



Australian Government

Department of Health and Ageing

Office of the Gene Technology Regulator

**Risk Assessment and
Risk Management Plan for
DIR 105**

Limited and controlled release of canola genetically
modified for herbicide tolerance

Applicant: Monsanto Australia Ltd

December 2010

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Executive Summary

Introduction

The Gene Technology Regulator (the Regulator) has made a decision to issue a licence in respect of application DIR 105 from Monsanto Australia Ltd (Monsanto). The licence authorises dealings involving the limited and controlled release of genetically modified (GM) canola into the environment.

The *Gene Technology Act 2000* (the Act), the Gene Technology Regulations 2001 and corresponding state and territory law govern the comprehensive and highly consultative process undertaken by the Regulator before making a decision whether or not to issue a licence to deal with a genetically modified organism (GMO).

The decision is based upon a Risk Assessment and Risk Management Plan (RARMP) prepared by the Regulator in accordance with requirements of the legislation. RARMPs apply the *Risk Analysis Framework* and are finalised following consultation with a wide range of experts, agencies and authorities, and the public¹.

The application

Monsanto has applied for a licence for dealings involving the intentional release of one line² of GM canola on a limited scale and under controlled conditions. The GM canola line has been genetically modified for herbicide tolerance. The trial is authorised to take place over four years, from March 2011 to December 2014, with up to 2 sites planted in the first year, 8 sites in the second and third years, and 20 sites in the fourth year. Sites will be a maximum of 4 ha in the first year and 10 ha in subsequent years. Sites will be located in canola growing regions in 46 possible local government areas (LGAs) in New South Wales, 28 possible LGAs in Victoria and 53 possible LGAs in Western Australia. The exact site locations will be selected by Monsanto closer to planting.

The GM canola has been modified to contain a gene derived from a common soil bacterium. Expression of the gene in the GM canola plants is expected to confer tolerance to herbicides containing glyphosate.

The purpose of the trial is to conduct experiments to evaluate agronomic performance of the GM canola line under field conditions. Material from the GM canola will not be used in human food or animal feed.

Monsanto proposed a number of controls to restrict the spread and persistence of the GM canola line and its introduced genetic material in the environment that were considered during the evaluation of the application.

Risk assessment

The risk assessment takes into account information in the application (including proposed containment measures), previous approvals and relevant scientific/technical knowledge. Advice relating to risks to human health and safety and the environment provided in submissions received

¹ More information on the process for assessment of licence applications to release a genetically modified organism (GMO) into the environment is available from the Office of the Gene Technology Regulator (OGTR) (Free call 1800 181 030 or at <<http://www.ogtr.gov.au/>>), and in the Regulator's *Risk Analysis Framework* (OGTR 2009) at <<http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/riskassessments-1>>.

² The term 'line' is used to denote plants derived from a single plant containing a specific genetic modification resulting from a single transformation event.

during consultation on the RARMP has also been considered. No new risks to people or the environment were identified from the advice received on the consultation RARMP.

Initially, potential pathways that might lead to harm to people or the environment as a result of gene technology are postulated (risk scenarios), and these scenarios are evaluated to identify those that warrant detailed characterisation. This process is described as risk identification.

Eight risk scenarios were postulated. This included consideration of whether or not expression of the introduced gene could: result in products that are toxic or allergenic to people or other organisms; alter characteristics that may impact on the spread and persistence of the GM canola; or produce unintended changes in the biochemistry of the GMO. The opportunity for gene flow to other organisms, and its effects if it were to occur, was also assessed.

A **risk** is only identified for further assessment when a risk scenario is considered to have some chance of causing harm. Pathways that do not lead to an adverse outcome, or could not reasonably occur, do not advance in the risk assessment process.

The characterisation of the eight risk scenarios in relation to both the seriousness and likelihood of harm, in the context of the control measures proposed by the applicant, did not identify risks that required further assessment.

Risks to the health and safety of people, or the environment, from the proposed release of the GM canola line into the environment are assessed to be **negligible**. Hence, the Regulator considers that the dealings involved in this limited and controlled release **do not pose a significant risk** to either people or the environment.

Risk management plan

Risk management is used to protect the health and safety of people and to protect the environment by controlling or mitigating risk. The risk management plan evaluates and treats identified risks, evaluates controls and limits proposed by the applicant, and considers general risk management measures. The risk management plan is given effect through the licence conditions.

As none of the eight risk scenarios characterised in the risk assessment gave rise to an identified risk that required further assessment, the level of risk from the proposed dealings was assessed to be **negligible**. The Regulator's *Risk Analysis Framework* defines negligible risks as insubstantial, with no present need to invoke actions for their mitigation in the risk management plan. However, conditions have been imposed to restrict the spread and persistence of the GMO and its genetic material in the environment and to limit the release to the size, locations and duration requested by the applicant, as these were important considerations in establishing the context for assessing the risks.

The licence conditions require Monsanto to **limit** the release to a maximum cumulative area of 368 ha planted between the date of issue of the licence and December 2014 in nominated local government areas (LGAs). No more than 2 sites in the first year, 8 sites in the second and third years, and 20 sites in the fourth year are proposed. The **control** measures include containment provisions at the trial site; preventing the use of GM plant materials in human food or animal feed; destroying GM plant materials not required for further studies; transporting GM plant materials in accordance with the Regulator's transportation guidelines; and conducting post-harvest monitoring at the trial site to ensure all GMOs are destroyed.

Conclusions of the RARMP

The risk assessment concluded that this limited and controlled release of a GM canola line on a maximum cumulative area of 368 ha planted at up to 38 sites over four years in New South Wales, Victoria and Western Australia, poses **negligible** risks to the health and safety of people or the environment as a result of gene technology.

The risk management plan concluded that these **negligible** risks do not require specific risk treatment measures. However, licence conditions have been imposed to restrict the release to the size, locations and duration proposed by the applicant, and to require controls in line with those proposed by the applicant, as these were important considerations in establishing the context for assessing the risks.

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Abbreviations

the Act	<i>Gene Technology Act 2000</i>
APVMA	Australian Pesticides and Veterinary Medicines Authority
AQIS	Australian Quarantine and Inspection Service
<i>cp4 epsps</i>	5-enolpyruvylshikimate-3-phosphate synthase gene
CP4 EPSPS	5-enolpyruvylshikimate-3-phosphate synthase enzyme
DIR	Dealings Involving intentional Release
DNA	Deoxyribonucleic Acid
FSANZ	Food Standards Australia New Zealand
GM	Genetically Modified
GMAC	Genetic Manipulation Advisory Committee
GMO	Genetically Modified Organism
FMV	Figwort Mosaic Virus
ha	hectare
HGT	Horizontal Gene Transfer
LGA	Local Government Area
mRNA	Messenger Ribonucleic Acid
OGTR	Office of the Gene Technology Regulator
PCR	Polymerase Chain Reaction
RARMP	Risk Assessment and Risk Management Plan
Regulations	Gene Technology Regulations 2001
Regulator	Gene Technology Regulator
RNA	Ribonucleic Acid
T-DNA	Transfer DNA
TGA	Therapeutic Goods Administration
Ti	Tumour-inducing

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Technical Summary

Introduction

The Gene Technology Regulator (the Regulator) has made a decision to issue a licence in respect of application DIR 105 from Monsanto Australia Ltd (Monsanto). The licence authorises dealings involving the limited and controlled release of genetically modified (GM) canola into the environment.

The *Gene Technology Act 2000* (the Act), the Gene Technology Regulations 2001 and corresponding state and territory law govern the comprehensive and highly consultative process undertaken by the Gene Technology Regulator (the Regulator) before making a decision whether or not to issue a licence to deal with a genetically modified organism (GMO).

The decision is based upon a Risk Assessment and Risk Management Plan (RARMP) prepared by the Regulator in accordance with requirements of the legislation. RARMPs apply the *Risk Analysis Framework* and are finalised following consultation with a wide range of experts, agencies and authorities, and the public³.

The application

Monsanto has applied for a licence for dealings involving the intentional release one line⁴ of GM canola on a limited scale and under controlled conditions. The GM canola line has been genetically modified for herbicide tolerance. The trial is proposed to take place over four years, from March 2011 to December 2014, with up to 2 sites planted in the first year, 8 sites in the second and third years, and 20 sites in the fourth year. Sites will be a maximum of 4 ha in the first year and 10 ha in subsequent years. Sites will be located in canola growing regions in 46 possible local government areas (LGAs) in New South Wales, 28 possible LGAs in Victoria and 53 possible LGAs in Western Australia. The exact site locations will be selected by Monsanto closer to planting.

The applicant proposes to release GM canola modified to contain the *5-enolpyruvylshikimate-3-phosphate synthase (cp4 epsps)* gene derived from the soil bacterium *Agrobacterium tumefaciens* strain CP4. The gene encodes EPSPS, an enzyme of the shikimic acid pathway which is involved in the biosynthesis of plant phenolics. In non-GM plants, glyphosate binds to and blocks the activity of this enzyme, which results in the plant being deprived of essential amino acids for growth and development. Expression of the introduced gene is expected to enable the GM canola plants to produce aromatic amino acids required for growth and development in the presence of glyphosate. Herbicides containing glyphosate could then be used for weed control in the GM canola crop.

The GM canola intended for release differs from the commercially released Roundup Ready[®] canola as it is expected to tolerate higher rates of glyphosate herbicides and have a wider window for herbicide application.

The introduced *cp4 epsps* gene is under the control of a chimeric constitutive promoter containing enhancer sequences from the Figwort mosaic virus 35S promoter. Other short regulatory sequences that contribute to control of expression of the introduced gene are also present in the GM canola.

³ More information on the process for assessment of licence applications to release a genetically modified organism (GMO) into the environment is available from the Office of the Gene Technology Regulator (OGTR) (Free call 1800 181 030 or at <<http://www.ogtr.gov.au/>>), and in the Regulator's *Risk Analysis Framework* (OGTR 2009) at <<http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/riskassessments-1>>.

⁴ The term 'line' is used to denote plants derived from a single plant containing a specific genetic modification resulting from a single transformation event.

These are derived from *Arabidopsis thaliana*, *Pisum sativum* (common garden pea) and *A. tumefaciens*.

The purpose of the trial is to conduct experiments to evaluate agronomic performance of the GM canola line under field conditions. Material from the GM canola will not be used in human food or animal feed during the release.

Monsanto proposed a number of controls to restrict the spread and persistence of the GM canola line and its introduced genetic material in the environment that were considered during the evaluation of the application.

Risk assessment

The risk assessment takes into account information in the application (including proposed containment measures), relevant previous approvals and current scientific/technical knowledge. Advice relating to risks to human health and safety and the environment provided in submissions received during consultation on the RARMP has also been considered. No new risks to people or the environment were identified from the advice received on the consultation RARMP.

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

Initially, potential pathways that might lead to harm to people or the environment as a result of gene technology are postulated (risk scenarios) and these scenarios are evaluated to identify those that warrant detailed characterisation. This process is described as risk identification.

Eight risk scenarios were postulated. This included consideration of whether or not expression of the introduced genes could: result in products that are toxic or allergenic to people or other organisms; alter characteristics that may impact on the spread and persistence of the GM canola; or produce unintended changes in the biochemistry of the GMO. The opportunity for gene flow to other organisms, and its effects if it were to occur, was also assessed.

A **risk** is only identified for further assessment when a risk scenario is considered to have some chance of causing harm. Pathways that do not lead to an adverse outcome, or could not reasonably occur, do not advance in the risk assessment process.

The characterisation of the eight risk scenarios in relation to both the seriousness and likelihood of harm, in the context of the control measures proposed by the applicant, did not identify risks that required further assessment. The principal reasons for this include:

- limits on the size, locations and duration of the release proposed by Monsanto
- suitability of controls proposed by Monsanto to restrict the spread and persistence of the GM canola plants and their genetic material
- limited ability and opportunity for the GM canola plants to transfer the introduced gene to other canola plants or other sexually related species
- none of the GM plant materials or products will be used for human food or animal feed
- widespread presence of the protein encoded by the introduced gene, or similar proteins, in the environment and lack of known toxicity or evidence of harm from them.

Risks to the health and safety of people, or the environment, from the proposed release of the GMO into the environment are assessed to be **negligible**. Hence, the Regulator considers that the dealings involved in this limited and controlled release **do not pose a significant risk** to either people or the environment.

Risk management plan

Risk management is used to protect the health and safety of people and to protect the environment by controlling or mitigating risk. The risk management plan evaluates and treats identified risks, evaluates controls and limits proposed by the applicant, and considers general risk management measures. The risk management plan is given effect through the licence conditions.

As none of the eight risk scenarios characterised in the risk assessment gave rise to an identified risk that required further assessment, the level of risk from the proposed dealings was assessed to be **negligible**. The Regulator's *Risk Analysis Framework* defines negligible risks as insubstantial, with no present need to invoke actions for their mitigation in the risk management plan. However, conditions have been imposed to restrict the spread and persistence of the GMO and its genetic material in the environment and to limit the release to the size, locations and duration requested by the applicant, as these were important considerations in establishing the context for assessing the risks.

Licence conditions

The Regulator has imposed a number of licence conditions, including requirements to:

- limit the release to a maximum cumulative area of 368 ha planted between the date of issue of the licence and December 2014 at up to 38 sites to be selected in nominated local government areas in New South Wales, Victoria and Western Australia
- limit each trial site to a maximum of 4 ha in the first year and 10 ha in subsequent years
- locate the trial sites at least 50 m away from waterways
- establish a 50 m zone around each trial site in which sexually compatible species are prevented from flowering
- maintain an isolation zone of at least 400 m, or at least 1 km if no pollen trap is used, around each trial site within which no sexually compatible species may be intentionally grown
- harvest the GM canola plant material separately from other crops
- clean all equipment used in connection with the GMO before it is used for any other purpose
- clean trial sites and surrounding areas after harvest
- apply measures to promote germination of any canola seeds that may remain in the soil, including at least two shallow tillage events
- monitor the site for at least 24 months after harvest until no volunteers are detected for a continuous 12 month period and destroy any canola plants that may grow
- destroy all plant material that is not required for experimentation or future planting
- transport and store all GMO in accordance with the Regulator's guidelines
- not allow the GM plant material or products to be used for human food or animal feed.

Other regulatory considerations

Australia's gene technology regulatory system operates as part of an integrated legislative framework that avoids duplication and enhances coordinated decision making. The Regulator is responsible for assessing risks to the health and safety of people and the environment associated with the use of gene technology. However, dealings conducted under a licence issued by the Regulator may also be subject to regulation by other Australian government agencies that regulate GMOs or GM products, including Food Standards Australia New Zealand (FSANZ), Australian

Pesticides and Veterinary Medicines Authority (APVMA), Therapeutic Goods Administration (TGA), National Industrial Chemicals Notification and Assessment Scheme (NICNAS) and Australian Quarantine Inspection Service (AQIS)⁵.

APVMA has regulatory responsibility for the use of agricultural chemicals, including herbicides and insecticidal products, in Australia. The GM canola has been modified to be tolerant to glyphosate herbicides and the applicant intends to apply these and other herbicides during the trial. The application of these herbicides is subject to regulation by the APVMA.

FSANZ is responsible for human food safety assessment and food labelling, including GM food. The applicant does not intend to use materials from the GM canola line in human food, accordingly an application to FSANZ has not been submitted. FSANZ approval would need to be obtained before materials from this GM canola line could be sold as food.

In addition, dealings authorised by the Regulator may be subject to the operation of State legislation declaring areas to be GM, GM free, or both, for marketing purposes.

Identification of issues to be addressed for future releases

Additional information has been identified that may be required to assess an application for a large scale or commercial release of this GM canola line, or to justify a reduction in containment conditions. This would include:

- additional biochemical characterisation of the GM canola line
- additional phenotypic characterisation of the GM canola line, particularly with respect to traits that may contribute to biotic or abiotic stress tolerance, weediness or persistence.

Suitability of the applicant

The Regulator is satisfied that Monsanto is suitable to hold a DIR licence as no relevant convictions have been recorded, no licences or permits have been cancelled or suspended under laws relating to the health and safety of people or the environment, and the organisation has the capacity to meet the conditions of the licence.

Conclusions of the RARMP

The risk assessment concluded that this limited and controlled release of a GM canola line on a maximum cumulative area of 368 ha planted at up to 38 sites over four years in New South Wales, Victoria and Western Australia, poses **negligible** risks to the health and safety of people or the environment as a result of gene technology.

The risk management plan concluded that these **negligible** risks do not require specific risk treatment measures. However, licence conditions have been imposed to limit the release to the size, locations and duration proposed by the applicant, and to require controls in line with those proposed by the applicant, as these were important considerations in establishing the context for assessing the risks.

⁵ More information on Australia's integrated regulatory framework for gene technology is contained in the *Risk Analysis Framework* available from the Office of the Gene Technology Regulator (OGTR). Free call 1800 181 030 or at <<http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/riskassessments-1>>.

Chapter 1 Risk context

Section 1 Background

1. This chapter describes the parameters within which potential risks to the health and safety of people or the environment posed by the proposed release are assessed (Figure 1).

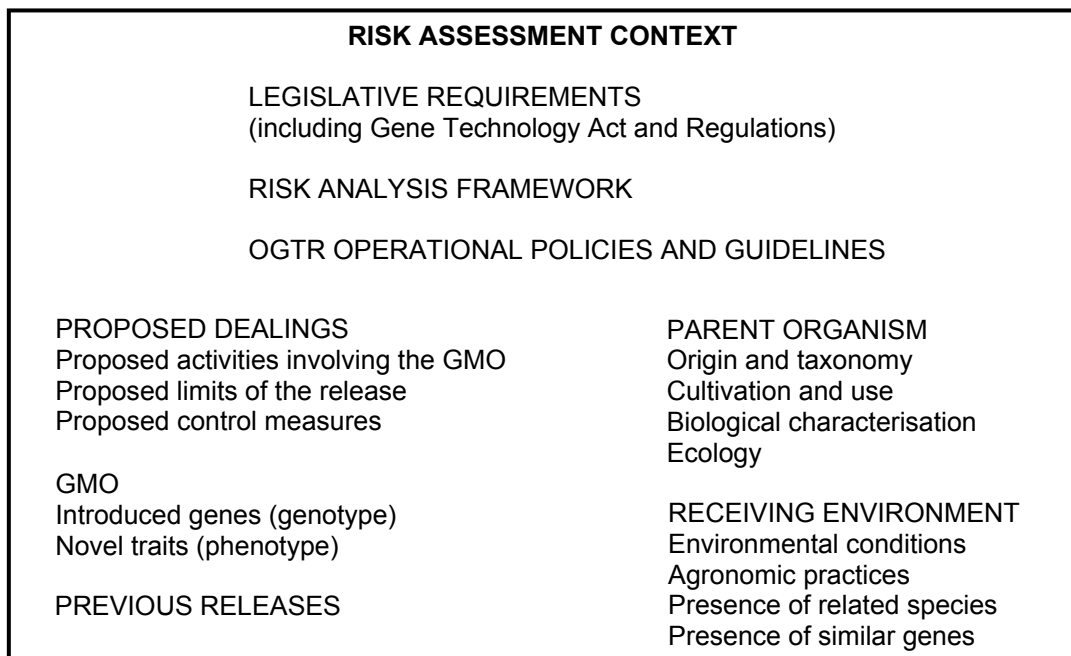


Figure 1. Parameters used to establish the risk assessment context

2. The risk assessment context is developed within the framework of the *Gene Technology Act 2000* (the Act) and Gene Technology Regulations 2001 (Section 2), the *Risk Analysis Framework*, and operational policies and guidelines <<http://www.ogtr.gov.au>>.

3. In addition, establishing the risk assessment context for this application includes consideration of:

- the proposed dealings (Section 3)
- the parent organism (Section 4)
- the genetically modified organism (GMO), nature and effect of the genetic modification (Section 5)
- the receiving environment (Section 6)
- previous releases of these or other GMOs relevant to this application (Section 7).

Section 2 The legislative requirements

4. Sections 50, 50A and 51 of the Act outline the matters which the Gene Technology Regulator (the Regulator) must take into account, and with whom he must consult, in preparing the Risk Assessment and Risk Management Plans (RARMPs) that form the basis of his decisions on licence applications. In addition, the Regulations outline matters the Regulator must consider when preparing a RARMP.

5. In accordance with section 50A of the Act, the Regulator considered information provided in the application and was satisfied that its principal purpose is to enable the applicant to conduct experiments. In addition, limits have been proposed on the size, locations and duration of the release and controls have been proposed by the applicant to restrict the spread and persistence of the

GMO and its genetic material in the environment. Those limits and controls are such that the Regulator considered it appropriate not to seek the advice referred to in subsection 50(3) of the Act. Therefore, this application is considered to be a limited and controlled release and the Regulator has prepared a RARMP for this application.

6. Section 52 of the Act requires the Regulator to seek comment on the RARMP from the States and Territories, the Gene Technology Technical Advisory Committee (GTTAC), Commonwealth authorities or agencies prescribed in the Regulations, the Minister for the Environment, local council(s) where the release is proposed to take place, and the public. The advice from the prescribed experts, agencies and authorities and how it was taken into account is summarised in Appendix A. Thirty-one submissions were received from the public and their consideration is summarised in Appendix B.

7. Section 52(2)(ba) of the Act requires the Regulator to decide whether one or more of the proposed dealings may pose a ‘significant risk’ to the health and safety of people or to the environment, which then determines the length of the consultation period as specified in section 52(2)(d). The decision is provided in Section 3 of Chapter 2.

Section 3 The proposed dealings

8. Monsanto Australia Ltd (Monsanto) proposes to release a GM canola line⁶, which has been genetically modified (GM) to confer herbicide tolerance, into the environment under limited and controlled conditions.

9. The dealings involved in the proposed intentional release would include:

- conducting experiments with the GMO
- breeding the GMO
- propagating, growing, raising or culturing the GMO
- transporting the GMO
- disposing of the GMO
- possession, supply or use of the GMO for the purposes of any of the above.

10. These dealings are detailed further throughout the remainder of the current Chapter.

3.1 The proposed activities

11. The applicant has stated that the purpose of the trial is to conduct experiments to evaluate the agronomic performance of the GM canola line under field conditions.

12. Seed from the GM canola line will be produced at Monsanto facilities in Chile and Canada, and imported into Australia under an AQIS permit.

13. The proposed release will comprise trial plots to generate data to be used in regulatory submissions for future commercial release; demonstration sites for industry, government and researchers; and seed increase sites for agronomic evaluation, demonstration and regulatory trials.

14. The applicant proposes to use the GM canola seed and plant material to conduct experiments and analysis, store the GM seed at an approved facility, and/or use the GM seed for further planting. Any GM seed or plant material not required for analysis or seed increase will be destroyed. Plant materials from the GM canola will not be used for either human food or animal feed.

⁶ The term ‘line’ is used to denote plants derived from a single plant containing a specific genetic modification resulting from a single transformation event.

3.2 The proposed limits of the dealings (size, locations and duration)

15. The release is proposed to take place at 2 sites in the first year, 8 sites in the second and third years, and up to 20 sites in the fourth year. Each site will be a maximum of 4 ha in the first year and 10 ha in subsequent years, and the trial will be conducted for four years from March 2011 to December 2014.

16. The field trials are proposed to take place in both current and potential commercial canola growing areas of Australia. Sites may be located in 46 possible local government areas (LGAs) in New South Wales, 28 possible LGAs in Victoria and 53 possible LGAs in Western Australia (Table 1). The exact site locations will be determined closer to planting, and will be dependent on a number of factors including: the availability of water and land during a growing season; the requirement for a range of geographic and climatic conditions to measure the regional adaptation across different canola growing areas; the proximity to field research operations; the ability to ensure isolation and containment; and the ability to segregate from commercial canola crops being grown for seed. Details of site locations will be provided to the Regulator prior to each planting season.

Table 1. Proposed Local Government Areas in which GM canola may be released

New South Wales	Victoria	Western Australia
Berrigan	Ararat	Albany
Bland	Ballarat	Beverley
Blaney	Benalla	Boddington
Boorowa	Buloke	Boyup Brook
Cabonne	Bendigo	Bridgtown-Greenbushes
Conargo	Central Goldfields	Brookton
Coolamon	Glenelg	Broomehill
Coonamble	Golden Plains	Carnamah
Cootamundra	Greater Geelong	Coorow
Corowa	Greater Shepparton	Corrigin
Cowra	Hepburn	Cranbrook
Deniliquin	Hindmarsh	Cuballing
Dubbo	Horsham	Cunderdin
Forbes	Indigo	Dalwallinu
Gilgandra	Loddon	Denmark
Greater Hume	Macedon Ranges	Donnybrook-Balingup
Griffith	Mitchell	Dowerin
Gunnedah	Moorabool	Dumbleyung
Gundagai	Mount Alexander	Esperance
Gwydir	Moyne	Gnowangerup
Harden	Northern Grampians	Goomalling
Jerilderie	Pyrenees	Greenough
Junee	Southern Grampians	Jerramungup
Leeton	Wangaratta	Katanning
Liverpool Plains	West Wimmera	Kent
Lockhart	Wodonga	Kojonup
Mid-Western	Wyndham	Manjimup
Moree Plains	Yarriambiack	Mingenew
Murray		Moorra
Muswellbrook		Morawa
Narrabri		Mullewa
Narrandera		Narrogin

New South Wales	Victoria	Western Australia
Narromine		Nannup
Orange		Northam
Parkes		Perenjori
Tamworth		Pingelly
Temora		Plantagenet
Upper Hunter		Quairading
Urana		Ravensthorpe
Wagga Wagga		Tambellup
Wakool		Tammin
Walgett		Three Springs
Warrumbungle		Toodyay
Weddin		Victoria Plains
Wellington		Wagin
Young		Wandering
		West Arthur
		Wickepin
		Williams
		Wongan-Ballidu
		Woodanilling
		Wyalkatchem
		York

17. Only authorised persons will be permitted access to the proposed locations.

3.3 The proposed controls to restrict the spread and persistence of the GMO and its genetic material in the environment

18. The applicant has proposed a number of controls to restrict the spread and persistence of the GM canola line and the introduced genetic material in the environment including:

- surrounding the trial sites with a 50 m monitoring zone that is free of *Brassica* weeds.
- adopting one of the following measures:
 - maintaining a 1 km isolation zone between the outer perimeter of the planted area and the nearest non-GM canola crop, or
 - surrounding the trial site with a 15 m wide pollen trap and maintain a 400 m isolation zone between the outer perimeter of the pollen trap and other non-GM canola crops
- cleaning trial sites and adjacent areas following harvest
- locating the trial sites at least 50 m away from natural waterways
- restricting access to trial sites to authorised persons
- post harvest monitoring of the trial site, pollen trap area and any areas used to clean equipment on a monthly basis for 24 months and destroying any volunteer canola plants (if no volunteers are found during 6 consecutive inspections, then reduce inspections to once every 3 months for the remainder of the inspection period)
- cleaning of equipment and places within 2 weeks of harvest
- harvesting of GM canola from trials separately to other canola
- destroying seed not used for evaluation or seed increase
- transporting and storing GM plant materials in accordance with Regulator's guidelines

- not allowing the GM plant material to be used for human food or animal feed.

19. These controls, and the limits outlined in Section 3.2, have been taken into account in establishing the risk assessment context (this chapter), and their suitability for containing the proposed release is evaluated in Chapter 3, Section 3.1.1.

Section 4 The parent organism

20. The parent organism is *Brassica napus* L., which is commonly known as canola, rapeseed or oilseed rape. The term canola refers to varieties that meet specific standards on the level of toxicants (see Chapter 2, Risk scenario 1).

21. Canola is exotic to Australia and grown as an agricultural crop mainly in New South Wales, Victoria, South Australia and Western Australia. Canola has been grown in Australia since the 1960s primarily for its seeds, which yield from 35% to over 45% oil. Further information about the parent organism is contained in a reference document, *The Biology of Brassica napus L. (canola)*, that was produced to inform the risk assessment process for licence applications involving GM canola plants (OGTR 2008).

22. The GM canola line proposed for release was produced by genetic modification of plants of the Ebony canola variety. Ebony is not commercially grown in Australia but is commonly used for genetic modification.

Section 5 The GMO, nature and effect of the genetic modification

5.1 Introduction to the GMO

23. The GM canola line contains the *cp4 epsps* gene which is expected to confer herbicide tolerance in the GM canola plants. The gene is derived from *Agrobacterium tumefaciens* strain CP4 and encodes 5-enol-pyruvylshikimate-3-phosphate synthase (EPSPS), an enzyme of the shikimic acid pathway which is involved in the biosynthesis of plant phenolics.

24. Short regulatory sequences that control expression of the introduced gene are also present in the GM canola line. These sequences are derived from *A. tumefaciens*, and the plants *Arabidopsis thaliana* (thale cress) and *Pisum sativum* (common garden pea), and the plant virus Figwort mosaic virus (FMV) (see Section 5.3).

5.2 The introduced gene, its encoded protein and associated effects

5.2.1 The introduced gene for herbicide tolerance, its protein and end product

25. The *cp4 epsps* gene in the GM canola line proposed for release confers tolerance to glyphosate (N-phosphonomethyl glycine). The gene was isolated from *Agrobacterium tumefaciens* species strain CP4 and encodes a 47.6 kDa 5-enolpyruvylshikimate-3-phosphate synthase (EPSPS) consisting of a single polypeptide of 455 amino acids (Padgett et al. 1996). EPSPS is a key enzyme involved in the shikimate biosynthetic pathway in plants and microorganisms. The shikimate pathway enables biosynthesis of aromatic compounds from carbohydrate precursors in a series of seven biosynthetic steps. The penultimate step in the pathway is the condensation of shikimate 3-phosphate and phosphoenol pyruvate to form 5-enolpyruvylshikimate 3-phosphate, a reaction catalysed by EPSPS (reviewed by Herrmann & Weaver 1999). EPSPS performs this function in plants, bacteria, algae and fungi but is absent from mammals, which are not able to synthesise these aromatic amino acids (Bentley 1990; Padgett et al. 1993b).

26. Glyphosate is the active ingredient in a number of broad-spectrum systemic herbicides that have been approved for use in Australia and was first marketed as the proprietary herbicide Roundup[®]. The herbicidal activity of glyphosate is derived from its ability to inhibit the function of EPSPS. Glyphosate competes with phosphoenol pyruvate for binding to the complex formed between EPSPS and shikimate 3-phosphate. Upon glyphosate binding, the EPSPS:shikimate 3-

phosphate complex is very stable and has a slow reversal rate, effectively terminating the shikimate pathway prematurely and preventing biosynthesis of essential aromatic compounds, including the amino acids phenylalanine, tyrosine and tryptophan, and eventually leading to cell death (Dill 2005).

27. The CP4 EPSPS protein encoded by the *cp4 epsps* gene from *Agrobacterium* is naturally insensitive to the effects of glyphosate (Padgett et al. 1993a), as are a number of other microbial EPSPS enzymes (Schulz et al. 1985; Eschenburg et al. 2002). Consequently, in GM plant cells expressing the *Agrobacterium cp4 epsps* gene, biosynthesis of aromatic amino acids is not inhibited in the presence of glyphosate.

28. The *A. tumefaciens cp4 epsps* gene and a variant of the *Ochrobactrum anthropi gox* gene are the basis of glyphosate tolerant Roundup Ready[®] canola (elite line GT73) which was developed by Monsanto and has been approved for commercial release in Australia (DIR 020/2002) and overseas (see Section 7.2 for additional information regarding overseas approvals). The nucleotide sequences of both genes were modified by Monsanto for plant-preferred codon usage but these nucleotide substitutions did not alter the sequence of the encoded proteins. The *gox* gene was isolated from the soil bacterium *O. anthropi* strain LBAA, and encodes a glyphosate detoxifying enzyme (GOX) that converts glyphosate into aminomethylphosphonic acid and glyoxylate (Pipke & Amrhein 1988). Additional information can be found in the DIR 020/2002 RARMP that was prepared to inform the decision to approve commercial release of GM Roundup Ready[®] canola in Australia.

29. The GM canola proposed for release differs from the commercially released Roundup Ready[®] canola in that it contains only one copy of the *cp4 epsps* gene, which is under the control of a different promoter to that used in Roundup Ready[®] canola, and does not contain the *gox* gene. The applicant anticipates that the GM canola proposed for release will tolerate higher rates of glyphosate herbicides and have a wider window for herbicide application compared to Roundup Ready[®] canola. Glyphosate can only be applied to Roundup Ready[®] canola plants prior to flower formation, with later application leading to loss of yield.

5.2.2 Toxicity/allergenicity of the protein/end products associated with the introduced gene for herbicide tolerance

30. The *cp4 epsps* gene has been used extensively in GM plants as a selectable marker or a source of field resistance to the glyphosate herbicide. Consequently, the toxicity and allergenicity of the CP4 EPSPS protein has been previously reviewed by the Regulator and other overseas regulatory agencies on numerous occasions. No homology was found between the CP4 EPSPS protein sequence and known toxins or allergens (DIR 020/2002) and GM cotton (Bollgard II/Roundup Ready[®], DIR 012/2002; Roundup Ready[®], DIR 023/2003; Roundup Ready[®] Flex, DIR 059/2005 and DIR 066/2006) and canola (Roundup Ready[®], DIR 020/2002) lines containing the *cp4 epsps* gene have been approved by the Regulator for commercial release in Australia. Food derived from GM canola, cotton, sugarbeet, maize, soybean and lucerne lines that express the *cp4 epsps* gene have also been considered safe for human consumption by FSANZ (e.g. (ANZFA 2000; FSANZ 2005; FSANZ 2006; FSANZ 2007). Furthermore, oil from Roundup Ready[®] canola has been approved for human consumption by FSANZ (ANZFA 2000).

31. The CP4 EPSPS protein is 47.6 kDa and, although this falls within the typical MW range for allergenic proteins, it is unlikely to be an allergen because it does not display characteristics common to known food allergen proteins (Harrison et al. 1996; Canadian Food Inspection Agency 1997; ANZFA 2001). The CP4 EPSPS protein is rapidly inactivated by heat, enzymatic digestion, and acid in simulated mammalian digestive or gastric fluid (Harrison et al. 1996; Canadian Food Inspection Agency 1997; ANZFA 2001).

32. The amino acid sequence of the CP4 EPSPS protein expressed in the GM canola proposed for release is identical to the amino acid sequence of the CP4 EPSPS protein expressed in other commercially produced GM crops. These GM crops include Roundup Ready[®] canola, Roundup

Ready[®] soybean, Roundup Ready[®] 2 Yield soybean and Roundup Ready Flex[®] cotton. People have consumed these GM crops and their processed products since 1996 without any reports of adverse effects (James 2005). Furthermore, Roundup Ready[®] soybean expressing the identical introduced CP4 EPSPS protein has been shown not to be allergenic to humans (Batista et al. 2005). An OECD report concluded that the expression of EPSPS in GM plants is not detrimental to plant growth based on the similar agronomic performance of the GM crops compared to their non-GM parents (OECD 1999). Moreover, the CP4 EPSPS protein has been considered an inert ingredient by regulatory agencies in the United States (EPA 1996; EPA 1997).

33. A range of animal studies were provided in support of Monsanto's application for commercial release of Roundup Ready[®] canola (DIR 020/2002). In these studies, animals (including mice, rats, trout, quail, chickens, lambs and pigs) were fed either purified GOX/CP4 EPSPS protein, unprocessed seed from Roundup Ready[®] canola or processed meal from Roundup Ready[®] canola seed. No treatment-related adverse effects were observed in these studies, supporting the conclusion that the genetic modifications present in Roundup Ready[®] canola have not resulted in additional toxicity or anti-nutritional effects compared to non-GM canola controls. Roundup Ready[®] canola has been grown overseas since 1995 (see Section 7.2) and there have been no reports of toxicity associated with the CP4 EPSPS protein.

34. The *cp4 epsps* gene introduced into the GM canola plants was isolated from the common soil bacterium *A. tumefaciens*. Homologues of the gene and the encoded enzyme occur naturally in a wide range of plants including food crops, algae and fungi (Bentley 1990; Padgett et al. 1993c). EPSPS is involved in the biosynthesis of aromatic amino acids, which are naturally produced in plants including those widely consumed by people and animals. The CP4 EPSPS protein is structurally similar and functionally identical to endogenous plant EPSPS (Padgett et al 1996). On this basis, humans and other organisms have a long history of exposure to the *cp4 epsps* gene, the encoded protein and its end products, via consumption of plant material.

5.3 The regulatory sequences

5.3.1 Regulatory sequences for expression of the introduced gene for herbicide tolerance

35. Promoters are DNA sequences that are required in order to allow RNA polymerase to bind and initiate correct transcription. The expression of *cp4 epsps* in the GM canola line is under the control of a chimeric constitutive promoter, *P-FMV/Tsfl*. This promoter contains enhancer sequences from the Figwort mosaic virus (FMV) 35S promoter and 479 bp of DNA from the promoter region of the *Arabidopsis thaliana Tsfl* gene, which encodes elongation factor EF-1 alpha (Richins et al. 1987; Axelos et al. 1989).

36. A leader and intron sequence derived from the *Tsfl* gene are also included in the introduced *cp4 epsps* gene construct (*L-Tsfl* and *I-Tsfl*) (Axelos et al. 1989). The inclusion of these sequences ensures strong and reliable constitutive expression of the *cp4 epsps* coding sequence.

37. In plants, the EPSPS enzyme and the site of aromatic amino acid synthesis are located in the chloroplast (Klee et al 1987; (Kishore & Shah 1988). In plants, EPSPS is synthesised as a preprotein, ie containing a chloroplast transit peptide at the end terminal of the protein (CTP), by free cytoplasmic ribosomes. The CTP targets the precursor for transport into the chloroplast stroma, where it is proteolytically processed to yield the mature enzyme (della-Cioppa et al. 1986). Once cleaved from the mature protein, chloroplast transit peptides are rapidly degraded (Bartlett et al. 1982; della-Cioppa et al. 1986). Thus, the *cp4 epsps* coding sequence in the GM canola line is also preceded by a CTP coding region, *ctp2* from the *epsps* gene of the plant *Arabidopsis thaliana* (Klee et al. 1987), to provide transport of the encoded CP4 EPSPS into the canola chloroplast. The *ctp2* sequence present in the GM canola line proposed for release is the same as that used in Roundup Ready[®] Flex cotton and Roundup Ready[®] 2 Yield soybean.

38. Also required for gene expression in plants is an mRNA termination region, including a polyadenylation signal. The mRNA terminator for the introduced *cp4 epsps* gene in the GM canola

line is the T-E9 DNA sequence derived from *Pisum sativum*, containing the 3' nontranslated region of the pea ribulose-1,5-bisphosphate carboxylase small subunit (RbcS2) E9 gene (Coruzzi et al. 1984).

5.4 Method of genetic modification

39. *Agrobacterium*-mediated transformation was used to generate the GM canola line in the proposed release. *A. tumefaciens* is a soil bacterium that causes gall formation on a wide range of plant species. The gall is induced by transfer of hormone-producing genes from the bacterial cell into the plant genome. The genes are carried on an extrachromosomal, circular DNA molecule found within the bacterial cell called a Tumour-inducing (Ti) plasmid. During the infection process, only a section of the Ti plasmid known as the Transfer DNA (T-DNA) is transferred to the plant. Molecular biologists have studied the infection and T-DNA transfer process of *A. tumefaciens* for many years and have harnessed this natural process to facilitate genetic modification of plants. Well-characterised *A. tumefaciens* Ti plasmids have been produced that lack the genes responsible for tumour formation (disarmed plasmids) and instead enable genes of interest to be inserted between the T-DNA border sequences. When used to infect plants, *A. tumefaciens* cells carrying such plasmids cannot produce a tumour but will transfer the T-DNA sequence carrying the genes of interest into the plant cell where they stably integrate into the plant genome (Bevan 1984; Klee & Rogers 1989).

40. In addition to transfer of the T-DNA sequence, recent publications have shown that small segments of flanking Ti plasmid sequence and *A. tumefaciens* chromosomal sequence may be transferred into the plant genome at a low frequency during the transformation process (Smith 1998; Ulker et al. 2008). However, *A. tumefaciens*-mediated plant transformation has been used extensively in Australia and overseas and is not known to adversely affect human health and safety or the environment.

41. The Ebony canola variety was transformed using the plasmid PV-BNHT2672, containing the *cp4 epsps* gene expression cassette. The plasmid was introduced into a disarmed *Agrobacterium* strain, which was then co-cultivated with hypocotyl explants of the Ebony canola variety. Plants were regenerated in the presence of glyphosate to select for those expressing the introduced gene construct.

5.5 Characterisation of the GMO

5.5.1 Stability and molecular characterisation

42. The applicant used Southern blot hybridisation analysis to determine the number of copies of the transgene present in the GM canola line. A single copy of the introduced gene at a single integration site was observed. DNA sequence analysis confirmed that the organisation and sequence of the genetic elements within the *cp4 epsps* expression cassette of the GM canola was identical to that in the plasmid PV-BNHT2672 (information supplied by the applicant). The applicant has also conducted preliminary bioinformatics analysis which has shown that the insertion of the *cp4 epsps* expression cassette is not within a known coding sequence in the GM canola.

43. The applicant has used single nucleotide polymorphism (SNP) markers to determine the exact genomic location of the introduced DNA. Based on linkage with 5 SNP markers, the introduced *cp4 epsps* gene is located on linkage group N4 on the A genome of *Brassica napus*. The closest SNP marker is at 5cM from the insertion event.

44. Western blot analysis has shown the presence of the CP4 EPSPS protein in leaf tissues of the GM canola for multiple generations (information supplied by the applicant). The analysis also shows that the size and N-terminal sequence of the CP4 EPSPS protein expressed in the GM canola is similar to the CP4 EPSPS expressed by *Escherichia coli*. These results also indicate that the chloroplast transit peptide has processed the introduced protein as expected. Herbicide tolerance has

been used as a selectable marker after the transformation process, confirming activity of the expressed CP4 EPSPS.

45. PCR and Southern blot analysis were used to confirm that plasmid backbone sequences (ie the part of the plasmid not intended to be transferred to the plants) are not present in the GM canola plants. The selectable marker gene *aadA*, which confers resistance to spectinomycin and streptomycin, is present in the backbone of the plasmid PV-BNHT2672, and was used to select for *Agrobacterium* containing the plasmid prior to generation of the GM canola plants in the laboratory. This selectable marker gene was not present in the GM canola plants proposed for release (information supplied by the applicant).

5.5.2 Characterisation of the phenotype of the GM canola line

46. The purpose of the proposed trial is to assess the efficacy of the herbicide tolerance trait in the GM canola plants grown under field conditions. No unintended effects have been observed in the limited testing done on the GM canola plants in the USA and Canada. These results will be confirmed during the proposed limited and controlled release.

Section 6 The receiving environment

47. The receiving environment forms part of the context in which the risks associated with dealings involving the GMO are assessed. This includes: any relevant biotic/abiotic properties of the geographic regions where the release would occur; intended agricultural practices, including those that may be altered in relation to normal practices; other relevant GMOs already released; and any particularly vulnerable or susceptible entities that may be specifically affected by the proposed release (OGTR 2009).

48. The proposed dealings involve planting the GM canola at 2 sites in the first year, 8 sites in the second and third years, and up to 20 sites in the fourth year. These sites may be located in any of 46 LGAs in New South Wales, 28 LGAs in Victoria or 53 LGAs in Western Australia, as shown in Table 1. Monsanto intends to contract land suitable for canola cultivation and will inform the Regulator of the trial site locations before planting (see Section 3.2).

6.1 Relevant abiotic factors

49. The abiotic factors relevant to the growth and distribution of commercial canola in Australia are discussed in *The Biology of Brassica napus L. (canola)* (OGTR 2008).

50. The proposed release will be carried out across a range of geographic and climatic conditions.

51. Monsanto proposes to locate the GM canola trial sites at least 50 m from the nearest natural waterway.

6.2 Relevant biotic factors

52. The biotic factors pertaining to the growth and distribution of commercial canola are discussed in *The Biology of Brassica napus L. (canola)* (OGTR 2008). In addition, the following points are of particular relevance to this release:

- The proposed trial would take place in areas where canola (both GM and non-GM) is commercially grown.
- Invertebrates, vertebrates and microorganisms are expected to be exposed to the introduced genes, their encoded proteins and end products.

6.3 Relevant agricultural practices

53. It is anticipated that the agronomic practices for the cultivation of the GM canola by the applicant will not differ significantly from industry best practices used in Australia. Plants at the release sites would therefore receive applications of water, fertilisers, herbicides, insecticides and other agronomic management practices similar to commercially grown canola plants, other than

possible greater application of glyphosate than used for Roundup Ready[®] canola. The applicant intends to sow the GM canola using small plot or commercial seeding machinery. Conventional cultivation practices for canola are discussed in more detail in *The Biology of Brassica napus L. (canola)* (OGTR 2008).

54. In Australia, spring varieties of canola are usually grown as a winter annual crop, with planting occurring in April or May and harvest in early summer. Small areas of canola are also sown in late spring/early summer, and harvested in early autumn. Canola is harvested either by windrowing (swathing) or by direct harvesting. Windrowing involves cutting the crop and placing it in rows to dry. The windrow lies in horizontal bundles, supported by the cut stems 10 – 20 cm off the ground, and remains in the paddock for 8 to 19 days prior to harvest. When most of the seed has matured and the moisture content is 9% or less, the windrow is picked up by the harvester (DPI Vic 2009; GRDC 2010).

55. The applicant proposes to allow the GM canola to set seed, and harvest it separately from other canola. Harvested material, including seed, would be transported to a contained facility for analysis. Harvested areas would be managed to promote the germination of any residual seed. Any volunteers that germinate in the following spring would be destroyed. The sites may be sown to cereals, grass pasture or left as fallow, and will be monitored for volunteers.

6.4 Presence of related plants in the receiving environment

56. The proposed trial sites are located in commercial canola growing regions. Commercial canola varieties grown in New South Wales, Victoria and Western Australia could include non-GM and GM varieties. Non-GM canola includes varieties that are tolerant to herbicides containing triazine and imidazolinone. GM glyphosate tolerant Roundup Ready[®] canola and GM glufosinate ammonium tolerant, InVigor[®] canola have been approved for commercial release under DIRs 020/2002 and 021/2002, respectively.

57. *B. napus* is known to cross with other species within the *Brassicaceae* tribe. Of the many *Brassica* species in Australia, canola may potentially hybridise under natural conditions with sexually compatible related species that include: other *B. napus* groups or subspecies (including vegetables such as Swedes, rutabaga, kale), *B. juncea* (Indian mustard), *B. rapa* (canola, turnip rape or white turnip; includes vegetables such as turnip, chinese cabbage and pak choi) and *B. oleracea* (wild cabbage; includes vegetables such as cauliflower, brussel sprouts and cabbage) (Salisbury 2002b). Naturally occurring hybrids between *B. napus* and species from other genera in the *Brassicaceae* tribe have been reported at very low frequencies for *Raphanus raphanistrum* (wild radish), *Hirschfeldia incana* (Buchan weed) and *Sinapis arvensis* (charlock) (Salisbury 2002b). The applicant proposes to maintain a 50 m monitoring zone that is free of *Brassica* weeds.

6.5 Presence of the introduced gene or similar genes and encoded proteins in the environment

58. The introduced genes and regulatory sequences were originally isolated from naturally occurring organisms, which are already widespread and prevalent in the environment.

59. The introduced *cp4 epsps* gene was isolated from the common soil bacterium *A. tumefaciens*. Homologues of *cp4 epsps* and its encoded enzyme occur naturally in a wide range of higher plants, including plants widely consumed by animals and people, and in some microorganisms which are plant pathogens (Kamada-Nobusada & Sakakibara 2009).

60. Short regulatory sequences are derived from *A. tumefaciens*, and the plants *Arabidopsis thaliana* (thale cress) and *Pisum sativum* (common garden pea), and the plant virus Figwort mosaic virus (FMV). Although *A. tumefaciens* and FMV are plant pathogens, the regulatory sequences comprise a small part of their total genome, and in themselves have no pathogenic properties.

Section 7 Australian and international approvals

7.1 Australian approvals of GM canola

7.1.1 Previous releases approved by Genetic Manipulation Advisory Committee or the Regulator

61. There has been no previous release of this GM canola line in Australia.
62. The Regulator has issued two licences for the commercial release of GM canola containing genes for herbicide tolerance, either alone or combined with a hybrid breeding system (DIR 020/2002: Roundup Ready[®] canola and DIR 021/2002: InVigor[®] canola). These GM canola lines are now grown in a number of States in Australia, including New South Wales, Victoria and Western Australia. The GM canola line proposed for release is similar to Roundup Ready[®] canola (refer to Section 5.2.1 for details).
63. The Regulator has also issued six licences for the limited and controlled release of various GM canola lines (see www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/ir-1). In addition, there have been field trials of GM canola lines with various traits under the former voluntary system overseen by the Genetic Manipulation Advisory Committee (GMAC) (see RARMP for DIR 103 for further detail).
64. There have been no credible reports of adverse effects on human health or the environment resulting from any of these releases.

7.1.2 Approvals by other Australian government agencies

65. Australia's gene technology regulatory system operates as part of an integrated legislative framework that avoids duplication and enhances coordinated decision making. The Regulator is responsible for assessing risks to the health and safety of people and the environment associated with the use of gene technology. However, dealings conducted under a licence issued by the Regulator may also be subject to regulation by other Australian government agencies that regulate GMOs or GM products, including Food Standards Australia New Zealand (FSANZ), Australian Pesticides and Veterinary Medicines Authority (APVMA), Therapeutic Goods Administration (TGA), National Industrial Chemicals Notification and Assessment Scheme (NICNAS) and Australian Quarantine Inspection Service (AQIS)⁷.
66. FSANZ is responsible for human food safety assessment and food labelling, including GM food. The applicant does not intend to use materials from the GM canola line in human food, accordingly no application has been submitted to FSANZ. FSANZ approval would need to be obtained before materials from this GM canola line could be sold as food or food ingredients.
67. APVMA has regulatory responsibility for the supply of agricultural chemicals, including herbicides and insecticidal products, in Australia. Monsanto intends to apply herbicides to the GM canola during the trial, which is subject to regulation by the APVMA.
68. The approval of AQIS will be required to enable import of GM canola seed from Canada or Chile.
69. In addition, dealings authorised by the Regulator may be subject to the operation of State legislation declaring areas to be GM, GM free, or both, for marketing purposes.

⁷ More information on Australia's integrated regulatory framework for gene technology is contained in the *Risk Analysis Framework* available from the Office of the Gene Technology Regulator (OGTR). Free call 1800 181 030 or at <http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/riskassessments-1>.

7.2 International approvals of GM canola

70. The GM canola line proposed for release in this application has been field trialled in Canada since 2005, in the USA since 2006 and in Chile since 2009.

71. Roundup Ready[®] canola elite line GT73 (also known as RT73) was approved for commercial release in Canada in 1995, Japan in 1996 and the United States in 1999 (see the RARMP for DIR 020/2002 for further details).

72. There have also been numerous international releases of other GM canola lines. The traits that have been modified include hybrid breeding system, increased yield, water use efficiency, nitrogen use efficiency, and modified oil composition⁸.

⁸ Sources: < <http://inspection.gc.ca/english/plaveg/bio/confine.shtml> >, <<http://www.aphis.usda.gov/brs/status/relday.html>>, <http://gmoinfo.jrc.ec.europa.eu/gmp_browser.aspx>, accessed 12 March 2010

Chapter 2 Risk assessment

Section 1 Introduction

73. The risk assessment identifies and characterises risks to the health and safety of people or to the environment from dealings with GMOs, posed by or as the result of gene technology (Figure 2). Risks are identified within the context established for the risk assessment (see Chapter 1), taking into account current scientific and technical knowledge. A consideration of uncertainty, in particular knowledge gaps, occurs throughout the risk assessment process.

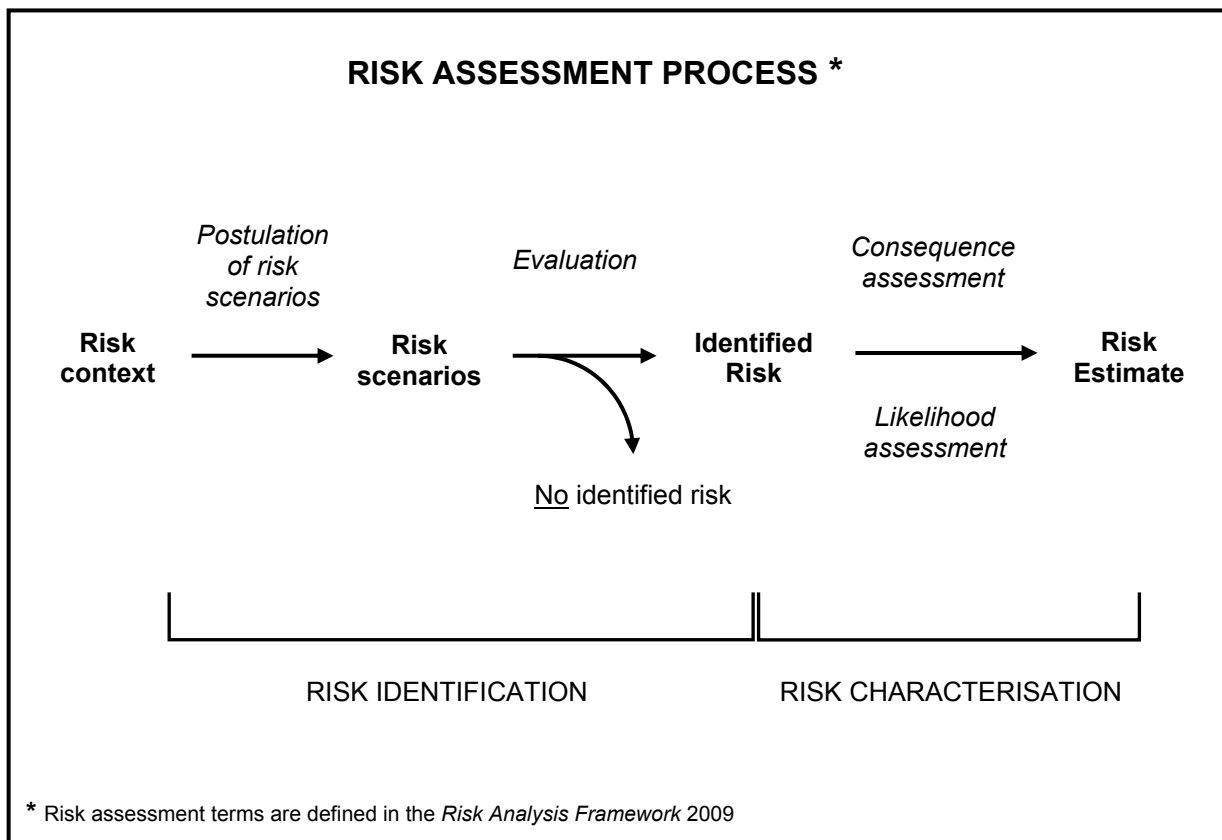


Figure 2. The risk assessment process.

74. Initially, risk identification considers a wide range of circumstances whereby the GMO, or the introduced genetic material, could come into contact with people or the environment. Consideration of these circumstances leads to postulating plausible causal or exposure pathways that may give rise to harm for people or the environment from dealings with a GMO (risk scenarios).

75. Each risk scenario is evaluated to identify those risks that warrant detailed characterisation. A risk is only identified when a risk scenario is considered to have some reasonable chance of causing harm. Pathways that do not lead to harm, or could not plausibly occur, do not advance in the risk assessment process.

76. A number of risk identification techniques are used by the Regulator and staff of the OGTR, including checklists, brainstorming, commonsense, reported international experience and consultation (OGTR 2009). In conjunction with these techniques, risk scenarios postulated in previous RARMPs prepared for licence applications of the same and similar GMOs are also considered.

77. Identified risks (*i.e.* those identified for further assessment) are characterised in terms of the potential seriousness of harm (Consequence assessment) and the likelihood of harm (Likelihood assessment). The level of risk is then estimated from a combination of the Consequence and Likelihood assessments.

Section 2 Risk Identification

78. The following factors are taken into account when postulating relevant risk scenarios:

- the proposed dealings, which may be to conduct experiments, develop, produce, breed, propagate, grow, import, transport or dispose of the GMOs, use the GMOs in the course of manufacture of a thing that is not the GMO, and the possession, supply and use of the GMOs in the course of any of these dealings
- the proposed limits
- the proposed controls
- characteristics of the parent organism(s)
- routes of exposure to the GMOs, the introduced gene(s) and gene product(s)
- potential effects of the introduced gene(s) and gene product(s) expressed in the GMOs
- potential exposure to the introduced gene(s) and gene product(s) from other sources in the environment
- the environment at the site(s) of release
- agronomic management practices for the GMOs.

79. Eight risk scenarios were identified and evaluated. These are summarised in Table 2, where circumstances that share a number of common features are grouped together in broader risk categories. None of the risk scenarios were considered to lead to an identified risk that required further assessment. More detail of the evaluation of these scenarios is provided later in this Section.

Table 2. Summary of risk scenarios from dealings with GM canola genetically modified for herbicide tolerance.

Risk category	Risk scenario		Identified risk?	Reason
	Pathway that may give rise to harm	Potential harm		
Section 2.1 Production of a substance toxic/allergenic to people or toxic to other organisms	1. Exposure to GM plant material containing the protein encoded by the introduced gene, or its end products	Allergic reactions in people or toxicity in people and other organisms	No	<ul style="list-style-type: none"> • The introduced gene, encoded protein and end products occur naturally in the environment and are unlikely to be toxic or allergenic to people or toxic to other organisms. • None of the GM canola material would be used for human food or animal feed. • The limited scale, short duration and other proposed limits and controls minimise exposure of people and other organisms to the GM plant material.
Section 2.2 Spread and persistence of the GM canola plants in the environment	2. Expression of the introduced gene improving the survival of the GM canola plants	Weediness; allergic reactions in people or toxicity in people and other organisms	No	<ul style="list-style-type: none"> • The genetic modification is not expected to alter the response of the GM canola line to biotic and abiotic stresses that naturally limit the geographical distribution of the species. • The genetic modification is expected to increase the fitness of GM canola plants in managed environments, but only when the corresponding herbicide is applied. • The limits and controls proposed for the release would minimise spread and persistence of the GM canola plants.

Risk category	Risk scenario		Identified risk?	Reason
	Pathway that may give rise to harm	Potential harm		
	3. Dispersal of reproductive GM plant materials through various means, including animals and extreme weather conditions	Weediness; allergic reactions in people or toxicity in people and other organisms	No	<ul style="list-style-type: none"> Birds and animals are unlikely to disperse viable canola seed. Dispersal would be minimised by the proposed limits and controls, which include: locating the sites away from waterways, inspecting monitoring zones around trial sites, reporting adverse weather conditions and movement of plant material, post-harvest cleaning and transporting material according to the Regulator's guidelines.
Section 2.3 Vertical transfer of genes or genetic elements to sexually compatible plants	4. Expression of the introduced gene or regulatory sequences in other canola plants	Weediness; allergic reactions in people or toxicity in people and other organisms	No	<ul style="list-style-type: none"> The majority of pollen travels less than 10 m and the amount of pollen decreases with distance from the source. Risk scenarios 1 – 3 associated with expression of the introduced gene did not constitute identified risks for people or the environment. The proposed limits and controls will restrict gene flow between the GM canola and other canola.
	5. Expression of the introduced gene in other sexually compatible plants	Weediness; allergic reactions in people or toxicity in people and other organisms	No	<ul style="list-style-type: none"> The majority of pollen travels less than 10 m and the amount of pollen decreases with distance from the source. Risk scenarios 1- 3 associated with expression of the introduced gene did not constitute identified risks for people or the environment. The proposed limits and controls will restrict gene flow between the GM canola and other sexually compatible plants.
Section 2.4 Horizontal transfer of genes or genetic elements to sexually incompatible organisms	6. Presence of the introduced genetic material in other organisms as a result of horizontal gene transfer	Weediness; allergic reactions in people or toxicity in people and other organisms	No	<ul style="list-style-type: none"> The introduced gene and regulatory sequences are already present in the environment and are available for transfer via demonstrated natural mechanisms. Risk scenarios 1 – 5 associated with expression of the introduced gene did not constitute identified risks for people or the environment.
Section 2.5 Unintended changes in biochemistry, physiology or ecology	7. Changes to biochemistry, physiology or ecology of the GM canola plants resulting from expression, or random insertion, of the introduced genetic material	Weediness; allergic reactions in people or toxicity in people and other organisms	No	<ul style="list-style-type: none"> Unintended, adverse effects, if any, would be minimised by the proposed limits and controls. Obvious unexpected alterations are likely to have been detected and eliminated during the production, laboratory screening and early field testing of the GM canola lines.
Section 2.6 Unauthorised activities	8. Use of the GMOs outside the proposed licence conditions (non-compliance)	Potential adverse outcomes mentioned in Sections 2.1 to 2.5	No	<ul style="list-style-type: none"> The Act provides for substantial penalties for non-compliance and unauthorised dealings with GMOs and also requires consideration of the suitability of the applicant to hold a licence prior to the issuing of a licence by the Regulator.

2.1 Production of a substance toxic/allergenic to people or toxic to other organisms

80. Toxicity is the adverse effect(s) of exposure to a dose of a substance as a result of direct cellular or tissue injury, or through the inhibition of normal physiological processes (Felsot 2000).

81. Allergenicity is the potential of a substance to elicit an immunological reaction following its ingestion, dermal contact or inhalation, which may lead to tissue inflammation and organ dysfunction (Arts et al. 2006).

82. A range of organisms may be exposed directly or indirectly to the protein (and end products) encoded by the introduced gene for herbicide tolerance. Workers cultivating the GM canola would be exposed to all plant parts. Organisms may be exposed directly to the protein through biotic interactions with GM canola plants (vertebrates, invertebrates, symbiotic microorganisms and/or pathogenic fungi) or through contact with root exudates or dead plant material (soil biota). Indirect exposure would include organisms that feed on organisms that feed on GM canola plant tissues or degrade them (vertebrates, invertebrates, fungi and/or bacteria).

Risk scenario 1. Exposure to GM plant material containing the protein encoded by the introduced gene, or its end products

83. Expression of the introduced gene for herbicide tolerance could potentially result in the production of novel toxic or allergenic compounds in the GM canola plants, or alter the expression of endogenous canola proteins. If humans or other organisms were exposed to the resulting compounds through ingestion, contact or inhalation of the GM plant materials, this may give rise to detrimental biochemical or physiological effects on the health of these people or other organisms.

84. The herbicide tolerance gene introduced into the GM canola line encodes a protein that is well characterised and not known to be toxic or allergenic, nor does it participate in biochemical reactions that produce toxic or allergenic products (Chapter 1, Section 5.2.2). Therefore, the GM canola line proposed for release is unlikely to be any more toxic or allergenic than its non-GM counterparts.

85. The potential for exposure of humans and other organisms to the novel proteins produced in the GM canola plants will be reduced by the limits and controls proposed by the applicant (see Chapter 1, Sections 3.2 and 3.3). In particular, access to the trial site will be restricted to authorised personnel only, all plant material will be destroyed at the end of the trial (with the exception of seed and tissue samples that may be required for laboratory analysis or use in future field trials), GM material will be transported according to the Regulator's guidelines, no GM material will be used for human food or animal feed, and the trial will be limited in size and duration. However, despite these control measures it can be expected that some organisms will have unrestricted access to GM plant material during the trial, including small mammals, birds, invertebrates and microorganisms. Given the lack of toxicity associated with the novel protein produced in the GM canola line (see Chapter 1, Section 5.2.2) and the fact that the novel gene was originally derived from an organism that is prevalent in the environment (see Chapter 1, Section 6.5), it is unlikely that this exposure will have a negative impact on organisms that interact with the GM plants during the trial.

86. The applicant has stated that GM plant material will not be used for human food or animal feed. However, canola is commonly utilised as a source of nectar and pollen for commercial honey production by honeybees. Therefore, if apiarist's hives are located close to a trial site it is possible that pollen from the GM canola could be incorporated into the honey produced at the hive. The percentage dry weight of canola pollen per wet weight of honey that is produced from hives placed in canola fields has been shown to be only 0.2 % (Hornitzky & Ghalayini 2006). If the honey is sieved or filtered the pollen content is further reduced (discussed in Malone 2002). The applicant has stated that there will be no beehives within 50 m of the GM canola trial sites.

87. Most honeybees forage close to the hive and between neighbouring plants (Rieger et al. 1999), but long range foraging (up to 12 km) has been observed when pollen and nectar sources are scarce

(Beekman & Ratnieks 2000). Honeybees tend to visit only one plant species per trip and will remain faithful to a particular species and foraging area as long as there is sufficient nectar or pollen available. Much of the pollen collected by bees will be deposited on the next few plants visited (see Scheffler (1995) and references therein).

88. The applicant proposes to surround the GM canola with a 50 m monitoring zone that is free of canola and compatible species. This would minimise the likelihood of honeybees foraging on the GM plants, as exclusion zones left unplanted or planted with sexually non-compatible crops create an unattractive barrier to foraging bees (Williams 2001). All trial sites will be isolated from the nearest *Brassica* crop by at least 400 m. In addition, for sites that are not at least 1 km from the nearest *Brassica* crop, the applicant proposes to surround the GM canola with a 15 m pollen trap of non-GM canola. Trap crops of only 6 m in width can restrict the transfer of GM pollen by bees by absorbing the GM pollen before it is transferred from the site (Williams 2001). It is unlikely that pollen from the GM canola plants grown in this trial will be present in detectable amounts in honey and, as stated above, the introduced protein and its end products are not considered to be toxic or allergenic.

89. The proposed limits and controls of the trial (Chapter 1, Sections 3.2 and 3.3) would minimise the likelihood of exposure of people and other organisms to GM plant materials. The proposed trial sites will be located on private property, overseen by the applicant. Only approved staff with appropriate training will have access to the site. People not directly involved in the trial will only be able to visit the trial sites when accompanied by approved staff. This will minimise exposure of the public to the GM plant material. There is little potential for exposure of the public to GM plant material via ingestion, skin contact or inhalation as no GM plant material would be used for human food. Livestock and other animals would not be intentionally exposed as the GM plant material will not be used as feed.

90. Contact with, or inhalation of, GM plant materials would be limited to trained and authorised staff who may be exposed to the GM plant materials during all phases of the trial. Workers may come into contact with the protein encoded by the introduced gene when the plant cells have been damaged. However, exposure to the GM canola plants is unlikely to lead to an adverse outcome as the GM plants are unlikely to be any more toxic or allergenic than non-GM equivalents. Moreover, GM plants modified with similar or identical genes have been released previously in Australia and overseas (see Chapter 1, Sections 5.2.2 and 7) with no reports of altered toxicity or allergenicity.

91. **Conclusion:** The potential for allergic reactions in people, or toxicity in people and other organisms as a result of exposure to GM plant materials containing proteins encoded by the introduced gene is not identified as a risk that warrants further assessment.

2.2 Spread and persistence of the GM canola plants in the environment

92. Baseline information on the characteristics of weeds in general, and the factors limiting the spread and persistence of non-GM canola plants in particular, is given in *The Biology of Brassica napus L. (canola)* (OGTR 2008). In summary, canola shares some characteristics with known weeds, ie having weedy relatives, high seed output, self- and cross-pollination and seed dormancy. Canola is considered a major weed in agricultural ecosystems in Australia and a minor weed in natural ecosystems (Groves et al. 2003). However, canola is a poor competitor and is not regarded as an environmentally hazardous colonising species. It is mainly a plant of disturbed habitats; unless the habitat is regularly disturbed, or seed replenished from outside, canola will be displaced by other plants (Salisbury 2002d).

93. The establishment, spread and persistence of canola populations is likely to be limited by water and nutrient availability, temperature and competition from other plants. To a lesser extent, high temperatures or frost during flowering as well as insect and disease pressures can greatly reduce seed set, thus limiting spread and persistence.

94. Scenarios that could lead to increased spread and persistence of the GM canola plants include expression of the introduced gene conferring tolerance to abiotic or biotic stresses, or increasing the dispersal potential of GM plant materials outside the release site. These risk scenarios could lead to increased exposure of vertebrates (including people), invertebrates and microorganisms to the encoded proteins or end products.

Risk scenario 2. Expression of the introduced gene improving the survival of the GM canola plants

95. If the GM canola plants were to establish or persist in the environment, the exposure of humans and other organisms to the GM plant material could be increased. The potential for increased allergenicity in people or toxicity in people and other organisms as a result of contact with GM plant materials has been considered in Risk scenario 1 and was not considered an identified risk.

96. If the expression of the introduced gene for herbicide tolerance were to provide the GM canola plants with a significant selective advantage over commercially released GM or non-GM canola plants and if they were able to establish and persist in favourable non-agricultural environments, this may give rise to lower abundance of desirable species, reduced species richness, or undesirable changes in species composition. Similarly, the GM canola plants could adversely affect agricultural environments if they exhibited a greater ability to establish and persist than commercially released GM or non-GM canola.

97. The geographic range of non-GM canola in Australia is limited by a number of biotic and abiotic factors, including disease pressure, water and nutrient availability (see Chapter 1, Sections 6.1 and 6.2). The introduced gene for herbicide tolerance has a highly specific mode of action and is unlikely to alter response of the GM canola plants to biotic or abiotic stresses that are naturally encountered in the environment. Therefore, although the response of the GM canola line to biotic and abiotic stress has not yet been examined, the introduced gene is unlikely to alter the potential geographic range of the GM canola plants.

98. The GM canola line proposed for release contains a herbicide tolerance gene. Expression of this gene will confer a selective advantage over non-GM counterparts in environments in which the corresponding herbicide is applied, such as agricultural settings and along roadsides. However, as the mode of action of the gene is herbicide-specific and cross-tolerance to other herbicides is not expected in the GM line (Chapter 1, Section 5.2.1), the GM canola plants could be managed by the application of alternative herbicides or by the use of other agricultural practices such as cultivation.

99. Canola is considered a weed of agricultural and disturbed habitats, but is of minor significance to natural ecosystems (Groves et al. 2003). The genotypes used for commercial canola cultivation are bred for maximum production in managed environments in which optimal water and nutrient availability is ensured. In natural environments where water and nutrient availability are limited, canola is considered a poor competitor compared with native species (Oram et al. 2005; Hall et al. 2005; Anon. 2007). Although canola plants are often observed growing near transport routes and at field margins (Agrisearch 2001; Crawley & Brown 2004; von der Lippe & Kowarik 2007b; Nishizawa et al. 2009), their presence is thought to be reliant on re-supply of seed from external sources rather than forming self-sustaining weed populations (Salisbury 2002d) and experimental data has shown that GM herbicide tolerant canola is no more likely to persist in natural environments than its non-GM counterpart (Crawley et al. 1993; Crawley et al. 2001).

100. The proposed limits and controls of the trial (Chapter 1, Sections 3.2 and 3.3) would minimise the likelihood of spread and persistence of the GM canola line proposed for release. The release would be of limited size and short duration and the applicant proposes a number of control measures. These include destruction of plant material upon completion of the trial and implementation of a post-harvest program to prevent seed from persisting in the soil and destroy

any volunteers that germinate. The efficacy of these controls with respect to spread and persistence of the GM canola plants is discussed in Chapter 3, Sections 3.1.1.

101. **Conclusion:** The potential for increased weediness, allergenicity or toxicity due to expression of the introduced gene for herbicide tolerance improving the survival of the GM canola plants is not identified as a risk that warrants further assessment.

Risk scenario 3. Dispersal of reproductive GM plant materials through various means, including animals and extreme weather conditions

102. If the GM canola plants were to be dispersed from the release site, the exposure of humans and other organisms to the GM plant material and/or establish and persist in the environment could be increased. The effects of contact, inhalation or ingestion of material from the GM canola line have been assessed in Risk scenario 1 and were not identified risks in the context of the proposed limits and controls. The potential for the introduced gene to result in improved survival of the GM canola plants in the environment was assessed in Risk scenario 2 and was not an identified risk.

103. Dispersal of reproductive GM plant materials, for example viable seed, could occur in a variety of ways including endozoochory (dispersal through ingestion by animals), the activity of animals such as rodents and herbivores or through extremes of weather such as flooding or high winds. As canola does not reproduce vegetatively under natural conditions, the most likely method of dispersal is via seed.

104. The gene introduced into the GM canola line is not expected to alter seed yield, palatability or any other physiological characteristics that would affect seed dispersal. Therefore, the potential for dispersal of the GM plant material is likely to be equivalent to that of non-GM canola. Canola seeds lack barbs, hooks or a sticky coat that would allow them to be carried on the fur of animals (Howe & Smallwood 1982). The seeds also lack specialised structures that would allow them to be carried by the wind. However, seed dispersal may occur via pod shatter, endozoochory or the action of humans.

105. Canola seeds are small, smooth and spherical. They are produced in pods that dehisce and shatter at maturity, locally dispersing seed to the surrounding soil. To reduce losses due to pod shatter, commercially cultivated canola is commonly harvested prior to drying by windrowing (swathing) (Walton et al. 1999) (Chapter 1 Section 6.3). The applicant proposes to employ this method when mechanically harvesting GM canola. Alternatively, the GM canola seeds may be hand-harvested to reduce seed loss. Post-harvest procedures will be employed to ensure that any seed entering the soil germinates rapidly and does not persist. The proposed post-harvest procedures, and the rationale upon which they are based, are further explained in Chapter 3, Section 3.1.1.

106. Widespread natural dispersal of canola seeds is not generally observed in the field. While pod shattering can disperse seeds over short distances, it is also possible that GM canola plant material from windrows, including seed, could be blown beyond field boundaries. Dispersal distance would depend on the wind strength, the amount of trash on the ground and the moisture content of the material. However, evidence for the likelihood of this occurring is conflicting and largely anecdotal.

107. Previously, it has been reported that wind has not been observed to disperse canola plant material outside of field trial sites (OGTR 2007). Rather, wind may move plant material from windrows but this material is generally caught in the next windrow or trapped by the remaining stubble. However, there remains a possibility of dispersal of plant material from windrows beyond field boundaries by strong wind. OGTR monitoring reports from eight years of limited and controlled releases of GM canola indicate one instance of plant material being blown from windrows into the monitoring zone by strong winds, to a distance of less than 50 m. In 2009, the Department of Agriculture and Food in Western Australia conducted a trial of commercially licensed Roundup Ready GM canola and, out of 19 commercial scale and 33 small scale plantings totalling 860 hectares, one incident was recorded of strong winds blowing swathed GM canola onto

and over the boundary fence onto a neighbouring property (DAFWA 2009). In a South Australian crop and pasture report for 2003, an observation was recorded of non-GM canola windrows being blown about by isolated thunderstorms (Rural Solutions SA 2003). Therefore, in some isolated instances, strong winds could transport GM plant material, including seed, away from trial sites. Post-harvest cleaning, as well as monitoring zones around trial sites which are monitored during and after trials, will constrain dispersal of GM plant material.

108. It is also possible that extreme flooding conditions could transport GM plant material away from the site. However, as canola does not tolerate waterlogged soils, the applicant is unlikely to choose trial sites that are prone to flooding and if any material were to move from the site it is unlikely to survive in extremely moist conditions.

109. Seeds may be transported out of the trial site by the activity of animals, birds and invertebrates. Birds, such as cockatoos and sparrows, can shred or remove pods during development and at maturity (Stanley & Marcroft 1999), mice may climb plants to feed on the seed and ants may take seed deep into the soil (OGTR 2008). However, studies suggest that canola seed is likely to be non-viable after passage through the animal digestive system. Sheep fed canola seed were found to excrete seed up to five days after consumption. However, only 1-1.5 % of the seed was excreted whole and, of this, only 10-40 % of seed was capable of germination. Therefore, overall less than 0.5 % of seed consumed was capable of germinating after excretion (Stanton et al. 2003). In a German study, Wiedermann (2009) found no intact rape (*B. napus*) seed in the faeces of wild boars fed a diet of maize and rape seed.

110. In a study of canola seed consumption by Australian birds in captivity, including four dove/pigeon species, one finch species and two duck species, seed was generally well macerated after passage through the digestive system. Whole seed was found only in faecal pellets obtained from wood ducks. However, the amount of seed detected was <0.01% of that consumed and the germination rate of the seed was less than 50 % (5 out of 11 seeds) (Twigg et al. 2008). Omnivorous/herbivorous species such as ducks are less efficient at digesting seeds compared to most obligate seed-eaters. In contrast, parrots are even less likely to pass viable seed because they generally dehusk seeds and consume only the kernel (Twigg et al. 2008). Therefore, it is likely that dissemination of GM canola seed by wild birds consuming seed directly from the crop would be very low.

111. Human activity is considered the most significant method of long-distance seed dispersal. Studies in the UK, Germany and Australia have shown that feral canola plants are often found growing near roads and railways, suggesting that seed is lost during transportation (Agrisearch 2001; Crawley & Brown 2004; von der Lippe & Kowarik 2007b). This fact is particularly evident in Japan where canola is not grown commercially, but seed is imported for processing. In a three-year study of Route 51, which joins the Port of Kashima to processing plants in the Keiyo District, canola plants were found along the roadside with the greatest number found adjacent to the inbound lane (Nishizawa et al. 2009). Similarly, in the UK and Germany the density of feral roadside canola populations was higher adjacent to the inbound lane of roads leading to canola seed processing facilities, compared to the outbound lane (Crawley & Brown 2004; von der Lippe & Kowarik 2007a). Seed may also be transported on clothing or machinery used at the trial sites. To minimise seed dispersal in the proposed field trials, all equipment will be cleaned after use and before it is used for other purposes, and plant material will be transported according to the Regulator's guidelines (Chapter 1, Section 3.3).

112. **Conclusion:** The potential for allergenicity, toxicity or increased weediness due to the dispersal of reproductive GM plant materials through various means including animals and extreme weather conditions is not identified as a risk that warrants further assessment.

2.3 Vertical transfer of genes or genetic elements to sexually compatible plants

113. Vertical gene flow is the transfer of genetic information from an individual organism to its progeny by conventional heredity mechanisms, both asexual and sexual. In flowering plants, pollen dispersal is the main mode of gene flow (Waines & Hegde 2003). For GM crops, vertical gene flow could therefore occur via successful cross-pollination between the crop and sexually compatible species including nearby canola plants, related weeds or native plants (Glover 2002).

114. It should be noted that vertical gene flow *per se* is not considered an adverse outcome, but may be a link in a chain of events that may lead to an adverse outcome. For an increased potential for adverse effects to arise as a result of gene flow of the introduced genetic elements from the GM canola to sexually compatible plants, both of the following steps must occur:

- transfer of the introduced genetic elements to sexually compatible plants
- increased potential for adverse effects, such as toxicity or spread and persistence of the recipient plants, due to expression of the introduced gene.

115. Baseline information on vertical gene transfer associated with non-GM canola plants can be found in *The Biology of Brassica napus L. (canola)* (OGTR 2008) and in the RARMP prepared for DIR 103. In summary, canola is predominantly self-pollinating with average inter-plant outcrossing rates of 30%. Most outcrossing between fields generally occurs within the first 10 m of the recipient field, and rates decline with distance.

Risk scenario 4. Expression of the introduced gene or regulatory sequences in other canola plants

116. Transfer and expression of the introduced gene for herbicide tolerance to other canola plants could increase the weediness potential, or alter the potential allergenicity and/or toxicity of the resulting plants.

117. All of the introduced regulatory sequences are expected to operate in the same manner as regulatory elements endogenous to the canola plants. While the transfer of either endogenous or introduced regulatory sequences could result in unpredictable effects, the impacts from the introduced regulatory elements are likely to be equivalent to, and no greater than, those from endogenous regulatory elements.

118. As discussed in Risk scenario 1, allergenicity to people and toxicity to people and other organisms are not expected to be changed in the GM canola plants by the introduced gene. This will be the same if the introduced gene is expressed in other GM or non-GM canola plants.

119. As discussed in Risk scenario 2, the gene introduced into the GM canola plants is not expected to alter the tolerance of plants to biotic or abiotic stresses that normally restrict geographic range and persistence of this species in natural habitats. Similarly, it would not be expected to alter the geographic range or persistence of other canola plants if the introduced trait was transferred to their progeny. However, the herbicide tolerance gene present in the GM canola line would confer a selective advantage in areas where the corresponding herbicide is applied. This would also be true if the traits were conferred to other canola plants in the environment.

120. Weeds are a major factor limiting commercial canola production in Australia (OGTR 2008) and the importance of effective weed control to growers is exemplified by the fact that most canola currently grown in Australia is herbicide tolerant (Norton & Roush 2007). Since the introduction of non-GM triazine tolerant canola varieties in 1993 their use has become widespread despite a significant yield loss associated with the mutation that confers herbicide tolerance. The first non-GM imidazolinone tolerant canola variety was released in 1995, and together triazine and imidazolinone tolerant varieties comprise approximately 75% of the Australian canola crop (Norton & Roush 2007).

121. GM Roundup Ready[®] canola, which is tolerant to glyphosate-based herbicides, was approved for unrestricted commercial release by the Regulator in 2003 (DIR 020/2002). However, it was not commercialised until 2008 (New South Wales and Victoria) and 2010 (Western Australia), due to restrictions imposed by State and Territory governments for marketing and trade reasons. GM InVigor[®] canola, tolerant to glufosinate-ammonium herbicides, was also approved for commercial release by the Regulator in 2003 (DIR 021/2002). This GM canola has not yet entered commercial production. Therefore, there are currently three herbicide tolerance traits present in commercial production systems that could inadvertently combine with each other, or with the GM canola proposed for release by Monsanto, to produce multiple-herbicide tolerant progeny.

122. Herbicide tolerant canola has been grown extensively in Canada since 1995. Over 95 % of the canola currently grown in Canada is herbicide tolerant, the main traits used being glyphosate and glufosinate-ammonium tolerance (Beckie & Owen 2007). Where canola varieties that are tolerant to different herbicides have been commercially planted in close proximity, the production of multiple-herbicide resistant volunteers has been noted (Hall et al. 2000; Beckie et al. 2003). However, such multiple-herbicide tolerant individuals are as susceptible to alternative herbicides as are single-herbicide tolerant canola plants or their conventional non-herbicide tolerant counterparts (Senior et al. 2002; Beckie et al. 2004; Dietz-Pfeilstetter & Zwerger 2009). In laboratory studies, multiple-herbicide tolerant canola plants were no more competitive than single-herbicide tolerant controls (Simard et al. 2005). Therefore, if multiple-herbicide tolerant canola plants were to occur, they are unlikely to be more invasive or persistent than non-herbicide tolerant canola plants and could be controlled by suitable herbicides or other agricultural practices.

123. In addition to transfer of the introduced gene to other commercial herbicide tolerant canola varieties, the possibility exists for transfer to other GM canola lines being trialled under limited and controlled conditions by other organisations. The Regulator has recently issued licences for the limited and controlled release of GM canola modified for enhanced yield and delayed senescence (DIR 103) and the limited and controlled release of GM canola and Indian mustard modified for herbicide tolerance with or without a hybrid breeding system (DIR 104). DIR 103 will take place in the LGAs of Horsham and the Southern Grampians between May 2010 and May 2012. DIR 104 will take place in 19 nominated LGAs in South Australia and Victoria between January 2011 and February 2014. Therefore, it is possible these field trials could occur simultaneously in the same LGAs as the proposed field trial. However, as these field trials are subject to limits and controls that effectively restrict gene flow, gene flow between the different trial sites is highly unlikely.

124. Canola is mainly self-pollinating, but outcrossing at levels of up to 55% between adjacent plants has been reported (Beckie et al. 2003). Canola pollen can be transferred by contact between plants, by wind or by insects. In general, wind borne pollen plays a minor role in long-distance pollination (McCartney & Lacey 1991). The vast majority of pollen travels less than 10 m and the amount of pollen decreases with distance from the source with a very steep decline over 50 m (Scheffler et al. 1993; Timmons et al. 1995). The dispersal range varies from a few metres to several hundred meters, but in extreme cases pollination over distances of up to 2 km has been attributed to wind (Timmons et al. 1995; Cai et al. 2008).

125. Insects, especially honeybees, play a more significant role in canola pollination over long distances (OECD 1997). Most bee movement occurs close to the hive and between neighbouring plants (Rieger et al. 1999), but foraging can occur regularly at distances of about 2 km from the hive (Ramsay et al. 1999) and, under specific conditions, foraging distances of up to 12 km have been reported (Beekman & Ratnieks 2000).

126. Canola pollen can remain viable for between 24 hours and one week (Mesquida & Renard 1982), with viability gradually decreasing over 4-5 days under natural conditions (Ranito-Lehtimäki 1995). Under very high temperatures, *Brassica* pollen can desiccate and lose viability within a few hours (Salisbury 2006).

127. Outcrossing rates vary according to variety, local topography, environmental conditions, abundance of insect pollinators and experimental design, including the size and arrangement of donor and recipient populations. In general, smaller source plot sizes result in lower outcrossing rates (Timmons et al. 1995). Overseas field scale studies using male sterile or emasculated bait plants have detected outcrossing at rates of 5% at 4 km from the source plot (Thompson et al. 1999). Studies using male sterile or emasculated plants only represent the potential for gene flow and would greatly overestimate normal outcrossing levels due to lack of pollen competition (Salisbury 2002c).

128. Outcrossing rates are much lower when fertile recipient plants are used. A summary of studies in fully fertile *B. napus* concluded that most outcrossing occurs within the first 10 m of the recipient field and rates decline with distance (Husken & Dietz-Pfeilstetter 2007; Cai et al. 2008). Very low levels (<0.01%) of outcrossing have been detected at distances of up to 2 km in small scale studies (Cai et al. 2008), and up to 3 km from the source in field scale experiments (Rieger et al. 2002). However, the majority of small scale studies using fertile recipient plants report outcrossing distances of less than 400 m (Salisbury 2002b; Beckie et al. 2003; Husken & Dietz-Pfeilstetter 2007).

129. In general, levels of outcrossing beyond 400 m are irregular and presumably associated with bee activity (Salisbury 2002b). An exception to this is a recent Chinese study, which correlated both short- and long-distance pollen dispersal with wind direction and not bee numbers (Cai et al. 2008). Cai et al (2008) observed that while outcrossing levels decreased sharply with increasing distance from the source plot over short distances, dispersal and pollination were more random beyond 33.5 m (Cai et al. 2008).

130. The only published Australian study did not show any consistent decline in canola pollen dispersal over distance (Rieger et al. 2002). Instead, variable rates of outcrossing were observed, with isolated pollination events detected between 0 and 3000 m. Outcrossing occurred in 63% of the fields sampled but only a few had outcrossing rates greater than 0.03%. A rate of <0.01% was detected at 3 km. One main difference between the Rieger et al. (2002) study and the overseas studies was that the former utilized large 25- to 100-hectare pollen source fields, whereas the latter used relatively small pollen sources (<1 ha).

131. Although the herbicide tolerance gene used to modify the GM canola line could be transferred to other canola plants, the applicant has proposed a number of limits and controls (Chapter 1, Sections 3.2 and 3.3) that will reduce the likelihood of pollen-mediated gene flow occurring. The trial will be of limited size and duration, with 2 sites proposed in the first year, 8 sites in the second and third years, and up to 20 sites in the fourth year. Each site will be a maximum of 10 ha and the trial will be conducted for four years. The applicant has also proposed a number of controls that will ensure spatial separation of the trial sites from other canola crops. In particular, an isolation zone of 400 m or 1 km will exist between the trial site and the nearest *Brassica* crop. Furthermore, pollen traps may be used to restrict pollen movement. The efficacies of the controls proposed by the applicant to minimise pollen-mediated gene flow are discussed in Chapter 3, Section 3.1.1.

132. **Conclusion:** The potential for allergenicity in people, toxicity in people and other organisms or increased weediness due to the expression of the introduced gene and regulatory sequences in other canola plants as a result of gene transfer is not identified as a risk that warrants further assessment.

Risk scenario 5. Expression of the introduced gene in other sexually compatible plants

133. Transfer and expression of the introduced gene for herbicide tolerance in other sexually compatible plants could increase the weediness potential, or alter the potential allergenicity and/or toxicity of the resulting plants. As discussed in Risk scenario 1, the introduced gene does not encode a protein that is considered toxic or allergenic. Therefore, even if the introduced gene was transferred to, and expressed in, sexually compatible species, the recipient species would likely be

no more toxic or allergenic than their unmodified precursors. As discussed in Risk scenario 2, the introduced gene is also unlikely to confer a selective advantage in natural environments. However, if the gene that confers herbicide tolerance was transferred to a sexually compatible species, it may confer a selective advantage in agricultural environments where the corresponding herbicide is applied.

134. The factors that limit the spread and persistence of hybrids between non-GM canola and other sexually compatible plants would be expected to limit the spread and persistence of any hybrids between the GM canola and other sexually compatible species.

135. As discussed in Chapter 1, Section 6.4, canola can cross with other *B. napus* groups or subspecies (including vegetable forms), *B. oleracea*, *B. juncea* and *B. rapa* under natural conditions. Naturally occurring hybrids between *B. napus* and *R. raphanistrum*, *H. incana* and *S. arvensis* have also been reported at very low frequencies (Salisbury 2002b). All of these species are naturalized in Australia and weedy forms are known to be present (Groves et al. 2003). *B. juncea*, *H. incana*, *R. raphanistrum* and *S. arvensis* are problematic weeds in commercial canola growing regions of Australia, which include some LGAs in which field trials are proposed. Therefore, it is likely that some or all of these sexually compatible species may be found growing at or near proposed field trial sites. Hybridisation would require synchronicity of flowering between the GM canola plants and sexually compatible species to enable cross-pollination and gene flow to occur.

136. Of the sexually compatible *Brassica* species, hybridisation occurs most readily between canola and *B. rapa*. Hybrids are often observed when the two species are grown in close proximity (Simard et al. 2006) and the transfer of traits from commercially grown canola to wild populations of *B. rapa* has been observed in Canada (Warwick et al. 2003). In a recent study, Warwick et al. (2008) showed that a herbicide tolerance trait from a commercial canola crop was transferred to, and stably maintained in, a wild *B. rapa* population for at least six years. The trait persisted despite the fact that the corresponding herbicide had not been applied during this period and, hence, no selective pressure had been applied. Currently this is the only report of a trait from canola being apparently introgressed into a sexually compatible species under natural conditions.

137. The research of Warwick et al. (2008) illustrates that, if plants are growing in close proximity with synchronous or overlapping flowering periods, gene flow to sexually compatible species can occur. However, with the exception of the relatively productive interspecific hybridisation that occurs between *Brassica* species that contain the A genome (*B. napus*, *B. juncea* and *B. rapa*), most other interspecific hybridisation events occur at very low frequency and yield hybrid plants that have greatly reduced fertility (see Chapter 1, Section 6.4) due to the considerable genetic barriers that exist, restricting the transfer of genes to other *Brassicaceous* species (Salisbury 2002a; Salisbury 2006).

138. In addition to the natural genetic barriers that constrain gene flow between species, the applicant has proposed a number of limits and controls (Chapter 1, Sections 3.2 and 3.3) that would further restrict the potential for pollen flow and gene transfer to sexually compatible plants. In particular, the applicant proposes to surround each trial site with a 50 m wide monitoring zone within which sexually compatible species would be removed before flowering and an isolation zone of at least 400 m within which no *Brassica* crops will be grown. At some trial sites, pollen-mediated gene flow will also be managed by the use of a pollen trap of non-GM canola or commercially released Roundup Ready® or InVigor® canola, which will further reduce the likelihood of hybridisation occurring between the GM canola line and compatible species. The efficacy of the proposed controls in restricting gene flow to sexually compatible species is further discussed in Chapter 3, Section 3.1.1.

139. **Conclusion:** The potential for allergenicity in people, toxicity in people and other organisms or increased weediness due to the expression of the introduced gene in other sexually compatible plant species as a result of gene transfer is not identified as a risk that warrants further assessment.

2.4 Horizontal transfer of genes or genetic elements to sexually incompatible organisms

140. Horizontal gene transfer (HGT) is the stable transfer of genetic material from one organism to another without reproduction (Keese 2008). Data is accumulating to show that HGT occurs more frequently than previously believed and can occur between plants, as well as between plants and less complex organisms (Bock 2010). All genes within an organism, including those introduced by gene technology, are capable of being transferred to another organism by HGT. HGT itself is not considered an adverse effect, but could be part of a scenario potentially leading to harm. A gene transferred through HGT could confer a novel trait to the recipient organism, through expression of the gene itself or by altering the expression of endogenous genes. The novel trait may result in negative, neutral or positive effects.

141. Risks that might arise from horizontal gene transfer have been considered in previous RARMPs (for example see DIR 057/2004 and DIR 085/2008), which are available from the OGTR website <<http://www.ogtr.gov.au>> or by contacting the Office. From the current scientific evidence, HGT from GM plants to other organisms presents negligible risks to human health and safety or the environment due to the rarity of such events, relative to other HGT events that occur in nature, and the limited chance of providing a selective advantage to the recipient organism.

142. Baseline information on the presence of the introduced or similar genetic elements is provided in Chapter 1, Section 6.5. All of the introduced genetic elements are derived from naturally occurring organisms that are already present in the wider Australian environment.

Risk scenario 6. Presence of the introduced genetic material in other organisms as a result of horizontal gene transfer

143. Possible risks arising from HGT of the introduced genetic material to other organisms involves consideration of potential recipient organisms and the nature of the introduced genetic material. Risks that might arise through HGT from a GMO to another organism have been recently reviewed (Keese 2008) and considered in detail in a previous RARMP (DIR 085/2008) which is available from the OGTR website <<http://www.ogtr.gov.au>> or by contacting the Office.

144. HGT could result in the presence of the introduced gene for herbicide tolerance in bacteria, plants, animals or other eucaryotes. However, the introduced gene was isolated from a bacterium that is already widespread in the environment (See Chapter 1, Section 6.5), and is thus already available for transfer from that source via demonstrated natural mechanisms.

145. A key consideration in the risk assessment process should be the safety of the protein product resulting from the expression of the introduced gene rather than horizontal gene transfer *per se* (Thomson 2000). If the introduced gene, the encoded protein or its end products are not associated with any risk then even in the unlikely event of HGT occurring, it should not pose any risk to humans, animals or the environment. Conclusions reached for Risk scenarios 1 - 5 associated with the expression of the introduced gene did not represent an identified risk. Therefore, any rare occurrence of HGT of introduced genetic material to other organisms is expected to be unlikely to persist and/or result in an adverse effect.

146. Baseline information on the presence of the introduced or similar genetic elements is provided in Chapter 1, Section 6.5. The introduced genetic elements are derived from organisms that are already present in the wider Australian environment.

147. **Conclusion:** The potential for an adverse outcome as a result of horizontal gene transfer is not identified as a risk that warrants further assessment.

2.5 Unintended changes in biochemistry, physiology or ecology

148. All methods of plant breeding can induce unanticipated changes in plants, including through pleiotropy⁹ (Haslberger 2003). Gene technology has the potential to cause unintended effects due to the process used to insert new genetic material or by producing a gene product that affects multiple traits. Such pleiotropic effects may include:

- altered expression of an unrelated gene at the site of insertion
- altered expression of an unrelated gene distant to the site of insertion, for example, due to the protein encoded by the introduced gene changing chromatin structure, affecting methylation patterns or modulating/influencing signal transduction and transcription
- increased metabolic burden associated with high level expression of the introduced gene
- novel traits arising from interactions of the protein encoded by the introduced gene product with endogenous non-target molecules
- secondary effects arising from altered substrate or product levels in the biochemical pathway incorporating the protein encoded by the introduced gene.

149. Such unintended pleiotropic effects might result in adverse outcomes such as toxicity or allergenicity; weediness, altered pest or disease burden; or reduced nutritional value as compared to the parent organism. However, accumulated experience with genetic modification of plants indicates that, as for conventional (non-GM) breeding programs, the process has little potential for unexpected outcomes that are not detected and eliminated during the early stage of selecting plants with new properties (Bradford et al. 2005).

Risk scenario 7. Changes to biochemistry, physiology or ecology of the GM canola plants resulting from expression, or random insertion, of the introduced genetic material

150. The applicant states that no secondary effects have been observed in the GM canola line in the limited testing, including early field testing, that has been done in the US and Canada. Considerations relevant to altered biochemistry, physiology and ecology, in relation to expression of the introduced gene, have already been discussed in Risk scenarios 1 to 3, and were not considered identified risks.

151. The protein encoded by the introduced gene has a highly specific, well characterised biochemical function (see Chapter 1, Section 5.2.1) and is unlikely to cause pleiotropic effects in the GM plants. The commercially approved Roundup Ready[®] canola shows no unintended effects on the observable phenotype.

152. The outcome of random insertion of an introduced gene is impossible to predict. Such outcomes may include, for example, alteration to reproductive capacity, altered capacity to deal with environmental stress, production of novel substances, and changes to levels of endogenous substances. Additionally, unintended changes that occur as a result of gene insertions are rarely advantageous to the plant (Kurland et al. 2003). During this limited and controlled release, the applicant proposes to measure the agronomic performance of the GM canola line, and any substantial unintended effects are likely to be detected during the trial.

153. Non-GM canola plants naturally produce proteins that have allergenic properties and reactions in humans can occur after exposure to non-GM canola pollen (Chardin et al. 2001), dust (Suh et al. 1998) and flour (Monsalve et al. 1997; Alvarez et al. 2001). A number of proteins have been

⁹ Pleiotropy is the effect of one particular gene on other genes to produce apparently unrelated, multiple phenotypic traits (Kahl 2001).

identified that contribute to this allergenicity, including BRA N 1 and BRA N 2 (Toriyama et al. 1995; Monsalve et al. 1997; Puumalainen et al. 2005). Both proteins belong to the 2S albumin family of seed storage proteins, members of which are found in many plant species and are often allergenic (Radauer & Breiteneder 2007). The allergenicity of the GM line proposed for release has not been determined. However, the novel protein produced in the GM canola line is not expected to affect the production of 2S albumin proteins and is identical, or similar, to that produced in other GM canola lines that have been grown previously in Australia and overseas (see Chapter 1, Section 7) without reports of enhanced allergenicity.

154. The likelihood of any pleiotropic effects causing adverse effects is minimised by the proposed limits and controls outlined in Chapter 1, Sections 3.2 and 3.3. In particular, the scale and duration of the trial would limit the potential for adverse effects. Only authorised people will have access to the trial sites, which limits exposure of the public to the GM plant material. Humans and livestock would not be intentionally exposed as the GM plant material will not be used as food or animal feed.

155. **Conclusion:** The potential for an adverse outcome as a result of altered biochemistry, physiology or ecology is not identified as a risk that warrants further assessment.

2.6 Unauthorised activities

Risk scenario 8. Use of the GMO outside the proposed licence conditions (non-compliance)

156. If a licence were to be issued, non-compliance with the proposed conditions of the licence could lead to spread and persistence of the GM canola plants outside of the proposed release areas and/or increased exposure of people and other organisms to GM material. The adverse outcomes that this risk scenario could cause are the same as those discussed in the sections above. The Act provides for substantial penalties for non-compliance and unauthorised dealings with GMOs. The Act also requires that the Regulator has regard for the suitability of the applicant to hold a licence prior to the issuing of a licence. These legislative provisions are considered sufficient to minimise risks from unauthorised activities.

157. **Conclusion:** The potential for an adverse outcome as a result of unauthorised activities is not identified as a risk that warrants further assessment.

Section 3 Risk estimate process and assessment of significant risk

158. The risk assessment begins with postulation of potential pathways that might lead to harm to the health and safety of people or the environment during the proposed release of GMOs due to gene technology, and how it could happen, in comparison to the parent organism and within the context of the receiving environment.

159. Eight risk scenarios were identified whereby the proposed dealings might give rise to harm to people or the environment. This included consideration of whether expression of the introduced gene could result in products that are toxic or allergenic to people or other organisms; alter characteristics that may impact on the spread and persistence of the GM plants; or produce unintended changes in their biochemistry or physiology. The opportunity for gene flow to other organisms and its effects if it occurred were also assessed.

160. A **risk** is only identified when a risk scenario is considered to have some chance of causing harm. Risk scenarios that do not lead to an adverse outcome, or could not reasonably occur, do not represent an identified risk and do not advance any further in the risk assessment process.

161. The characterisation of the eight risk scenarios in relation to both the seriousness and likelihood of harm, in the context of the control measures proposed by the applicant, did not give rise to any identified risks that required further assessment. The principal reasons for this include:

- limits on the size, locations and duration of the release proposed by Monsanto

- the controls proposed by Monsanto to restrict the spread and persistence of the GM canola plants and their genetic material
- limited ability and opportunity for the GM canola plants to transfer the introduced gene to commercial canola crops or other sexually compatible species
- none of the GM plant materials or products will be used in human food or animal feed
- widespread presence of the protein encoded by the introduced gene, and similar proteins, in the environment and lack of known toxicity or evidence of harm from them.

162. Therefore, any risks of harm to the health and safety of people, or the environment, from the proposed release of the GM canola plants into the environment are considered to be **negligible**. Hence, the Regulator considers that the dealings involved in this proposed release **do not pose a significant risk** to either people or the environment.

Section 4 Uncertainty

163. Uncertainty is an intrinsic property of risk and is present in all aspects of risk analysis, including risk assessment, risk management and risk communication. Both dimensions of risk (consequence and likelihood) are always uncertain to some degree.

164. Uncertainty in risk assessments can arise from incomplete knowledge or inherent biological variability¹⁰. For field trials, because they involve the conduct of research, some knowledge gaps are inevitable. This is one reason they are required to be conducted under specific limits and controls to restrict the spread and persistence of the GMOs and their genetic material in the environment, rather than necessarily to treat an identified risk.

165. For DIR 105, which involves the first Australian field trial of the GM canola line, uncertainty is noted particularly in relation to the characterisation of:

- Risk scenario 7, associated with the potential for any unintended effects as a result of changes in biochemistry, physiology or ecology of the GM canola plants.

166. Additional data, including information to address this uncertainty, would be required to assess possible future applications for a larger scale trial, reduced containment conditions or the commercial release of this GM canola line.

167. Chapter 3, Section 4 discusses information that may be required for future releases.

¹⁰ A more detailed discussion is contained in the Regulator's *Risk Analysis Framework* (OGTR 2009) available at <<http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/riskassessments-1>> or via Free call 1800 181 030.

Chapter 3 Risk management plan

Section 1 Background

168. Risk management is used to protect the health and safety of people and to protect the environment by controlling or mitigating risk. The risk management plan evaluates and treats identified risks, evaluates controls and limits proposed by the applicant, and considers general risk management measures. The risk management plan informs the Regulator's decision-making process and is given effect through imposed licence conditions.

169. Under section 56 of the Act, the Regulator must not issue a licence unless satisfied that any risks posed by the dealings proposed to be authorised by the licence are able to be managed in a way that protects the health and safety of people and the environment.

170. All licences are subject to three conditions prescribed in the Act. Section 63 of the Act requires that each licence holder inform relevant people of their obligations under the licence. The other statutory conditions contemplate the Regulator maintaining oversight of licensed dealings: section 64 requires the licence holder to provide access to premises to OGTR inspectors; and section 65 requires the licence holder to report any information about risks or unintended effects of the dealing to the Regulator on becoming aware of them. Matters related to the ongoing suitability of the licence holder are also required to be reported to the Regulator.

171. The licence is also subject to any conditions imposed by the Regulator. Examples of the matters to which conditions imposed by the Regulator may relate are listed in section 62 of the Act. Licence conditions can be imposed to limit and control the scope of the dealings. In addition, the Regulator has extensive powers to monitor compliance with licence conditions under section 152 of the Act.

Section 2 Risk treatment measures for identified risks

172. The risk assessment of risk scenarios listed in Chapter 2 concluded that there are **negligible** risks to people and the environment from the proposed trial of GM canola. The *Risk Analysis Framework* (OGTR 2009), which guides the risk assessment and risk management process, defines negligible risks as insubstantial with no present need to invoke actions for their mitigation.

173. These risk scenarios were considered in the context of the scale of the proposed release (a maximum cumulative area of 368 ha planted at up to 38 sites over four years in New South Wales, Victoria and Western Australia), the proposed containment measures (Chapter 1, Section 3), and the receiving environment (Chapter 1, Section 6).

Section 3 General risk management

174. Licence conditions have been imposed to restrict the spread and persistence of the GMO and its genetic material in the environment and limit the release to the size, locations and duration requested by the applicant. Both of these considerations were important in establishing the context for the risk assessment and in reaching the conclusion that the risks posed to people and environment are negligible. The conditions are detailed in the licence and summarised in Section 3.1.2 of this Chapter.

3.1 Licence conditions

3.1.1 Consideration of limits and controls proposed by Monsanto

175. Sections 3.2 and 3.3 of Chapter 1 provide details of the limits and controls proposed by Monsanto in their application, and these are discussed in the eight risk scenarios characterised for the proposed release in Chapter 2. The appropriateness of these controls is considered further below.

176. The duration of the proposed release will be limited to four years. A total of 2 sites will be planted in the first year, 8 sites in the second and third years and up to 20 sites in the fourth year. Each site will be a maximum of 10 hectares (four hectares in the first year), and may take place in 46 possible LGAs in New South Wales, 28 possible LGAs in Victoria and 53 possible LGAs in Western Australia. The applicant will provide the Regulator with site locations prior to planting. The applicant does not intend to use any of the GM plant material as human food or animal feed. Only authorised persons would be allowed access to the trial sites. These measures will limit the potential exposure of humans, vertebrates and other organisms to the GMO (Risk scenario 1) and the potential for the GM canola line to disperse and establish outside the proposed release site (Risk scenario 3).

177. The applicant has stated that natural waterways, dams, main supply channels and creeks will not be within 50 m of proposed trial sites, which reduces the likelihood of plant material being washed away from the site (Risk scenario 3). It is a standard DIR licence condition that a trial site be located at least 50 metres from a waterway to restrict the dispersal of viable GM plant material in the event of flooding.

178. As discussed in Chapter 1, Section 6.4 and Risk scenario 5, under natural conditions canola can cross with cultivated *Brassica* species (*B. napus*, *B. juncea*, *B. rapa* and *B. oleracea*) and, at very low frequencies, with three weed species important in Australia (*R. raphanistrum*, *H. incana* and *S. arvensis*) (Salisbury 2002b).

179. The applicant has proposed a number of measures to control pollen-mediated gene flow from the GM canola (Risk scenarios 4 and 5), including the use of monitoring zones, isolation zones and pollen traps. The proposed trial sites will be surrounded by a 50 m monitoring zone, and will be located at least 400 m from the nearest *Brassica* crop if a pollen trap is used, or 1 km from the nearest *Brassica* crop if there is no pollen trap. The applicant proposes to inspect for and destroy any compatible species occurring among the GM canola, in the pollen trap and in the monitoring zone prior to flowering.

180. Levels of outcrossing in canola decrease with increasing distance from the pollen source, with most outcrossing occurring within the first 10 m of the recipient field (Scheffler et al. 1993; Timmons et al. 1995). Very low levels of outcrossing have been detected at distances of up to 3 km from the pollen source but the majority of experimental studies report outcrossing at distances of less than 400 m (see Risk scenario 4).

181. Isolation distances required internationally for GM canola trials range from 50 – 400 m (Salisbury 2002b). For example, Canadian regulations require: a 200 m isolation zone from *Brassica* species; or 10 m wide borders of synchronously flowering, non-GM *B. napus*; or growth of the GM canola plants in cages or bags. In addition, the GM canola plants must be isolated from weedy relatives by at least 50 m¹¹. An isolation distance of 400 m is required for GM trials in France, Belgium and Sweden (Salisbury 2002b).

182. In Australia, requirements for basic and certified seed production for canola are aligned with Organisation for Economic Cooperation and Development (OECD) rules (Australian Seeds Authority Ltd. 2006). The production of basic seed requires an isolation of 200 m from other varieties or any other *Brassica* or cruciferous crop or weed species. The production of certified seed requires an isolation distance of only 100 m. OECD rules stipulate maximum acceptable levels of off-types or other cultivars of the same species of 0.1% for basic canola seed and 0.3% for certified canola seed (OECD 2008).

¹¹ Source: <http://www.inspection.gc.ca/english/plaveg/bio/dt/term/2009/branape.shtml>, accessed 7 April 2010

183. The applicant proposes to surround the GM canola at some sites with a 15 m wide pollen trap planted with non-GM canola (including herbicide tolerant triazine and imidazolinone varieties) or commercially released GM canola, such as Roundup Ready[®] and InVigor[®] canola. Pollen traps are an effective means of reducing pollen-mediated gene flow (Staniland et al. 2000) and are more effective at reducing gene flow than leaving the area barren (Morris et al. 1994; Reboud 2003). Pollen traps function by absorbing the majority of pollen dispersed by the wind or insect vectors. A Canadian study examining the effectiveness of pollen traps of up to 30 m in width found that 95% of the outcross events occurred within the first 15 m of the pollen trap (Staniland et al. 2000). In the case of pollinating insects, the presence of pollen trap plants flowering synchronously with the GM canola may provide sufficient forage for incoming pollinating insects without them needing to visit the GM plants within. Alternatively, pollen trap plants may absorb the pollen deposited by visiting insects as they exit the trial site (Williams 2001). Therefore, the use of a 15 m pollen trap is expected to minimise gene transfer to sexually compatible plants and is included as an option in the licence conditions in conjunction with other gene flow control measures.

184. The applicant proposes to surround each trial sites with a 50 m monitoring zone in which sexually compatible species will be destroyed prior to flowering. As experimental evidence suggests that the rate of out-crossing is greatly reduced beyond 50 m from the pollen source, and as most *Brassicaceous* weeds hybridise inefficiently with canola (Chapter 1, Section 6.4), this measure will minimise the likelihood of pollen-mediated gene flow to other *Brassicaceous* species (Risk scenario 5) and is imposed as a licence condition.

185. The applicant has also proposed to maintain an isolation zone between the GM canola line and any other *Brassica* crop. The isolation zone will be 400 m from the outer edge of the pollen trap or 1 km from the edge of the area planted to the GMO if no pollen trap is used. On the basis of the scientific literature on gene flow, international containment measures for GM canola trials, and the rules for producing basic and certified seed, these distances are considered adequate to minimise gene flow from the GM canola to any *Brassica* crops being grown for breeding, commercial or research purposes. Therefore, preventing the planting of *Brassica* crops within 400 m of the GM canola line if a pollen trap is present, or within 1 km if no pollen trap is used, is imposed as a licence condition.

186. Hybridisation between the GM canola and other sexually compatible species would be possible if they were in close proximity and there was synchrony of flowering. Hybrids between *B. napus* and *B. rapa* or *B. juncea* generally have reduced fertility and low seed set, with gene introgression occurring only at low frequencies (Salisbury 2002b). Hybrids between *B. napus* and *B. oleracea* are difficult to obtain (Ford et al. 2006). Similarly, hybrids between *B. napus* and *R. raphanistrum*, *H. incana* or *S. arvensis* are rare and are generally sterile or predominantly sterile (Salisbury 2002b). The pollen traps and/or isolation zones in combination with monitoring zones will effectively restrict gene flow to sexually compatible species.

187. In determining post-harvest monitoring requirements, one important consideration is the potential dispersal of seed during sowing and harvesting (mechanical dispersal). This is most likely to result in dispersal of seed into the area immediately around the trial, including the monitoring zone.

188. Canola can produce large numbers of small seeds (average seed weight of 5 mg) which can result in significant losses during sowing, harvest and transportation as well as losses from plants in the field due to pod shattering. Average losses of 3000 viable seeds/m² have been reported in Canada (Gulden et al. 2003), and losses of up to 10,000 seeds/m² have been measured in the United Kingdom (Lutman 1993). This can result in high densities of these plants occurring as weeds ('volunteers') in subsequent crops (Legere et al. 2001). However, seed losses vary greatly from year to year and also with harvest method (Harker et al. 2006). Seed losses in spring sown canola have been measured at less than half that of winter sown canola (Price et al. 1996).

189. The survival of canola seed in the seedbank is very low compared with wild relatives (Chadoeuf et al. 1998). Canola has no primary dormancy and most volunteers germinate within 1 – 2 years following harvest (Salisbury 2002b; Harker et al. 2006; Mewett et al. 2008). However, induced secondary dormancy can result in some canola seeds surviving in the soil for several years, with European studies reporting dormancy of up to 11 years (Gruber et al. 2008). Induction of secondary dormancy depends on genotype, environmental conditions during seed maturation and post harvest conditions (Gruber et al. 2005). Post harvest conditions that can induce secondary dormancy in canola seeds include long exposure to darkness and low water availability (Gulden et al. 2004; Gruber et al. 2008).

190. Studies in Canada and Europe have shown that incorporation of seeds into the soil immediately after harvest (usually via tillage) exposes seeds to dormancy inducing conditions (i.e. dry soil and darkness) and usually results in a large soil seed bank (Gruber et al. 2005; Harker et al. 2006; Gruber et al. 2008; Gruber et al. 2010). Therefore, delaying tillage for 2 – 4 weeks can result in smaller seedbanks and reduced secondary dormancy and persistence (Harker et al. 2006; Gruber et al. 2008). Models have confirmed these field observations and suggest delaying tillage as long as possible or at least until it has rained enough to moisten the top soil layers and allow seeds to imbibe sufficient water for germination (Colbach et al. 2008). In the case of winter grown canola in Australia, leaving residual seed on the surface for a period of time could also expose it to very high soil surface temperatures that can contribute to seed death (Gulden et al. 2004).

191. As well as timing of tillage, the method and depth of cultivation can also affect seed persistence and volunteer emergence (Gruber et al. 2008). In general, seeds are more likely to persist at deep rather than shallow depths (Andersson & Vicente 2010). Greenhouse experiments have shown that the majority of canola seeds emerge from depths of 1 – 5 cm. Germination and emergence were reduced at 0 and 7 cm and completely inhibited at 12 cm (Gruber et al. 2010). In field studies in Europe, shallow non-inversion tillage, where the seeds remain in the upper 10 cm of the soil, results in increased emergence of volunteers within the first year following harvest. In contrast, ploughing to a depth of 10 – 20 cm preserves seeds in deep soil layers (Gruber et al. 2005; Gruber et al. 2008). Shallow tillage under suitable conditions would also serve to enable degradation of the plant material remaining at the sites after harvest.

192. Very few studies of canola seed persistence have been conducted under Australian conditions. In one study of farmer-managed fields in South Australia, soil samples were collected from minimum- and no-tillage farms known to have had a canola crop in the past three years (Baker & Preston 2008). Samples were collected at 0.5, 1.5, 2.5 or 3.5 years after harvest and were used to estimate the number and viability of canola seed over time. The variety of canola that had been grown was not considered as a factor in this study. At 2.5 years post harvest, 50-140 seeds/m² were recovered from the surveyed fields, but an average of less than 2% germinated. By 3.5 years post harvest, none of the recovered seeds germinated. Overall, the data indicate that the number of seeds recovered and the proportion that germinated declined rapidly with time (Baker & Preston 2008).

193. Monitoring requirements have been completed for several GM canola trials in Australia, and the data collected provides further information about canola seed persistence in Australian conditions. Analysis of the monitoring reports indicates that the germination pattern of volunteers varies for winter grown canola compared to summer grown canola. For winter sown GM canola, the vast majority of volunteers germinate in the first year, with relatively few volunteers in the second year, and none in year three for the majority of trials (Salisbury 2002b). For summer grown GM canola, the germination pattern of volunteers is more variable and delayed germination is more common. In approximately half of the summer grown trials, most volunteers germinated in the first year. In the other half of trials, the majority of germination occurred in years 2 and/or 3, and for some trials germination of volunteers was also reported in year four. One trial site was volunteer-free for a period nine months before further volunteers emerged in the third year after harvest.

194. The applicant has proposed a number of measures to minimise the persistence of any GM canola plants and seeds in the seed bank at the proposed release site after harvest of the proposed trial (Risk scenario 2). These measures include treating harvested areas to encourage germination of any residual seed with two light tillage events post-harvest. Each tillage event will be separated by at least 28 days. Plant material remaining at the site will be incorporated into the soil by cultivation. The applicant has also proposed to monitor the proposed release sites for 24 months after harvest on a monthly basis and to destroy any volunteers by hand removal or herbicide application. If no volunteers are found within 6 consecutive inspections, the applicant proposes to reduce inspections to once every 3 months for the remainder of the inspection period. In addition to this, the applicant proposes to conduct post harvest monitoring of the release sites until no volunteers are detected for at least 12 continuous months.

195. The combination of these measures would effectively reduce survival and persistence of viable canola seeds in the soil. However, as germination patterns of volunteers can be variable, it is considered that inspections should occur every month. Therefore, the licence conditions require: post harvest monitoring every month for at least 24 months, and until no volunteers are observed in the most recent 12 month period; and at least two light tillage events, the first occurring no more than 60 days after harvest and another occurring in the 12 month volunteer-free period prior to an application to sign-off a site. Tillage must not bury plant material to a depth of more than 5 cm and must occur in conditions where germination of the GMO is reasonably likely to ensue (eg after irrigation or rainfall). These treatments will promote germination by ensuring any remaining seeds are placed at an appropriate depth in conditions that promote germination and will also encourage the microbial decomposition of any residual seed. These measures will minimise the persistence of the GMO in the environment (Risk scenario 2).

196. The applicant proposes to grow other crops at the sites following harvest and cleaning. The OGTR's Policy on Post Harvest Crops (available at <http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/policies-1>) lists a number of crop species that have been assessed in relation to their effect on the detection and control volunteer GM Brassica plants and that are permitted on GM Brassica field sites in the post harvest monitoring period. The post harvest crops proposed by the applicant will include those listed in the Policy on Post Harvest Crops, such as cereals (wheat, barley or oats) and grass pasture species.

197. Further to these considerations, there is also a possibility of seed dispersal via movement of plant material under strong winds, since the applicant proposes to employ windrowing when mechanically harvesting GM canola. Depending on seasonal conditions and grain moisture content, windrowed crops are ready to harvest 8 to 19 days after windrowing (DPI Vic 2009; GRDC 2010). As discussed in Chapter 2, there is potential for dispersal of material from windrows, raising the possibility that GM canola may spread outside the trial area in an unusually strong wind event. Standard canola licence conditions require the applicant to clean any area of land into which plant material is dispersed during harvesting or threshing. Therefore, any area into which GM plant material had moved by wind dispersal would also be subject to these cleaning requirements.

198. In addition, licence conditions have been imposed that require the licence holder to notify the Regulator in writing of the intended method of harvesting for each trial site (eg hand harvesting, direct heading or windrowing). The Regulator must also be informed of extreme weather events such as strong winds or flooding, and of any movement of harvested plant material off the site. This will facilitate monitoring of the release by the Regulator and help to ensure that if any dispersal occurs it is appropriately managed.

199. If any plant material including seed was to move outside the trial area, it is unlikely to establish and persist, as discussed in risk scenario 2. The genotypes used for commercial canola cultivation are bred for maximum production in managed environments in which optimal water and nutrient availability is ensured. In natural environments where water and nutrient availability are

limited, canola is considered a poor competitor compared with native species (Oram et al. 2005; Hall et al. 2005; Anon. 2007).

3.1.2 Summary of measures imposed by the Regulator to be implemented to limit and control the release

200. A number of licence conditions have been imposed to limit and control the release, based on the above considerations. These include requirements to:

- limit the release to a maximum cumulative area of 368 ha planted between the date of issue of the licence and December 2014 at up to 38 sites to be selected in nominated local government areas in New South Wales, Victoria and Western Australia
- limit each trial site to a maximum of 4 ha in the first year and 10 ha in later years
- locate the trial sites at least 50 m away from waterways
- establish a 50 m zone around each trial site in which sexually compatible species are prevented from flowering
- maintain an isolation zone of at least 400 m, or at least 1 km if no pollen trap is used, around each trial site within which no sexually compatible species may be intentionally grown
- harvest the GM canola plant material separately from other crops
- clean all equipment used in connection with the GMO before it is used for any other purpose
- destroy all GM plant material remaining at or around trial sites after harvest
- apply measures to promote germination of any canola seeds that may remain in the soil, including at least two shallow tillage events
- monitor the site for at least 24 months after harvest until no volunteers are detected for a continuous 12 month period and destroy any canola plants that may grow
- destroy all plant material that is not required for experimentation or future planting
- transport and store all GMOs and GM material in accordance with the Regulator's guidelines
- not allow the GM plant material or products to be used for human food or animal feed.

3.2 Other risk management considerations

201. All DIR licences issued by the Regulator contain a number of conditions that relate to general risk management. These include conditions relating to:

- applicant suitability
- contingency plans
- identification of the persons or classes of persons covered by the licence
- reporting structures
- a requirement that the applicant allows access to the trial sites for the purpose of monitoring or auditing.

3.2.1 Applicant suitability

202. In making a decision whether or not to issue a licence, the Regulator must have regard to the suitability of the applicant to hold a licence. Under section 58 of the Act, matters that the Regulator must take into account include:

- any relevant convictions of the applicant (both individuals and the body corporate)
- any revocation or suspension of a relevant licence or permit held by the applicant under a law of the Commonwealth, a State or a foreign country
- the applicant's history of compliance with previous approved dealings
- the capacity of the applicant to meet the conditions of the licence.

203. On the basis of information submitted by the applicant and records held by the OGTR, the Regulator considers Monsanto suitable to hold a licence.

204. The licence includes a requirement for the licence holder to inform the Regulator of any circumstances that would affect their suitability or their capacity to meet the conditions of the licence.

205. Monsanto must continue to have access to a properly constituted Institutional Biosafety Committee and be an accredited organisation under the Act.

3.2.2 Contingency plan

206. Monsanto is required to submit a contingency plan to the Regulator within 30 days of the issue date of the licence. This plan would detail measures to be undertaken in the event of any unintended presence of the GM canola line outside of the permitted areas.

207. Monsanto is also required to provide a method to the Regulator for the reliable detection of the presence of the GMO and the introduced genetic materials in a recipient organism. This instrument would be required within 30 days of the issue date of the licence.

3.2.3 Identification of the persons or classes of persons covered by the licence

208. The persons covered by the licence are the licence holder and employees, agents or contractors of the licence holder and other persons who are, or have been, engaged or otherwise authorised by the licence holder to undertake any activity in connection with the dealings authorised by the licence.

3.2.4 Reporting requirements

209. The licence obliges the licence holder to immediately report any of the following to the Regulator:

- any additional information regarding risks to the health and safety of people or the environment associated with the trial
- any contraventions of the licence by persons covered by the licence
- any unintended effects of the trial.

210. A number of written notices are also required under the licence that would assist the OGTR in designing and implementing a monitoring program for all licensed dealings. The notices include:

- location of trial sites
- expected and actual dates of planting
- expected and actual dates of commencement of flowering
- expected and actual dates of harvest and cleaning after harvest.

3.2.5 Monitoring for Compliance

211. The Act stipulates, as a condition of every licence, that a person who is authorised by the licence to deal with a GMO, and who is required to comply with a condition of the licence, must allow inspectors and other persons authorised by the Regulator to enter premises where a dealing is being undertaken for the purpose of monitoring or auditing the dealing. Post-release monitoring continues until the Regulator is satisfied that all the GMOs resulting from the authorised dealings have been removed from the release sites.

212. If monitoring activities identify changes in the risks associated with the authorised dealings, the Regulator may also vary licence conditions, or if necessary, suspend or cancel the licence.

213. In cases of non-compliance with licence conditions, the Regulator may instigate an investigation to determine the nature and extent of non-compliance. The Act provides for criminal sanctions of large fines and/or imprisonment for failing to abide by the legislation, conditions of the

licence or directions from the Regulator, especially where significant damage to health and safety of people or the environment could result.

Section 4 Issues to be addressed for future releases

214. Additional information has been identified that may be required to assess an application for a large scale or commercial release of this GM canola line, or to justify a reduction in containment conditions. This includes:

- additional biochemical characterisation of the GM canola line
- phenotypic characterisation of the GM canola line, particularly with respect to traits that may contribute to biotic or abiotic stress tolerance, weediness or persistence.

Section 5 Conclusions of the RARMP

215. The risk assessment concluded that this proposed limited and controlled release of a GM canola line on a maximum total cumulative of 368 ha planted at up to 38 sites over four years in New South Wales, Victoria and Western Australia poses **negligible** risks to the health and safety of people or the environment as a result of gene technology.

216. The risk management plan concluded that these **negligible** risks do not require specific risk treatment measures. However, licence have been imposed to limit the release to the size, locations and duration proposed by the applicant, and to require controls in line with those proposed by the applicant, as these were important considerations in establishing the context for assessing the risks.

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Appendix A Summary of issues raised in submissions received from prescribed experts, agencies and authorities¹² on the consultation RARMP for DIR 105

The Regulator received several submissions from prescribed experts, agencies and authorities on the consultation RARMP. All issues raised in submissions that related to risks to the health and safety of people and the environment were considered in the context of the currently available scientific evidence and were used in finalising the RARMP that formed the basis of the Regulator's decision to issue the licence. The submissions received that raised issues relating to risks to the health and safety of people and the environment are summarised below.

Summary of issues raised	Comments
<p>Council has declared the Shire a GM Free Cropping zone.</p> <p>The State Minister for Agriculture is aware of the Council's position.</p>	<p>The Act requires the Regulator to identify and manage risks to human health and safety and the environment posed by or as a result of gene technology. Some areas may be designated under State or Territory law for the purpose of preserving the identity of GM or non-GM crops (or both) for marketing purposes. However, marketing issues are outside the matters to which the Regulator may have regard when deciding whether or not to issue a licence.</p>
<p>LGA does not wish to make a comment.</p>	<p>Noted.</p>
<p>LGA adopted a policy which states that they do not support field trials within its district for genetically modified crops.</p>	<p>The Act requires the Regulator to identify and manage risks to human health and safety and the environment posed by or as a result of gene technology. Some areas may be designated under State or Territory law for the purpose of preserving the identity of GM or non-GM crops (or both) for marketing purposes. However, marketing issues are outside the matters to which the Regulator may have regard when deciding whether or not to issue a licence.</p>
<p>Has determined that any dealings under the issue of this licence do not fall under area of agency responsibility. Therefore does not have any further comment on the proposed licence.</p>	<p>Noted.</p>
<p>Do not support the growing of GM crops within the Shire.</p> <p>The Council has advised the State Minister for Agriculture of their position on this application.</p> <p>Shire has significant variation in topography, soil, water and other physical attributes.</p> <p>Therefore, actual proposed location of the trial crops would need to be disclosed to provide further meaningful response, particularly from people familiar with the area where the release could take place.</p>	<p>The Act requires the Regulator to identify and manage risks to human health and safety and the environment posed by or as a result of gene technology. Some areas may be designated under State or Territory law for the purpose of preserving the identity of GM or non-GM crops (or both) for marketing purposes. However, marketing issues are outside the matters to which the Regulator may have regard when deciding whether or not to issue a licence.</p> <p>Precise locations are not known prior to issue of a licence. Monsanto will select suitable sites prior to each growing season. Site details must be notified to the Regulator before planting and will be posted on the OGTR website: www.ogtr.gov.au</p>

¹² GTTAC, State and Territory Governments, Australian Government agencies, LGAs and the Minister for the Environment.

Summary of issues raised	Comments
<p>Adopts the precautionary principle.</p> <p>Opposes trials of GM canola being undertaken in the Shire due to uncertainties and potential impacts of GMOs on health, environment and agriculture in the Shire district.</p>	<p>The RARMP for this release considered the currently available scientific information, including any areas of uncertainty, and concluded that risks to human health and the environment are negligible. Licence conditions have been imposed to minimise exposure to the GMOs and their genetic material including prohibiting use in food and feed and to limiting the trial to the proposed size, locations and duration.</p>
<p>Supportive of application as the evidence supplied indicates that the proposed containment measures are adequate to minimise the risk of the GMOs spreading and permeating within the environment.</p>	<p>Noted.</p>
<p>Advises that Council does not wish to comment on application.</p>	<p>Noted.</p>
<p>Concerned about the potential for gene flow from GM canola. Canola can be considered a high risk crop for pollen mediated gene flow, both from crop to crop and from crop to wild relative.</p> <p>Recent paper by Schafer and Sagers identified established populations of canola plants in the wild containing GM traits, as well as evidence of two wild canola plants containing stacked genes.</p> <p>The OGTR have considered this issue through the use of isolation zones. However, there is a low but significant possibility of gene flow beyond this distance, especially if the trial sites are close to other commercial GM canola crops.</p> <p>Requests that the OGTR reconsider the adequacy of the containment strategies proposed in this RARMP.</p>	<p>Risks to people and the environment that might arise as a result of gene transfer were assessed in the RARMP and were considered negligible. In establishing measures to restrict gene flow for this limited and controlled release, containment measures used by overseas regulators and industry standards for seed production were also taken into consideration.</p> <p>Text has been added to Chapter 2 (Risk scenario 4) to clarify evidence relating to canola pollen movement. Extensive experimental data suggest that the majority of pollen travels less than 10 m and the amount of pollen decreases with distance from the source. The majority of experimental studies also report that outcrossing occurs at distances of less than 400 m. The containment measures that have been imposed in the licence conditions have been imposed in a number of other canola licences, including DIR 010/2001, DIR 011/2001, DIR 032/2002, DIR 069/2006, DIR 103 and DIR 104. No adverse effects have been reported from these releases.</p>
<p>Considers that the proposed licence conditions are appropriate given the nature of the modifications, the purpose of the release and the previous limited and controlled releases of GM canola containing genes for herbicide tolerance under OGTR licences.</p>	<p>Noted.</p>
<p>Council has no objection/comment on the RARMP.</p>	<p>Noted.</p>
<p>OGTR states that GM canola will not be used for human consumption. What will it be used for?</p>	<p>The purpose of the limited and controlled release is to conduct experiments to evaluate the agronomic performance of the GM canola line, including performance of the introduced herbicide tolerance trait, under field conditions.</p> <p>Licence conditions have been imposed to prohibit use for food or feed. GM material not required for experiments or future planting must be destroyed.</p>

Summary of issues raised	Comments
<p>What safeguards will be put in place to prevent the escape of the GM canola from the trial areas?</p> <p>How will the trial areas be protected from bees which have the capacity of spreading the GM canola?</p>	<p>The possibility of spread and persistence of the GM canola and its genetic material has been considered in Section 2.2 of the RARMP. Licence conditions have been imposed that include requirements to:</p> <ul style="list-style-type: none"> • surround trial sites with a 50 m monitoring zone that must be kept free of canola and sexually compatible species. • maintain an isolation zone of at least 400 m, or at least 1 km if no pollen trap is used, around each trial site within which no sexually compatible species may be intentionally grown. <p>These measures would restrict gene flow via wind or bees to sexually compatible species.</p> <p>Licence conditions also require post-harvest monitoring of the site every month for at least 24 months until no volunteers are detected for a continuous 12 month period, and the destruction of any canola plants that may grow.</p>
<p>Will the owners of non-GM canola be responsible for any contamination of their own canola crop from any escape of the GM canola?</p>	<p>Field trials are limited and controlled, and measures are imposed to effectively restrict gene flow. Issues related to segregation, marketing and liability for contamination are outside the scope of assessments required to be conducted by the Regulator.</p> <p>The Review of the Act, conducted in 2005/06, noted that common law and other consumer protection legislation provided remedies to those affected by the presence of GM varieties in non-GM crops.</p>
<p>When will the trial areas be confirmed and will Council be advised of the location of the trial areas?</p>	<p>Monsanto will select suitable sites prior to each growing season. Site details must be notified to the Regulator before planting and will be posted on the OGTR website: www.ogtr.gov.au when available.</p>
<p>The out-crossing nature of canola is likely to result in gene flow from GM to non-GM canola and vice versa. Cross pollination between commercial canola fields is known to occur to a considerable distance but at low frequencies (Reiger et al 2002; Beckie et al 2003). The trials are proposed in canola growing regions of Australia which may enhance the risks of cross contamination occurring.</p> <p>Thresholds for off types and impurities have always been necessary in seed and grain production and trade. The presence of trace levels of approved GM materials in non-GM materials can be maintained by conservative approaches to limit possible gene flow.</p> <p>Licence conditions to control pollen-mediated gene flow from the GM canola be amended to at least 3 kilometre isolation zone around each trial site within which no sexually compatible species may be intentionally grown.</p>	<p>Text has been added to Chapter 2 (Risk scenario 4) to clarify evidence relating to canola pollen movement. Extensive experimental data suggest that the majority of pollen travels less than 10 m and the amount of pollen decreases with distance from the source. The majority of experimental studies also report that outcrossing occurs at distances of less than 400 m. The containment measures that have been imposed in the licence conditions have been imposed in a number of other canola licences, including DIR 010/2001, DIR 011/2001, DIR 032/2002, DIR 069/2006, DIR 103 and DIR 104. No adverse effects have been reported from these releases.</p>

Summary of issues raised	Comments
<p>Alternative licence provisions for the use of a pollen trap and a reduced isolation zone are not considered optimal for control of pollen-mediated gene flow [Damgaard and Kjellsson (2005) Agriculture, Ecosystems and Environment 108: 291–301].</p>	<p>As outlined above, the majority of pollen travels less than 10 m and most experimental studies report outcrossing at distances of less than 400 m (Chapter 2, Risk scenario 4). The cited reference discusses management strategies for reducing pollination of non-GM crops by pollen from a neighbouring GM crop, including comparative effectiveness of isolation distance or non-harvested buffer zones surrounding recipient non-GM canola fields. The use of pollen traps surrounding the GM field is not discussed. Pollen traps are an effective means of reducing pollen-mediated gene flow and are more effective at reducing gene flow than leaving the area barren (Chapter 3). Therefore, the use of a 15 m pollen trap in conjunction with a 400 m isolation zone is expected to effectively restrict gene transfer to sexually compatible plants and is included as an option in the licence conditions.</p>
<p>Not uncommon for pods to shatter during the harvesting of canola crops, leading to seeds forming a soil seed bank in the field. Most volunteer plants will germinate and emerge within three years. However, studies have shown that a considerable percent of undisturbed seeds could survive for 10 years or more.</p> <p>The persistence of seeds provides an opportunity for temporal gene flow. Also, seeds from volunteer plants can easily become contaminants in other crops.</p> <p>Licence conditions for volunteer plants be amended to extend postharvest monitoring (and destruction of volunteer plants) to every month for at least three years after harvest until no volunteers are detected as recommended in the primary literature.</p>	<p>As discussed in Chapter 3, delayed post-harvest shallow tillage can result in smaller seedbanks and reduced secondary dormancy and persistence. Therefore, the licence holder must complete at least two shallow tillage events to promote germination of remaining seed in the soil. Tillage must occur in conditions where germination of the GMO is reasonably likely to ensue (eg after irrigation or rainfall).</p> <p>Analysis of the monitoring reports for several completed GM canola trials in Australia indicates that the majority of germination occurred in year 1 for winter grown GM canola and in years 2 and/or 3 for summer grown GM canola. Evidence from another Australian study suggests that the number of seeds recovered and the proportion that germinate declines rapidly with time. The longest volunteer-free period before further volunteer emergence was 9 months.</p> <p>The combination of two light tillage events and post-harvest monitoring every month for at least 24 months, until no volunteers are observed in the most recent 12 month period, is considered appropriate to manage persistence of viable canola seeds in the soil.</p>
<p>Application lacked the data to support the claim that Roundup Ready 2 canola is tolerant to higher rates of glyphosate and has a wider window for treatment with glyphosate than Roundup Ready canola.</p>	<p>DIR 105 is a limited and controlled release for the purpose of conducting experiments to evaluate the agronomic performance of the GM canola line under field conditions. The efficacy of glyphosate tolerance was not considered to be related to risks to people and the environment arising from gene technology, and therefore related data was not required.</p> <p>Issues relating to the efficacy of herbicides are outside the scope of the Regulator's assessments. The APVMA has regulatory responsibility for the supply, use and efficacy of agricultural chemicals, including herbicides, in Australia.</p>
<p>Reference for Beckie and Owen (2007) does not contain the source of the paper.</p>	<p>Full details for Beckie and Owen (2007) have been listed in the final RARMP.</p>
<p>Supports the conclusion of the OGTR that the proposed dealings pose negligible risks to the health and safety of people or the environment.</p>	<p>Noted.</p>

Summary of issues raised	Comments
<p>Objects to the proposed release within the Shire. Council has a stated objective to control the use GMOs within the Shire.</p> <p>Due to the potential market advantages, Council does not support the growing, storage and transport of GM crops within the Shire.</p> <p>Should the licence be issued, Council requests that the Shire is removed as a possible release location.</p>	<p>The Act requires the Regulator to identify and manage risks to human health and safety and the environment posed by or as a result of gene technology. Some areas may be designated under State or Territory law for the purpose of preserving the identity of GM or non-GM crops (or both) for marketing purposes. However, marketing issues are outside the matters to which the Regulator may have regard when deciding whether or not to issue a licence.</p>
<p>Two references cited in paragraphs 35 and 36 were not listed in the reference list at the end of the consultation RARMP. Therefore, the accuracy of claims about some of the regulatory sequences could not be verified.</p>	<p>The two references have been listed in the final RARMP.</p>
<p>It is noted in the RARMP that while allergenicity of the GM canola line has not been determined, the novel protein is identical or similar to that produced in other GM canola lines grown in Australia and overseas and is not expected to affect production of allergenic proteins. This ought to be a specific issue for applicant to address for any future releases.</p>	<p>The CP4 EPSPS protein produced in the GM canola line is identical, or similar, to that produced in other GM canola lines that have previously been grown in Australia and overseas without reports of enhanced allergenicity. Furthermore, the protein is well characterised and not known to be toxic or allergenic (Chapter 1, Section 5.2.2).</p> <p>The RARMP identifies that information on unintended effects as a result of changes in biochemistry, physiology or ecology of the GM plants may be required to assess possible future applications for a larger scale or commercial release (Chapter 3, Section 5).</p>
<p>No comment as RARMP indicated that there were negligible risks. Would like to be updated if there are changes to the assessment.</p>	<p>Noted.</p>
<p>Supports a position which is to oppose introduction of GMOs, and demand greater transparency and disclosure regarding current and proposed trials.</p> <p>Does not support the introduction of GMOs into Shire community.</p>	<p>The Act requires the Regulator to identify and manage risks to human health and safety and the environment posed by or as a result of gene technology. Prior to issuing a licence for field trials, the Regulator must prepare a RARMP and seek comment/advice from experts, agencies, local government authorities and members of the public via email, letters, advertisements in the press, and via the OGTR website: www.ogtr.gov.au. The RARMP and a range of other related documents are publicly available on the OGTR website. Details of the location of trial sites will be posted on the OGTR website when available.</p>
<p>Notes that none of the eight events compiled during hazard identification were identified as risks in the RARMP.</p>	<p>Noted.</p>

Summary of issues raised	Comments
<p>Pollen is still detected up to 4 km from the source, even though the majority travels less than 10 m. Decline of pollen could not be predicted as pollinating agents of canola contribute to the randomness of long-distance pollination events.</p> <p>Probability of vertical gene transfer of genes or genetic elements to sexually compatible plants still exists though it may occur at relatively low levels.</p> <p>Out-crossing has been detected at distances beyond the maximum 1 km containment provisions in the proposed licence, so believes that the probability of vertical gene transfer is not negligible beyond this distance.</p> <p>While consider that the proposed licence conditions would minimise the probability of gene transfer, it is recommended that the distance canola pollen travel be more accurately reflected in the RARMP, and addressed in the risk analysis.</p>	<p>Text has been added to Chapter 2 (Risk scenario 4) to clarify evidence relating to canola pollen movement. Extensive experimental data suggest that the majority of pollen travels less than 10 m and the amount of pollen decreases with distance from the source. The majority of experimental studies also report that outcrossing occurs at distances of less than 400 m. The containment measures that have been imposed in the licence conditions have been imposed in a number of other canola licences, including DIR 010/2001, DIR 011/2001, DIR 032/2002, DIR 069/2006, DIR 103 and DIR 104. No adverse effects have been reported from these releases.</p>
<p>Inconsistency in use of terminology in the draft RARMP regarding 'Brassica weeds, 'related' species (or weeds, or plants), and 'sexually compatible' species (or plants).</p> <p>Recommends that the inconsistency be amended and the term used be defined in the RARMP.</p>	<p>Use of 'related species' and 'sexually compatible species' in the RARMP have been amended to improve clarity.</p>
<p>Agrees with the additional requirements identified in the RARMP for any future larger scale or commercial release application of this GM canola line.</p>	<p>Noted.</p>
<p>Submission states that the GM canola proposed for release is expected to tolerate higher rates of glyphosate herbicides and includes the addition of triazine.</p> <p>Supports application of the precautionary principle in light of health and environmental aspects put forward and lack of scientific certainty around the cumulative impacts of triazine application with glyphosate on GM canola.</p>	<p>DIR 105 is a limited and controlled release of a GM canola line that contains a gene that is expected to enable the GM canola plants to continue growing in the presence of glyphosate. The GM canola is not genetically modified for tolerance to triazine.</p> <p>Monsanto intends to apply glyphosate to the GM canola and may use other herbicides during the course of the trial. However, issues relating to the safety and use of herbicides are outside the scope of the Regulator's assessments. The APVMA has regulatory responsibility for the supply of agricultural chemicals, including herbicides, in Australia.</p>

Appendix B Summary of issues raised in submissions received from the public on the consultation RARMP for DIR 105

The Regulator received 31 submissions from the public on the consultation RARMP, 29 from individuals and two from companies. Issues raised in these submissions are summarised in the table below. Issues relating to human health and safety and the environment were considered in the context of currently available scientific evidence in finalising the RARMP that formed the basis of the Regulator’s decision to issue the licence.

Issues raised: **A:** Allergenicity; **B:** Agricultural benefit; **App:** Application; **AS:** Applicant suitability; **C:** Containment, **E:** Environment; **FS:** Food safety; **GF:** Gene flow; **H:** Human health; **HGT:** Horizontal gene transfer; **HU:** Herbicide use; **O:** Opposition to GM foods; **P:** Persistence; **RA:** Risk Analysis; **S:** Segregation; **U:** Uncertainty; **UE:** Unintended effects; **W:** Weeds.

Other abbreviations: **Act:** *Gene Technology Act 2000*; **Ch:** Chapter; **EFSA:** European Food Safety Authority; **FSANZ:** Food Standards Australia New Zealand; **GM:** Genetically Modified; **GMO:** Genetically Modified Organism; **LC:** Licence Conditions; **OSA:** Outside scope of assessment; **RAF:** Risk Analysis Framework; **RARMP:** Risk Assessment and Risk Management Plan.

Sub. No:	Issue	Summary of issues raised	Comment
1, 9, 23 28, 30, 31	H, U	Effects on human health are unknown, including long-term effects	The RARMP concluded that risks to human health from this limited and controlled release are negligible. As discussed in Risk scenario 1, the GM canola is not expected to be more toxic or allergenic than non-GM canola. Licence conditions have been imposed to minimise exposure to the GMOs and their genetic material, including: prohibiting use in food and feed; limiting the size and duration of the release; and measures to restrict the spread and persistence of GMO and its genetic material in the environment.
4, 5, 6, 7, 8, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 24, 25, 26, 27, 29, 31	FS	The GM canola has not been approved by FSANZ	The purpose of the limited and controlled release is to conduct experiments to evaluate the agronomic performance of the GM canola line under field conditions. The applicant does not intend to use any material from the GM canola for human food or animal feed. Accordingly, the applicant has not applied to FSANZ to evaluate the GM canola line. FSANZ approval would need to be obtained before it could be sold for human food in Australia. Licence conditions have been imposed to prohibit use for food or feed. In addition, GM material not required for experiments or future planting must be destroyed.

Sub. No:	Issue	Summary of issues raised	Comment
31	A, H	<p>Potential for priming of allergenic responses.</p> <p>Severe allergy and adverse food reaction has been increasing in all age groups since 1998/9. GM crops have been in the food supply since 1996 or earlier.</p> <p>The <i>cp4 epsps</i> sequence for the GM crops is vastly different to the wildtype sequence, and includes immunogenic CpG motifs.</p> <p>Refers to EFSA released a Scientific Opinion on the allergenicity assessment of GM plants [EFSA Journal 2010, 8(7): 1700].</p>	<p>The trial is for the release of one GM canola line on a limited scale under controlled conditions.</p> <p>As discussed in Chapter 1 (Section 5.2.2), the CP4 EPSPS protein expressed in the GM canola proposed for release is identical to the amino acid sequence of the CP4 EPSPS protein expressed in other commercially produced GM crops. The CP4 EPSPS protein is well characterised and not known to be toxic or allergenic, nor does it participate in biochemical reactions that produce toxic or allergenic products. The nucleotide sequence of the <i>cp4 epsps</i> gene in Roundup Ready® canola was modified by Monsanto for plant-preferred codon usage but these nucleotide substitutions did not alter the sequence of the encoded protein.</p> <p>The GM canola is unlikely to be any more toxic or allergenic than non-GM equivalents. GM plants modified with similar or identical genes have been released previously in Australia and overseas (see Chapter 1, Sections 5 and 7) with no reports of altered toxicity or allergenicity.</p> <p>Licence conditions imposed will minimise exposure to GM materials. Conditions include prohibiting use in food and feed and to limiting the trial to the proposed size, locations and duration. GM material not required for experiments or future planting must be destroyed.</p> <p>The RARMP identifies that information on unintended effects as a result of changes in biochemistry, physiology or ecology of the GM plants may be required to assess possible future applications for a larger scale or commercial release (Chapter 3, Section 5).</p>
23	H, HGT	DNA material can be transferred to our gut flora, affecting our wellbeing.	<p>The trial is for the release of one GM canola line on a limited scale under controlled conditions. As discussed in Risk scenario 1, the potential for exposure of humans and other organisms to the novel proteins produced in the GM canola plants will be reduced by the limits and controls proposed by the applicant. Material from the GM canola will not be used in food or feed.</p> <p>Risks to human health and safety and environment arising as a result of HGT were assessed in Risk scenario 6 (Chapter 2). Important considerations were that:</p> <ul style="list-style-type: none"> the introduced gene is already widely present in the environment, and so naturally available for HGT from these other sources assessment of the potential toxicity or allergenicity of the expressed proteins did not identify a risk for human health and safety or the environment. <p>Given the rarity of HGT occurring and that adverse consequences are unlikely, the risk is considered to be negligible.</p>
1, 4, 5, 6, 7, 8, 9 12, 13, 14, 15, 16, 18, 19, 20, 21, 22, 23, 24, 26, 27, 28, 29, 30	E, U	Effects on the environment are unknown, including long-term effects	<p>The RARMP concluded that risks to the environment from this limited and controlled release are negligible. Long term effects are unlikely as a result of this field trial since licence conditions have been imposed to minimise exposure to the GMOs and their genetic material including: limiting the size and duration of the release; and measures to restrict the spread and persistence of GMO and its genetic material in the environment.</p>

Sub. No:	Issue	Summary of issues raised	Comment
4, 5, 6, 7, 8, 9, 12, 13, 14, 15, 16, 18, 19, 20, 21, 22, 24, 26, 27, 29, 30	P, LC	Two years have been allowed to clean up sites after trials. GM volunteers can appear after several years.	<p>The possibility of spread and persistence of the GM canola and its genetic material has been considered in Section 2.2 of the RARMP.</p> <p>As discussed in Chapter 3, delayed post-harvest shallow tillage can result in smaller seedbanks and reduced secondary dormancy and persistence. Therefore, the licence holder must complete at least two shallow tillage events to promote germination of remaining seed in the soil. Tillage must occur in conditions where germination of the GMO is reasonably likely to ensue (eg after irrigation or rainfall).</p> <p>The combination of two light tillage events and post-harvest monitoring every month for at least 24 months, until no volunteers are observed in the most recent 12 month period, is considered appropriate to manage persistence of viable canola seeds in the soil.</p>
1	B	Threat to biodiversity already posed by the monoculture of hybrid seeds. Trial approvals by the Regulator are also a threat to biodiversity.	Risks to the environment were assessed as negligible in the context of the proposed limited and controlled release. The assessment considered potential for adverse impacts on other organisms.
10, 11, 12, 16, 16, 25	GF, W	Glyphosate resistance may be transferred to weeds, increasing weed problems	The possibility of gene flow to non-GM canola, as well as other sexually compatible plants, has been considered in Section 2.3 (Chapter 2). As discussed in Risk scenario 4, extensive experimental data suggest that the majority of pollen travels less than 10 m and the amount of pollen decreases with distance from the source. The majority of experimental studies also report that outcrossing occurs at distances of less than 400 m. The risk to people and the environment arising from gene flow is considered negligible.
1, 4, 5, 6, 7, 8, 12, 13, 14, 15, 16, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31	GF	Likelihood gene flow to other brassica crops	<p>Licence conditions have been imposed to contain the GMOs and their genetic material, including requirements to: surround trial sites with a 50 m monitoring zone that is free of canola and related species; maintain an isolation zone of at least 400 m, or at least 1 km if no pollen trap is used, around each trial site within which no sexually compatible species may be intentionally grown; ensure that pollen trap plants flower at the same time as the GMOs; apply measures to promote germination of any canola seeds that remain in the soil; monitor the site for at least 24 months after harvest until no volunteers are detected for a continuous 12 month period and destroy any canola plants that may grow.</p>
1	W	GM canola has become a pest plant in North America	<p>Canola is not currently listed as being a noxious weed in any State or Territory in Australia.</p> <p>The potential for the introduced gene to increase the survival of the GM canola was assessed in Risk Scenario 2 (Chapter 2). It was concluded that: the introduced gene is unlikely to alter the response of the GM line to biotic and abiotic stresses that naturally limit the geographical distribution of the parent species; the genetic modification would only confer a selective advantage in managed environments in which the corresponding herbicide is applied; and the limits and controls would effectively restrict the spread and persistence of the GM canola plants.</p>

Sub. No:	Issue	Summary of issues raised	Comment
4, 5, 6, 7, 8, 12, 13, 14, 15, 16, 18, 19, 20, 21, 22, 24, 26, 27, 29, 30	RA	RARMP acknowledges that there are risks associated with this application	Risks to health and safety of people, or the environment, from this release are assessed to be negligible in the context of this limited and controlled release. Licence conditions have been imposed to restrict the spread and persistence of the GMO and its genetic material in the environment and to limit the size and duration of the release. Both of these considerations were important in establishing the context for the risk assessment and in reaching the conclusion that the risks posed to people and environment are negligible.
4, 5, 6, 7, 8, 12, 13, 14, 15, 16, 18, 19, 20, 21, 22, 24, 26, 27, 29, 30	RA	RARMP is often based on the presumption of 'substantial equivalence' meaning that the GM variety is the same as conventional varieties. This variety has a patented combination of inserted genes and is not 'the same'	RARMPs are prepared using the risk analysis model described in the Regulator's Risk Analysis Framework (RAF), which is based on the internationally recognised Australia-New Zealand Standard on Risk Management (AS/NZS 4360:2004). The term 'substantial equivalence' is not used in the RAF or the RARMP. Risks are assessed within the risk assessment context, which includes consideration of the properties of the parent organism.
2, 3	RA	Agrees with Regulators assessment that the release does not pose significant risks to human health or the environment / risks are no greater than those posed by non-GM canola	Noted.
1, 9, 31	AS	Applicant has previously allowed "accidental" releases in the past / has a history of unethical behaviour.	Applicant suitability was considered by the Regulator, as required by section 58 of the Act. The Act provides for substantial penalties for non-compliance with licence conditions or unauthorised dealings with GMOs.
1, 4, 5, 6, 7, 8, 10, 11, 12, 13, 14, 15, 16, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 29, 30	HU	Increased use of glyphosate may have detrimental effects on human health	Issues relating to the safety and use of herbicides are outside the scope of the Regulator's assessments. The APVMA has regulatory responsibility for the supply of agricultural chemicals, including herbicides, in Australia.
10, 11, 20, 30	E	Increased use of glyphosate may have detrimental effects on the environment	
1, 15, 16, 23	AS	Ethical issues posed by multinational company becoming only supplier for many Australian food producers	Economic and marketing issues, and ethical issues relating to these, are outside the scope of the Regulator's assessments.
2	B	Notes that enhanced glyphosate tolerance in canola would be a very useful agronomic trait and a significant advance on previous weed management systems	The RARMP concluded that risks to human health and safety and the environment are negligible. The Regulator does not consider benefits as this is outside the scope of assessment required by the Act.
9, 15, 16, 23, 25 30	B, RA	Risks out weigh benefits, or no benefit	The RARMP concluded that risks to human health and safety and the environment are negligible. The Regulator does not consider benefits as this is outside the scope of assessment required by the Act.

Sub. No:	Issue	Summary of issues raised	Comment
4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 18, 19, 20, 21, 22, 24, 26, 27, 28, 29, 30	S	Contamination of non-GM crops with GM canola will affect the livelihood of non-GM farmers and could result in loss of organic certification, effect market access.	Marketability, trade and segregation issues are outside the scope of the Regulator's assessments. These are matters for States and Territories, who may designate GM free zones for marketing purposes (Note, management of gene flow is addressed above). The independent Statutory Review of the Act, conducted in 2005/06, considered the issue of liability for contamination of non-GM crops by GMOs and noted that common law and other consumer protection legislation provided remedies to those affected by the presence of GM varieties in non-GM crops.
10, 11, 20, 23, 28, 30	S	Concern that the trials are being conducted in Australia, in WA or in shires that have declared themselves GM free.	The Act requires the Regulator to identify and manage risks to human health and safety and the environment posed by or as a result of gene technology. Some areas may be designated under State or Territory law for the purpose of preserving the identity of GM or non-GM crops (or both) for marketing purposes. However, marketing issues are outside the matters to which the Regulator may have regard when deciding whether or not to issue a licence.
9, 15, 16, 23	O	Public opposition to GM foods.	The consideration of social, cultural and trade issues and the appropriateness of using gene technology is outside the scope of issues to which the Regulator must have regard when deciding whether or not to issue a licence.