µmol/g akyl glucosinolates.

‘Clean’ (or ‘Cleaned’), as the case requires, means:

(a) in relation to a Location or other area, the Destruction of the GMOs, Material from the GMOs, Pollen Trap plants and Material from Pollen Trap plants in that Location or area, to the reasonable satisfaction of the Regulator; or

(b) in relation to Equipment, the removal and Destruction of the GMOs, Material from the GMOs, Pollen Trap plants and Material from Pollen Trap plants from the Equipment, to the reasonable satisfaction of the Regulator.

‘Destroy’, (or ‘Destroyed’ or ‘Destruction’) means, as the case requires, killed by one or more of the following methods:

(a) treatment with herbicide(s);
(b) slashing;
(c) mowing;
(d) hand weeding;
(e) shredding/mulching mechanically;
(f) burning;
(g) cutting;
(h) autoclaving;
(i) incineration;
(j) burial under at least 1 metre of soil;
(k) light tillage.

Note ‘As the case requires’ has the effect that, depending on the circumstances, one or more of these techniques may not be appropriate. For example, in the case of killing the remains of harvest of the GMO, treatment of post harvest remains by herbicide would not be a sufficient mechanism.

‘Equipment’ includes harvesters, seeders, storage equipment, transport equipment (eg bags, containers, trucks), clothing and tools.

‘GM’ means genetically modified.

‘GMOs’ means the genetically modified organisms authorised for release by this licence.

‘Isolation Zone’ means, in respect of a Location, an area of land surrounding either the Location, or the Location’s Pollen Trap (if the Location is surrounded by a Pollen Trap) that is known not to contain any Brassica crops when the GMO is planted at the Location.

Note: the size of the Isolation Zone is variable depending on what other measures to manage gene flow are adopted by the licence holder. More detail about the size of Isolation Zone is set out at Condition 5 of Part 3 Specific Licence Conditions.
‘Light tillage’ or ‘Lightly tilled’ means the use of a technique to disturb the soil in an area in order to promote the growth of any GMOs in that area and to reduce onset of secondary dormancy of GMO seed in that area, but so as not to bury plant material in the area to a depth of more than 50 mm.

‘Location’ means an area of land where the GMOs are planted and grown.

‘Material from Pollen Trap plants’ means seed, stubble, pollen or any GM material (including parts of a plant) that is derived from or produced by Canola from a Pollen Trap.

‘Material from the GMOs’ means genetically modified material, including parts of GMOs that are derived from or produced by the GMOs.

‘Monitoring Zone’ means an area extending outwards by 50 m in all directions from the outer edge of a Location, or the Location’s Pollen Trap (if the Location is surrounded by a Pollen Trap).


‘Permitted Plants’ means grasses, cereals, clover, lucerne, vetch and chickpeas.

‘Pollen Trap’ means an area of land, extending at least 15 metres in all directions from the outside edge of a Location.

‘Pollen Trap plant’ means Canola from a Pollen Trap.

‘Prohibited Plants’ means Brassica plants of any kind (including Canola), beans, lupins, poppies, peas, potatoes, pumpkins and radish.

‘Regulator’ means the Gene Technology Regulator.

‘Volunteer Plants’ means progeny of the GMOs or a Pollen Trap plant.
SECTION 2 GENERAL CONDITIONS

Duration of Licence
1 This licence remains in force until it is suspended, cancelled or surrendered. No dealings with GMOs are authorised during any period of suspension.

Holder of Licence
2 The holder of this licence (‘the licence holder’) is Bayer CropScience Pty Ltd.

Project Supervisor
3.1 The Project Supervisor in respect of this licence is identified at Attachment A.
3.2 The licence holder must immediately notify the Regulator in writing if any of the contact details of the Project Supervisor change.

No dealings with GMOs except as authorised by this licence
4 Persons covered by this licence must not deal with the GMOs except as expressly permitted by this licence.

GMOs covered by this licence
5 The GMOs covered by this licence are described at Attachment B.

Permitted dealings
6 The permitted dealings with the GMOs are to plant, grow and conduct experiments with the GMOs, and the possession, supply, use, transport and disposal of the GMOs for the purpose of any of the permitted dealings with the GMOs, or in the course of any of these dealings.

Persons covered by this GMO licence
7 The persons covered by this licence are the licence holder and employees, agents or contractors of the licence holder and other persons who are, or have been, engaged to undertake any activity in connection with GMOs grown in a Location pursuant to this licence.

Informing people of their obligations
8.1 The licence holder must inform any person covered by this licence, to whom a particular condition of this licence applies, of the following:

   (a) the particular condition (including any variations of it);
   (b) the cancellation or suspension of the licence;
   (c) the surrender of the licence.

8.2 The licence holder must provide the Regulator, on the Regulator’s written request, signed statements from persons covered by this licence that the licence holder has informed those people of the conditions of this licence that apply to them.

Licence holder to notify of circumstances that might affect suitability
9.1 The licence holder must immediately, by notice in writing, inform the Regulator of:
   (a) any relevant conviction of the licence holder occurring after the commencement of this licence;
(b) any revocation or suspension of a licence or permit held by the licence holder under a law of the Australian Government, a State or a foreign country, being a law relating to the health and safety of people or the environment;

(c) any event or circumstances occurring after the commencement of this licence that would affect the capacity of the holder of his licence to meet the conditions in it.

Additional information to be given to the Regulator

10.1 The licence holder must inform the Regulator if the licence holder:

(a) becomes aware of additional information as to any risks to the health and safety of people, or to the environment, associated with the dealings authorised by the licence; or

(b) becomes aware of any contraventions of the licence by a person covered by the licence; or

(c) becomes aware of any unintended effects of the dealings authorised by the licence.

People dealing with GMOs must allow auditing and monitoring of the dealing

11.1 If a person is authorised by this licence to deal with GMOs and a particular condition of this licence applies to the dealing by that person, the person must allow the Regulator, or a person authorised by the Regulator, to enter premises where the dealing is being undertaken, for the purposes of auditing or monitoring the dealing.

Remaining an Accredited organisation

12 The licence holder must, at all times, remain an accredited organisation in accordance with the Act and comply with its instrument of accreditation.
SECTION 3  SPECIFIC LICENCE CONDITIONS

Location, size of release and restrictions on when the GMOs may be planted

Winter planting

1.1 The GMOs may be planted between 1 March and 31 August (‘the Canola winter growing seasons’) in 2004, 2005 and 2006, within the Shires set out in following table:

Table 1: Shires where permitted dealings with GMOs may be conducted

<table>
<thead>
<tr>
<th>VIC</th>
<th>SA</th>
<th>NSW</th>
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<tr>
<td>Ararat</td>
<td>Naracoorte/Lucindale</td>
<td>Collamon</td>
</tr>
<tr>
<td>Hindmarsh</td>
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<td>Culcairn</td>
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<td>Glenelg</td>
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<td>Lockhart</td>
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<td>Horsham</td>
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<td>Junee</td>
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</tbody>
</table>

1.2 For the Canola winter growing seasons, the maximum number of Locations for those growing seasons (where permitted dealings may be conducted) are set out in Table 2 at Column 2. The maximum combined area of all Locations where permitted dealings may occur in those growing seasons is limited to the size set out in Table 2 at Column 3:

Table 2: Maximum numbers of Locations and combined areas

<table>
<thead>
<tr>
<th>Canola winter growing season</th>
<th>Maximum number of Locations/year</th>
<th>Maximum combined area of all Locations/year</th>
</tr>
</thead>
<tbody>
<tr>
<td>2004</td>
<td>4</td>
<td>16</td>
</tr>
<tr>
<td>2005</td>
<td>4</td>
<td>16</td>
</tr>
<tr>
<td>2006</td>
<td>4</td>
<td>16</td>
</tr>
</tbody>
</table>

1.3 In the Canola winter growing seasons, the maximum size of any individual Location is 4 hectares. (No individual field trial site can be more than 4 hectares.)

Summer plantings

1.4 The GMOs may be planted between 1 September and 31 January (‘the Canola summer growing seasons’) in 2004/2005, 2005/2006 and 2006/2007, within the Shires set out in following table:
Table 3: Shires where permitted dealings with GMOs may be conducted

<table>
<thead>
<tr>
<th>VIC</th>
<th>SA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glenelg</td>
<td>Naracoorte/Lucindale</td>
</tr>
<tr>
<td>Grant</td>
<td>Wattle Range</td>
</tr>
</tbody>
</table>

1.5 For the Canola summer growing seasons, the maximum number of Locations for those growing seasons (where permitted dealings may be conducted) are set out in Table 4 at Column 2. The maximum combined area of all Locations where permitted dealings may occur in those growing seasons is limited to the size set out in Table 4 at Column 3:

Table 4: Maximum numbers of Locations and combined areas

<table>
<thead>
<tr>
<th>Canola summer growing season</th>
<th>Maximum number of Locations/year</th>
<th>Maximum combined area of all Locations/year</th>
</tr>
</thead>
<tbody>
<tr>
<td>2004</td>
<td>2</td>
<td>6</td>
</tr>
<tr>
<td>2005</td>
<td>2</td>
<td>6</td>
</tr>
<tr>
<td>2006</td>
<td>2</td>
<td>6</td>
</tr>
</tbody>
</table>

1.6 In the Canola summer growing seasons, the maximum size of any individual Location is 3 hectares. (No individual field trial site can be more than 3 hectares.)

1.7 At least 7 days prior to commencing to grow the GMOs at a Location, the Location’s GPS coordinates and either a street address, or other directions to the Location must be provided to the Regulator by notice in writing.

1.8 The GMOs must not be grown at any Location in more than one growing season. (A Location cannot be used in successive or multiple growing seasons.)

1.9 The licence holder must be able to access and control a Location to the extent necessary to comply with this licence, for the duration of the life of the licence.

1.10 If the GMOs are planted they may be grown.

1.11 No GMOs may be planted after 31 January 2007.

Use of GMOs, Material from the GMOs, Pollen Trap plants and Material from Pollen Trap plants

2 The licence holder must ensure that the GMOs, Material from the GMOs, Pollen Trap plants or Material from Pollen Trap plants are not consumed by humans or used in manufacture of animal feed.

Notice of planting

3.1 The licence holder must provide a notice in writing to the Regulator each time the GMOs are planted at a Location.

The notice must set out:

(a) The date on which planting of the GMOs commenced;

(b) Details of the Location where the GMOs are planted, including a street address and GPS coordinates for the Location if requested.
(c) The period during which the licence holder considers the GMOs are likely to flower; and

(d) The period during which the licence holder considers the GMOs are likely to be harvested (or Destroyed at a Location in lieu of harvest).

3.2 The notice must be provided to the Regulator within 14 days of the date on which planting of the GMOs commenced.

Notice of harvest or Destruction of the GMOs

4.1 The licence holder must provide a notice in writing to the Regulator when a Location is Cleaned (following harvest or Destruction of GMOs at a Location in lieu of harvest).

4.2 The notice must be provided to the Regulator within 14 days of the date on which Cleaning the Location concluded.

Measures to manage gene flow

5 For each Location, one of the following methods for managing gene flow must be adopted:

(a) the GMOs at the Location must be male sterile Canola only. The Location must be surrounded by an Isolation Zone extending outwards by at least 400 m in all directions from the outer edge of the Location;

(b) all flowering heads of the GMOs at the Location must be covered with selfing bags at least 7 days prior to flowering. The bags must remain on the GMOs during flowering. The Location must be surrounded by an Isolation Zone extending outwards by at least 400 m in all directions from the outer edge of the Location;

(c) the GMOs at the Location must be covered by an insect proof cage. The cage must remain in place during flowering. The Location must be surrounded by an Isolation Zone extending outwards by at least 400 m in all directions from the outer edge of the Location;

(d) the Location must be surrounded by an Isolation Zone extending outwards by 1 km in all directions from the outer edge of the Location; or

(e) the Location must be surrounded by a Pollen Trap. The Pollen Trap must be surrounded by an Isolation Zone extending outwards by 400 m in all directions from the outer edge of the Pollen Trap.

Conditions relating to Isolation Zones

6.1 No Brassica crop may be grown in an Isolation Zone while GMOs are being grown at the Location within it.

6.2 If any Brassica crop occurs in an Isolation Zone while the GMOs are being grown at the Location within it, either the Brassica crop or the GMOs in the Location (and its Pollen Trap, if any) must be Destroyed prior to flowering. If GMOs are Destroyed pursuant to this condition, the GMOs (and Pollen Trap, if any) are taken to have been harvested for the purposes of this licence.

6.3 An Isolation Zone must be able to be accessed and controlled by the licence holder to an extent that is commensurate with the licence holder’s rights to access and control the Location within it.
Note: if a Location (and Pollen Trap, if any) has to be Destroyed because a Brassica crop is planted in the Isolation Zone, the Location is taken to have been harvested. Cleaning of the Location and Pollen Trap must occur soon afterwards (see the conditions below about Cleaning Locations post harvest) and post harvest monitoring of the Location and Pollen Trap must be commenced.

**Conditions relating to Pollen Traps**

7.1 Each Pollen Trap must contain non-genetically modified Canola or genetically modified male sterile Canola that is grown in such a way as to reasonably promote a dense and vigorous growth and flowering at the same time as the GMOs.

7.2 Pollen Trap plants must be handled and controlled as if they are the GMOs (ie subject to other applicable conditions elsewhere in this licence), and Material from Pollen Trap plants must be handled and controlled as if it is Material from the GMOs (ie subject to other applicable conditions elsewhere in this licence).

7.3 A Pollen Trap must be able to be accessed and controlled by the licence holder to an extent that is commensurate with the licence holder’s rights to access and control the Location within it.

**Inspections to be conducted for Brassica plants and Brassicaceous weeds while GMOs are being grown**

8.1 Fourteen days before the expected commencement of flowering of the GMOs at a Location, the following areas must be inspected for the presence of *Brassica* plants and Brassicaceous weeds:

   (a) The Location; and  
   (b) The Location’s Pollen Trap, if any; and  
   (c) The Location’s Monitoring Zone.

8.2 The areas must be reinspected at least once every 35 days and thereafter until either harvest of the GMOs or the Location is Cleaned.

8.3 Any *Brassica* plants or Brassicaceous weeds detected during inspections must be Destroyed before they flower.
Inspections to be conducted for Canola in Monitoring Zone while GMOs are being grown

9.1 If GMOs are planted at a Location, the Location’s Monitoring Zone must be inspected at least once every 35 days for the presence of Canola until either harvest of the GMOs or the Location is Cleaned.

9.2 Any Canola detected during inspections must be Destroyed before it flowers.

Inspections to be conducted for Brassica crops in Isolation Zone around flowering period while GMOs are being grown

10.1 Fourteen days before the expected commencement of flowering of the GMOs at a Location, the Location’s Isolation Zone must be inspected for the presence of Brassica crops.

10.2 The Isolation Zone must be reinspected at least once every 35 days thereafter until the GMOs at the Location have finished flowering.

Note: Other conditions in this licence, above, in relation to Isolation Zones, require the Destruction of the Brassica crop or the Cleaning of the Location and Pollen Trap if a Brassica crop is found in an Isolation Zone.

Logbook to be kept of inspections conducted while GMOs are growing

11 The results of inspection activities must be recorded in a logbook. The logbook must be available on request for examination or photocopying by the OGTR. The findings of the inspections as recorded in the logbook must be included in the licence holder’s annual report to the Regulator. The logbook must contain at least the following:

(a) details of the areas inspected;

(b) details of the date of inspection;

(c) the names of the person or persons who undertook the inspections and details of the experience, training or qualification that enabled them to recognise Volunteer plants, Brassica crops, Brassica plants and Brassicaceous weeds;

(d) the number of Volunteer plants, Brassica crops, Brassica plants and Brassicaceous weeds observed, if any;

(e) details of where Volunteer plants, Brassica crops, Brassica plants and Brassicaceous weeds were observed and the development stages reached by them, if any; and

(f) details of methods used to Destroy Volunteer plants, Brassica crops, Brassica plants and Brassicaceous weeds and the dates on which Destruction took place, if any.

Conditions relating to the planting of non-genetically modified Canola and GMOs possessing fertility restorer traits

12.1 Non-genetically modified Canola may be planted in a Location alongside the GMOs.

12.2 Non-genetically modified Canola that is planted in a Location must either be Destroyed prior to setting seed or Harvested.

12.3 Non-genetically modified Canola that is planted in a Location must be handled and controlled as if it is a GMO for the purposes of this licence (ie subject to other applicable conditions elsewhere in this licence) and Material from non-genetically modified Canola that is planted in a Location must be handled and controlled as if it is Material from a GMO for...
the purposes of this licence (ie subject to other applicable conditions elsewhere in this licence).

12.4 GMOs that possess a fertility restorer trait must either be Destroyed prior to setting seed or harvested.

**Harvest of GMOs**

13.1 GMOs at a Location and Pollen Trap plants may be harvested for seed.

13.2 If the GMOs or Pollen Trap plants are harvested, they must be harvested separately from any other Canola.

13.3 Following harvest of the GMOs and Pollen Trap plants (if any,) any harvested seed must be immediately, or as soon as reasonably practicable:

   (a) stored in a sealed container that is signed so as to indicate that it contains GM Canola seed, within a locked facility that is signed so as to indicate that GM Canola seed is stored within the facility; or

   (b) exported; or

   (c) Destroyed by burning or autoclaving or deep burial.

13.4 Any Canola seed obtained from harvest may only be transported to the extent necessary to store it, export it or Destroy it.

**Cleaning – post harvest and generally**

14.1 Equipment, Locations, Pollen Traps and other areas used pursuant to this licence in respect of GMOs, Material from the GMOs, Pollen Trap plants or Material from Pollen Trap plants, must be Cleaned.

14.2 For each Location and Pollen Trap (if any), either within 14 days of Harvest of the GMOs or by 30 June 2007, whichever occurs first, the Location and Pollen Trap must be Cleaned.

14.3 If Equipment is Cleaned, the area in which the Equipment is Cleaned must also be Cleaned. (For the sake of clarity, it is not necessary for Equipment to be Cleaned only at a Location.)

14.4 Cleaning must occur immediately or as soon as practicable after the use and before it is used for any other purpose.

**Conditions relating to destruction by burial**

15.1 Subject to Condition 15.2 below, if the GMOs, Pollen Trap plants, Material from the GMOs or Material from Pollen Trap plants are Destroyed by burial, the licence holder must:

   (a) Within 30 days of burial, provide the Regulator by notice in writing of the precise location of the Burial site (GPS coordinates and either a street address or other directions to the Location) and the date on which it was buried. The notice must identify the GMOs (by reference to its ‘GMO details’ as set out at Attachment B) or Pollen trap plants, buried at a Burial site;

   (b) Monitor the Burial site at least once every 3 month for a period of three years to identify:
(i) any significant disturbance that may effect the emergence of volunteer plants and if disturbance is identified, notify the Regulator of appropriate remedial action taken; and

(ii) any emergence of Volunteer plants. If Volunteer plants are identified, the Burial site must be Cleaned.

15.2 Monitoring of the Burial site is not required if burial takes place at a Municipal or commercial land fill and the Regulator is provided with a written notice from the manager of the land fill undertaking:

(a) not to disturb the Burial site for a period of at least 3 years from the date of burial; and

(b) to notify both the licence holder and the Regulator in writing of any significant disturbance of the Burial site that may affect the emergence of Volunteer plants.

Reduction of seed bank and secondary dormancy – conditions in relation to tillage

16.1 Following Cleaning of a Location or Pollen Trap, the Location or Pollen Trap must be lightly tilled twice, unless the Location or Pollen Trap was lightly tilled in the course of Cleaning it, in which case the Location or Pollen Trap must be lightly tilled again.

16.2 If a Location or Pollen Trap is lightly tilled it must not be lightly tilled again within the next 28 days. (NB: A person must wait at least 28 days to till a Location or Pollen Trap a second time.)

16.3 Occasions of light tillage activities must be recorded in a logbook. The logbook must be available on request for examination or photocopying by the OGTR. Records in the logbook must be included in the licence holder’s annual report to the Regulator. The logbook must contain at least details of the following:

(a) the Locations and Pollen Traps tilled;

(b) the tillage methods used; and

(c) the dates tillage occurred.

Condition about when light tillage can be used to assist Cleaning a Location or Pollen Trap

17 Light tillage may only be adopted as a method for Cleaning a Location or Pollen Trap in conditions where germination of the GMOs is reasonable likely to ensue (for example, immediately after rain or irrigation).

Note: this condition prohibits the incorporation of light tillage method as a method of destruction at times when germination of the GMOs is not likely to ensue as a result (eg during a drought).

Post harvest Inspections to be conducted

18.1 Following Cleaning of the GMOs, Material from the GMOs, Pollen Trap plants and Material from Pollen Trap plants at a Location or other area, the following places must be inspected for the existence of Volunteer plants:

(a) the Location;

(b) the Pollen Trap in respect of the Location;

(c) the Monitoring Zone in respect of the Location; and
(d) any areas used to Clean Equipment used in connection with the GMOs or Pollen Trap plants or to Destroy the GMOs, Material from the GMOs, Pollen Trap plants or Material from Pollen Trap plants.

18.2 Inspection must be performed by a person who is able to recognise Volunteer plants.

18.3 Any Volunteer plant identified during inspections must be Destroyed prior to the plant flowering.

18.4 All the places required to be inspected must be inspected at least once a month for a period of 24 months that commences the last day of Cleaning of the Location.

18.5 Subject to the condition immediately below, at the conclusion of the 24 months period of monthly inspections, the places required to be inspected must be inspected for the existence of Volunteer plants once every 35 days until:

(a) no Volunteer plants are identified at those places for 12 months; and
(b) the Regulator has provided a notice in writing to the licence holder that further inspection is no longer required.

18.6 If no Volunteer plants are identified during 6 consecutive inspections then inspections may take place at intervals of at least once every three months, for the remainder of the period that inspections are required (instead of once every 35 days).

18.7 The results of inspection activities must be recorded in a logbook. The logbook must be available on request for examination or photocopying by the OGTR. The findings of the inspections as recorded in the logbook must be included in the licence holder’s annual report to the Regulator. The logbook must contain at least the following:

(a) details of the areas inspected;
(b) details of the date of inspection;
(c) the names of the person or persons who undertook the inspections and details of the experience, training or qualification that enabled them to recognise Volunteer plants;
(d) the number of Volunteer plants observed and where those plants or weeds were found, if any;
(e) details of the development stages reached by the Volunteer plants if any; and
(f) details of methods used to Destroy Volunteer plants and dates on which Destruction occurred, if any.

Transportation of the GMOs, Material from GMOs, Pollen Trap plants and Material from Pollen Trap plants

19.1 The GMOs, Material from the GMOs, Pollen Trap plants and Material from Pollen Trap plants must be transported in accordance with the OGTR Guidelines for the Transport of GMOs (June 2001) issued by the Regulator.

19.2 Every container used to transport the GMOs, Material from the GMOs, Pollen Trap plants and Material from Pollen Trap plants must be labelled:

(a) to indicate that it contains genetically modified Canola; and
(b) with telephone contact numbers for the licence holder and instructions to contact the licence holder in the event that the container is broken or misdirected.
19.3 The licence holder must have in place accounting procedures to verify whether the same quantity of GMOs, Material from the GMOs, Pollen Trap Plant or Material from Pollen Trap plants sent is delivered and must document routes, methods and procedures used for transportation of GMOs, Material from the GMOs, Pollen Trap plants and Material from Pollen Trap plants.

Limits on use of Location and other areas after the Location has been Cleaned

20.1 Following Cleaning of the GMOs, Material from the GMOs, Pollen Trap plants and Material from Pollen Trap plants at a Location, Prohibited Plants must not be grown in:

(a) the Location;
(b) the Pollen Trap in respect of the Location; or
(c) the Monitoring Zone in respect of the Location;

until all inspection obligations in this licence in connection with those places have been completed and the Regulator has provided a notice in writing to the licence holder that further inspection is no longer required in those places.

20.2 Subject to the condition immediately below, following Cleaning of the GMOs, Material from the GMOs, Pollen Trap plants and Material from Pollen Trap plants at a Location, Permitted Plants may be planted in:

(a) the Location;
(b) the Pollen Trap in respect of the Location; and
(c) the Monitoring Zone in respect of the Location.

Contingency Plans

21.1 Within 30 days of the date of the commencement of this licence, a written Contingency Plan must be submitted to the Regulator detailing measures to be taken in the event of the unintended presence of the GMOs, Material from the GMOs, Pollen Trap plants or Material from Pollen Trap plants, outside an area that must be inspected.

21.2 The Contingency Plan must include details of procedures to:

(a) ensure the Regulator is notified immediately if the licence holder becomes aware of the event;
(b) destroy any of the GMOs, Material from the GMOs, Pollen Trap plants or Material from Pollen Trap plants; and
(c) inspect and Destroy any Volunteer plants that may exist as a result of the event.

21.3 The Contingency Plan must be implemented in the event that the unintended presence of the GMOs, Material from the GMOs, Pollen Trap plants and Material from Pollen Trap plants is discovered outside an area that must be inspected.

Compliance Management Plan

22 Prior to growing the GMOs, a written Compliance Management Plan must be provided to the Regulator. The Compliance Management Plan must describe in detail how the licence holder intends to ensure compliance with these conditions and document that compliance.

Reporting

23 The licence holder must provide the Regulator with a written report within 90 days of each anniversary of this licence, in accordance with any Guidelines issued by the Regulator.
in relation to annual reporting. This report must include information on any adverse impacts on human health and safety or the environment, caused as a result of the GMOs, Material from the GMOs, Pollen Trap plants or Material from Pollen Trap plants.

**Research requirements**

24 The licence holder must, in consultation with the OGTR, develop an agreed research program to collect information regarding:

(a) the agronomic characteristics of the GMOs in terms of the potential weediness of GM canola under Australian field conditions;

(b) out-crossing to confirm previous research on containment measures; and

(c) stability of the inserted genes in the GM canola over successive generations.

In accordance with any Guidelines issued by the Regulator in relation to annual reporting, the licence holder must provide the Regulator with a written report of the progress and results of the research program. This report must accompany the annual report to be sent to the Regulator.

**Testing methodology**

25 The licence holder must provide a written instrument to the Regulator describing an experimental method that is capable of reliably detecting the presence of the GMOs and the presence of the genetic modifications described in this licence (at Attachment B) in a recipient organism. The instrument must be provided within 35 days of the issuing of this licence.

**Attachments A and B** are included with the licence.
APPENDIX 6 LEGISLATIVE REQUIREMENTS FOR ASSESSING DEALINGS INVOLVING INTENTIONAL RELEASES

SECTION 1 THE REGULATION OF GENE TECHNOLOGY IN AUSTRALIA

253 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 current regulatory system replaces the former voluntary system overseen by the Genetic Manipulation Advisory Committee (GMAC).

254 The Act establishes a statutory officer, the Gene Technology Regulator (the Regulator), to administer the legislation and make decisions under the legislation.

255 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.

256 The Act prohibits persons from dealing with GMOs unless the dealing is exempt, a Notifiable Low Risk Dealing, on the Register of GMOs, or licensed by the Regulator (see Section 31 of the Act).

257 The requirements under the legislation for consultation and for considering and assessing licence applications and preparing risk assessment and risk management plans are discussed in detail in Division 4, Part 5 of the Act and summarised below.

258 Detailed information about the national regulatory system and the gene technology legislation is also available from the OGTR website (www.ogtr.gov.au)

SECTION 2 THE LICENCE APPLICATION

259 Licence applications for dealing involving the intentional release of a genetically modified organism (DIR) must be submitted in accordance with the requirements of Section 40 of the Act. As required by Schedule 4, Part 2 of the Regulations, the application must include information about:

- the parent organism;
- the GMOs;
- the proposed dealing with the GMOs;
- interaction between the GMOs and the environment;
- risks the GMOs may pose to the health and safety of people;
- risk management;
- previous assessments of approvals; and
- the suitability of the applicant.
The application must also contain:

- additional information required for a GMO that is:
  - a plant;
  - a micro-organism (not living in or on animals and not a live vaccine);
  - a micro-organism that lives in or on animals;
  - a live vaccine for use in animals;
  - a vertebrate animal;
  - an aquatic organism;
  - an invertebrate animal;
  - to be used for biological control;
  - to be used for bioremediation; and
  - intended to be used as food for human or vertebrate animal consumption;

- supporting information from the Institutional Biosafety Committee.

A preliminary screening of an application is undertaken by the OGTR staff to determine whether it complies with the Act and the Regulations, by containing the required information. If this information is provided in the application, the Regulator may then accept the application for formal consideration. Section 43 of the Act provides that the Regulator is not required to consider an application if the application does not contain the required information.

After accepting an application for consideration, the Regulator must decide to issue, or refuse to issue, a licence. The decision must be taken following an extensive consultation and evaluation process, as detailed in Sections 3-6 of this Appendix. Regulation 8 of the Regulations prescribe a period of 170 working days within which this decision must be taken. This period does not include weekends or public holidays in the Australian Capital Territory. Also, this period does not include any days in which the Regulator is unable to progress the application because information sought from the applicant in relation to the application has not been received.

**SECTION 3 THE INITIAL CONSULTATION PROCESSES**

In accordance with Section 50 of the Act, the Regulator must seek advice in preparing a risk assessment and risk management plan (RARMP) from prescribed agencies:

- State and Territory Governments;
- the Gene Technology Technical Advisory Committee (GTTAC);
- prescribed Australian government agencies (Regulation 9 of the *Gene Technology Regulations 2001* refers);
- the Environment Minister; and
- relevant local council(s) where the release is occurred.

Section 49 of the Act requires that if the Regulator is satisfied that at least one of the dealings proposed to be authorised by the licence may pose significant risks to the health and
safety of people or to the environment, the Regulator must publish a notice (in national and regional newspapers, in the Gazette and on the OGTR website) in respect of the application inviting written submissions on whether the licence should be issued.

265 As a measure over and above those required under the Act, in order to promote the openness and transparency of the regulatory system, the Regulator may take other steps. For example, receipt of application is notified to the public by posting a notice of each application's receipt on the OGTR website and directly advising those on the OGTR mailing list. Copies of the application are available on request from the OGTR.

SECTION 4 THE EVALUATION PROCESSES

266 The risk assessment process is carried out in accordance with the Act and Regulations, using the Risk Analysis Framework (the Framework) developed by the Regulator (available on the OGTR website). It also takes into account the guidelines and risk assessment strategies used by related agencies both in Australia and overseas. The Framework was developed in consultation with the States and Territories, Australian government agencies, GTTAC and the public. Its purpose is to provide general guidance to applicants and evaluators and other stakeholders in identifying and assessing the risks posed by GMOs and in determining the measures necessary to manage any such risks.

267 In undertaking a risk assessment, the following are considered and analysed:

- the data presented in the proponent’s application;
- data provided previously to GMAC, the interim OGTR or the OGTR in respect of previous releases of relevant GMOs;
- submissions or advice from States and Territories, Australian government agencies and the Australian Government Minister for Environment and Heritage and the public;
- advice from GTTAC;
- information from other national regulatory agencies; and
- current scientific knowledge and the scientific literature.

268 In considering this information and preparing the risk assessment and risk management plan, the following specific matters are taken into account, as set out in Section 49 and required by Section 51 of the Act:

- the risks posed to human health and safety or risks to the environment;
- the properties of the organism to which the dealings relate before it became a GMO;
- the effect, or the expected effect, of the genetic modification that has occurred on the properties of the organism;
- provisions for limiting the dissemination or persistence of the GMO or its genetic material in the environment;
- the potential for spread or persistence of the GMO or its genetic material in the environment;
- the extent or scale of the proposed dealings;
- any likely impacts of the proposed dealings on the health and safety of people.
In accordance with Regulation 10 of the Regulations, the following are also taken into account:

- any previous assessment, in Australia or overseas, in relation to allowing or approving dealings with the GMO;
- the potential of the GMO concerned to:
  - be harmful to other organisms;
  - adversely affect any ecosystems;
  - transfer genetic material to another organism;
  - spread, or persist, in the environment;
  - have, in comparison to related organisms, a selective advantage in the environment; and
  - be toxic, allergenic or pathogenic to other organisms.
- the short and long term when taking these factors into account.

**SECTION 5  FURTHER CONSULTATION**

Having prepared a RARMP, the Regulator must, under Section 52 of the Act, seek comment from stakeholders, including those outlined in Section 3 and the public.

All issues relating to the protection of human health and safety and the environment raised in written submissions on an application or RARMP are considered carefully, and weighed against the body of current scientific information, in reaching the conclusions set out in a final RARMP. Section 56 of the Act requires that these be taken into account in making a decision on whether or not to issue a licence for the proposed release.

Comments received in written submissions on this RARMP are very important in shaping the final RARMP and in informing the Regulator’s final decision on an application. A summary of public submissions and an indication of where such issues have been taken into account will be provided in an Appendix to the final RARMP.

It is important to note that the legislation requires the Regulator to base the licence decision on whether risks posed by the dealings are able to be managed so as to protect human health and safety and the environment. Matters in submissions that do not address these issues and/or concern broader issues outside the objective of the legislation will not be considered in the assessment process. In most instances, as determined in the extensive consultation process that led to the development of the legislation, they fall within the responsibilities of other authorities.

**SECTION 6  DECISION ON LICENCE**

Having taken the required steps for assessment of a licence application, the Regulator must decide whether to issue or refuse a licence (Section 55 of the Act). The Regulator must not issue the licence unless the Regulator is satisfied that any risks posed by the dealings proposed to be authorised by the licence are able to be managed in such a way as to protect the health and safety of people and the environment.
275 The Regulator must also have regard to any policy guidelines issued by the Ministerial Council that relate to risks to human health and safety and the environment, or the management of such risks. At this time no policy guidelines have been issued.

276 The Regulator must not issue a licence if this would be inconsistent with a policy principle issued by the Ministerial Council. The Gene technology Ministerial Council recently agreed a policy principle “Gene technology (Recognition of Designated Areas) Principle 2003” (the Principle) which allows for recognition of GM or non-GM designated areas for marketing purposes. The Principle is designed to ensure the valid operation of State and Territory laws declaring areas to be GM, non-GM or both for marketing purposes.

277 The Regulator must also be satisfied, under section 57 of the Act that the applicant is a suitable person to hold the licence, Section 58 outlines matters the Regulator must consider in deciding whether a person or company is suitable to hold a licence eg:

- Any relevant convictions;
- Any relevant revocations or suspensions of a licence or permit; and
- The capacity of the person or company to meet the conditions of the licence.

278 The Regulator carefully considers all of this information which is supplied in a declaration signed by licence applicants.

279 The Monitoring and compliance Section of the OGTR complies compliance histories of applicants, considering all previous approvals to deal with GMOs under the Act and the previous voluntary system. These histories as well as other information such as follow-up actions from audits may be taken into account. The ability of an organisation to provide resources to adequately meet monitoring and compliance requirements may also be taken into account.

280 If a licence is issued, the Regulator may impose licence conditions (Section 62 of the Act). Conditions may be imposed to:

- limit the scope of the dealings;
- require documentation and record-keeping;
- require a level of containment;
- specify waste disposal methods;
- manage risks posed to the health and safety of people, or to the environment;
- require data collection, including studies to be conducted;
- limit the geographic area in which the dealings may occur;
- limiting the dissemination or persistence of the GMO or its genetic material in the environment; and
- require contingency planning in respect of unintended effects of the dealings.

281 It is also required as a condition of a licence that the licence holder inform any person covered by the licence of any condition of the licence which applies to them (Section 63). Access to the site of a dealing must also be provided to persons authorised by the Regulator for the purpose of auditing and monitoring the dealing and compliance with other licence conditions (Section 64). It is a condition of any licence that the licence holder inform the Regulator of:
- any new information as to any risks to the health and safety of people, or to the environment, associated with the dealings authorised by the licence;
- any contraventions of the licence by a person covered by the licence; and
- any unintended effects of the dealings authorised by the licence.

282 It should be noted that, as well as imposing licence conditions, the Regulator has additional options for risk management. The Regulator has the legislative capacity to enforce compliance with licence conditions, and indeed, to direct a licence holder to take any steps the Regulator deems necessary to protect the health and safety of people or the environment. The OGTR also independently monitors trial sites to determine whether the licence holder is complying with the licence conditions, or whether there are any unforseen problems.
APPENDIX 7  SUMMARY OF PUBLIC SUBMISSIONS ON THE RISK ASSESSMENT AND RISK MANAGEMENT PLAN

Submission from: A: agricultural organisation; I: individual

Issues raised/consideration: A: allergenicity; The Act: the Gene Technology Act; APVMA: Australian Pesticides and Veterinary Medicines Authority; C: community concern; D: insufficient data; EN: environmental risk; ET: ethical concerns; F: food and feed; FC: food chain; FSANZ: issues dealt with by FSANZ; G: gene transfer; GTR: the Gene Technology Regulator; H: human safety; HR: herbicide resistance; HU: herbicide use; L: liability; LC: licence conditions; MA: markets; OSA: outside scope of the assessment; P: persistence of GMOs; PU: pesticide use; RAF: Risk Analysis Framework; SEG: segregation; SE: Socioeconomic impacts; T: toxicity; U: unknown risk; W: weediness.

<table>
<thead>
<tr>
<th>Sub. no</th>
<th>Type</th>
<th>Summary of issue raised</th>
<th>Issue</th>
<th>Consideration of issues</th>
</tr>
</thead>
<tbody>
<tr>
<td>01</td>
<td>I</td>
<td>…you do not have any intention of listening and taking into consideration the objections raised by the farming community….</td>
<td>U</td>
<td>OSA</td>
</tr>
<tr>
<td></td>
<td></td>
<td>…the international chemical companies agenda to enslave this precious land.</td>
<td>ET</td>
<td>OSA</td>
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<td></td>
<td></td>
<td>…why trials are done in secrecy. The farmers who agreed to the companies using their land have to sign secret agreement….</td>
<td>ET</td>
<td>OSA</td>
</tr>
<tr>
<td></td>
<td></td>
<td>…chemical companies …is to gain control of the food chain…</td>
<td>ET</td>
<td>OSA</td>
</tr>
<tr>
<td>02</td>
<td>I</td>
<td>…containment conditions have been breached in previous trials… There is no insurance against the possibility of seeds or pollen escaping from 66 ha of GM canola.</td>
<td>G, LC</td>
<td>Ch 2; App 4, 5</td>
</tr>
<tr>
<td></td>
<td></td>
<td>If someone was prepared to take the responsibility of paying a significant amount of money as insurance against this possibility (contamination), then the public may have more respect for these trials.</td>
<td>L</td>
<td>OSA</td>
</tr>
<tr>
<td></td>
<td></td>
<td>How will the ground… be cleaned of GM contamination after the trial? …this is impossible.</td>
<td>G, P, W</td>
<td>App 3, 5</td>
</tr>
<tr>
<td>03</td>
<td>I</td>
<td>…opposed to the sustained and widespread release of irretrievable genetic strains into our major farming lands.</td>
<td>P</td>
<td>App 3</td>
</tr>
<tr>
<td></td>
<td></td>
<td>If there is no risk of contamination why do we need a controlled release.</td>
<td>G</td>
<td>App 4</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Why are we doing trials with a pollen producing plant that will guarantee to infect all other pollen plants.</td>
<td>G</td>
<td>App 4</td>
</tr>
<tr>
<td></td>
<td></td>
<td>My main concern is the disastrous effect in Canada and the US …(and possibility of the same happening in Australia)</td>
<td>EN</td>
<td>OSA</td>
</tr>
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<td></td>
<td></td>
<td>…you have responsibility not to help companies set up manufacturing cartels at the expense of Australian farmers, consumers and future generations.</td>
<td>ET, SE</td>
<td>OSA</td>
</tr>
<tr>
<td></td>
<td></td>
<td>…it looks as if the companies will own basic things like patented genetic codes that will infect the seeds that grow all foods but this is not what should happen and you are the only people that can change it.</td>
<td>SE</td>
<td>OSA</td>
</tr>
<tr>
<td>Submission</td>
<td>Issue</td>
<td>Details</td>
<td></td>
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<td>04</td>
<td>I</td>
<td>GMOs are at early of development, genetic modification could produce all sorts of variations...inevitably... will cross pollinate giving rise to a multitude of unknown variations... consequences that may arise eg sterilisation of a large proportions of the human race, poison, cancer, diseases... some scientists are quite concern about the impact on soil and environment... organisations who own the patent...need to retain ownership of GMOs on the one hand, yet on the other, they sign contracts with farmers in such a way that makes farmers fully responsible for what happens. the owner of the GMOs should be responsible for all the consequences...</td>
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<td>05</td>
<td>I</td>
<td>I would like to see the Office enforce regulation in regard to: the application evaluation process toxicity and allergenicity to humans and other organisms weediness gene transfer herbicide resistance</td>
<td></td>
<td></td>
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<tr>
<td>06</td>
<td>I</td>
<td>In this submission farm animals and poultry are being defined as: part of the environment, so questions as to the health of these animals and birds form necessary part of the terms of reference for the GTR; as being an intricate part of the human food chain, so come into the definition regarding human health the soil in which the GM canola is grown is to be defined as being part of the human food environment. The GM canola meal, being residue after extraction of the canola oil, and its use as farm-animal and poultry feed. What proportion of the farm-animal and poultry feed will/does the GM canola meal constitute? Are/will there be a recommended maximum proportions? Are/will there be any requirements to report any adverse reactions, from use of the GM meal? To which authority does/would one report?</td>
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<td></td>
<td></td>
<td>G App 4 EN, T App 2, 4 G App 2, 4 EN App 2, 4 L; SE OSA L, SE OSA LC App 5, App 6 RM Ch 1, App 6 Ch 1, App 6 RM App 2 RM App 3 RM App 4 RM App 3 FC, H App 2 F App 2 F Ch 2; App 2; App 5 OSA</td>
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<tr>
<td>➢ Long term blind test controlled experiments on larger numbers of farm animals and poultry, be undertaken.</td>
<td>F, T</td>
<td>Ch 2; App 2</td>
<td></td>
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<td>➢ That prompt and mandatory reporting to an independent authority be required, re any adverse reactions.</td>
<td>T</td>
<td>Ch 2; App 2; App 5</td>
<td></td>
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<tr>
<td>➢ That all information be promptly reported by the independent authority, this information being easily accessed by the public.</td>
<td>T</td>
<td>App 2; App 5</td>
<td></td>
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<td>The incorporation into GM canola plant tissues of the breakdown products of the spray used by Bayer on the GM canola during growth.</td>
<td>HU, PU</td>
<td>Herbicide and pesticide residue issues will be considered if larger scale release of the GMOs is proposed.</td>
<td></td>
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<td>➢ It is unknown what long-term effects there may be by farm animal ingestion of the GM canola hay…</td>
<td>F</td>
<td>App 2</td>
<td></td>
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<tr>
<td>➢ that independent long term blind test controlled experiments be undertaken on large numbers of farms animals/poultry than is at present the case in the toxic reaction tests.</td>
<td>T</td>
<td>Ch 2; App 2; App 5</td>
<td></td>
<td></td>
</tr>
<tr>
<td>➢ …Prompt report required…(on any adverse effect…)</td>
<td>T</td>
<td>App 2; App 5</td>
<td></td>
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</tr>
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<td>The soil in which the GM canola is grown is to be defined as part of the human food environment</td>
<td>F, FC</td>
<td>App 2</td>
<td></td>
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<td>➢ investigate the survival of soil biota after harvesting the GMOs.</td>
<td>T</td>
<td>App 2</td>
<td></td>
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</tr>
<tr>
<td>➢ investigate how much 2, 4-D is made available for incorporation into the subsequent food crops…</td>
<td>HU</td>
<td>OSA</td>
<td></td>
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<td>➢ Australian State Government that the commercial GM canola be delayed until much needed long term data be collected …</td>
<td>M, D</td>
<td>OSA</td>
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<td>➢ the GTR … a more cautious approach be adopted, to question more widely the data supplied by the GM companies …</td>
<td>RA</td>
<td>Ch 2, App2-5</td>
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<td>➢ Considering that …GM canola is not to involve the production of food for humans or animal, the only risk of toxicity and allergenicity to humans and animals would be from occupational exposure to the GM canola, or consumption of the GM canola plants by wild animals. …when larger GM canola (trials)…proposed … for food, then considerations of food safety would be relevant.</td>
<td>T, F</td>
<td>Ch 2; App 2</td>
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</table>
- Many canola possess seed dormancy and seed shattering, these result in a large number of seed entering soil after cropping…

- Of particular concern is the occurrence of gene exchange via pollen among canola cultivars resistant to different herbicides.

- …Note that there was an ‘escape’ of flowering canola plants from Bayer trials crop into neighbouring wheat field in NSW. If an escape has occurred in a previously approved release, what will happen with this one, and what will happen with larger releases?

- Quote from a Canadian grower warn UK farmers of GMOs risks… “I took the decision to stop growing GM canola …because it was impossible to stop it spreading to other fields… the seed cling to the machinery and are easily transferred, even with intensive cleaning…”

- …transgenic DNA is inherently unstable, which means it has a tendency to break and join up or recombine with other genes….often there are other genetic signals such as the origins of replication left over from the plasmid vector, which can act as recombination hot spots and enable transgenic DNA to be replicated independently as a plasmid that readily transferred horizontally amongst bacteria.

- Promiscuity in transgenic plants: Nature 1998, 395, 25: transgenes from transgenic plants are up to 30 times more likely to escape and spread than the same gene obtained by mutagenesis. …demonstrate a high frequency of gene transfer of 5.8 x 10-2 per recipient bacteria (Schluter et al 1995)…. German experiment provided evidence of transgenic DNA transfer from GM sugar beet plant debris to bacteria in soil (Gebhard and Smalla FEMS Mocrobiol. Ecol. 1999 28: 261-72). The possible hazards of gene transfer include the generation of new cross-specific viruses that cause disease, the generation of new bacteria, the spread of drug and antibiotic resistance genes, the random insertion into genomes of oncogenic cells…

- In evolutionary terms, the practice of genetic engineering represents a sudden, astronomically large increase in the rate of horizontal gene transfer between species whose genomes have been isolated from another for aeons. Genetic engineering opens up completely new pathway of gene transfer. Releasing genetically engineer organisms into the environment can be expected to generate new selective pressures that have never before operated during biological evolution.

- From Wald and Strauss:… gene transfer could lead to the permanent alteration of wild species, and inevitably result in genetic pollution….The newly created hybrids, or the engineered crops themselves, could become established and disrupt the ecosystem…The overall effects on ecosystems are unpredictable
<p>| ➢ Haywood et al ..... That transgenic crop genes can spread quickly to the wild despite containment measures... …transgene escape – when artificially inserted genes flow from crops to nearby wild populations and become a permanent feature of their genomes – is worrisome.... | G | App 4, 5 |
| ➢ Haywood described a gene confinement strategy being developed which involved inserting genetic information into the DNA of the chloroplast. ...he noted that while this may lessen the problem of gene transfer via pollen, it has been shown that chloroplast DNA transmission through pollen can occur at a low rate. ... Haywood and his colleagues from UW- Madison say that they hope this paper provides the impetus for other scientists and regulatory officials to evaluate the true effectiveness of gene containment strategies on specific crops. | G | App 4, 5, noted |
| ➢ Mellon and Rissler Union of Concerned Scientists 2004 concluded that seeds of traditional varieties of crop plants used by US farmers are pervasively contaminated with low levels of DNA sequences originating in genetically engineered varieties of these crops.....believe the contamination is endemic. ...due to physical mixing (grain elevator) and outcrossing. ...Instances of contamination: Starlink corn, foundation seed non GM soybean – North Dakota; Monsanto GM canola contaminated with ...(RT200) not approved for marketing. Advanta Seeds UK traditional canola contaminate with GM canola in the UK;......corn in Mexico contaminated with genetic sequences from GE corn in the US...... | G | App 4 |
| ➢ ...the implications ... are significant in several areas: pharmaceutical and industrial crops, food safety, the environment, trade, organic food production; intellectual property; the food system; agriculture if developing countries and seed repositories.... | G, F, M, E | App 4, 5 some are OSA |
| ➢ ...while GM food safety testing is still rudimentary, the possible spread of transgenes through non-GM crops is of concern. | G | App 4, 5 |
| ➢ ...the precautions noted in the OGTR’s RARMP for Bayer trial of herbicide-tolerant canola ... are very important and must be stringently adhered to and monitored. ...considerations of ecological risk must take into account the ability of favourable environments to select for and increase the proportion of harmful transgenes in plant populations. | G | App 4, 5 |
| ➢ ...nothing is more fundamental to the future of our agriculture and food system than a continued supply of safe, high quality seed. ...the contamination of seed repositories by transgenes is not theoretical, but real.... | G | App 4 |
| ➢ ...until we gain a better understanding of genetic engineering, it is premature to allow transgenically derived DNA and transgenic seeds to creep unobserved into seed repositories. | G | App 4 |
| ➢ ...triple herbicide resistant canola volunteers were found in Alberta Canada in 1998..... | G | App 4 |</p>
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<td>…it is … interesting that one of the triple resistant plants was found over 550 m from the pollen sources, greatly exceeding the 100 buffer mandated for seed producers.</td>
<td>G</td>
</tr>
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<td>…emphasising how important planting distance, crop rotation precautions and herbicide/weed control techniques are and their need to be varied regularly.</td>
<td>HR, W, RM</td>
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<td>…the risks were generally thought to be very low in almost all aspects of the assessment</td>
<td>RA</td>
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<td></td>
<td>…there are vital aspects of gene technology which are not addressed because they do not form part of the OGTRs spectrum of assessment……ethical and moral agricultural effects on conventional and organic farming systems, here and overseas, trade, political, food safety…..</td>
<td>ET, EN, MA, F</td>
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<td>I am concerned that GM crop trials are going ahead regardless of the results of further research into food safety…..and regardless of concerns in those other areas.</td>
<td>D, F</td>
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<td></td>
<td>To say …”there have been no reports of adverse effects on human health or the environment resulting from the field releases of InVigor canola is meaningless unless it is qualified with a statement that the field releases have been going for a very short period of time. Effects on natural system can occur short term, medium term and in the long term….We cannot conclude until more research has been done and more time has been passed</td>
<td>D</td>
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<td>…one of the least understood issues associated with GM organisms is their potential impact on biodiversity…..it is important to recognise that biodiversity includes an intra-specific component, specifically the genetic diversity within species….whether GM crops will exacerbate or alleviate the problem…</td>
<td>EN</td>
</tr>
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<td></td>
<td>…it is vital to know as far as we can, the risk to human, animal and environmental health of this specific trial, and to consider them from a scientific point of view. But science doesn’t work in vacuum, and by addressing the issues in isolation, the broader concerns are left behind.</td>
<td>RAF, the Act</td>
</tr>
</tbody>
</table>
APPENDIX 8 REFERENCES


ANZFA (2001a). Final assessment report. Application A372: Oil derived from glufosinate-ammonium tolerant canola lines Topas 19/2 and T45 AND Oil derived from glufosinate-ammonium tolerant and pollination controlled canola lines MS1, MS8, RF1, RF2 and RF3. Report No. 05/02,


Hoffman, T., Golz, C., Schieder, O. (1994). Foreign DNA sequences are received by a wild-type strain of *Aspergillus niger* after co-culture with transgenic higher plants. *Current Genetics* **27**: 70-76.


