



**Australian Government**

**Department of Health**

Office of the Gene Technology Regulator

# Risk Assessment and Risk Management Plan for

## **DIR 138**

Commercial release of canola genetically  
modified for dual herbicide tolerance and a  
hybrid breeding system  
(InVigor® x TruFlex™ Roundup Ready®)

Applicant: Bayer CropScience Pty Ltd

March 2016

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# Summary of the Risk Assessment and Risk Management Plan

## for

### Licence Application No. DIR 138

#### ***Decision***

The Gene Technology Regulator (the Regulator) has decided to issue a licence for this application for the intentional, commercial scale release of herbicide tolerant genetically modified (GM) canola in Australia. A Risk Assessment and Risk Management Plan (RARMP) for this application was prepared by the Regulator in accordance with requirements of the *Gene Technology Act 2000* (the Act) and corresponding state and territory legislation, and finalised following consultation with a wide range of experts, agencies and authorities, and the public. The RARMP concludes that this commercial release poses negligible risks to human health and safety and the environment and no specific risk treatment measures are proposed. However, general licence conditions have been imposed to ensure that there is ongoing oversight of the release.

#### ***The application***

Application number	DIR 138
Applicant	Bayer CropScience Pty Ltd (Bayer)
Project title	Commercial release of canola genetically modified for dual herbicide tolerance and a hybrid breeding system (InVigor® x TruFlex™ Roundup Ready®) <sup>1</sup>
Parent organism	<i>Brassica napus</i> L. (canola)
Introduced genes and modified traits	<ul style="list-style-type: none"> <li>• phosphinothricin acetyl transferase (<i>bar</i>) gene derived from the bacterium <i>Streptomyces hygroscopicus</i> (tolerance to herbicide glufosinate)</li> <li>• 5-enolpyruvylshikimate-3-phosphate synthase (<i>cp4 epsps</i>) gene derived from the bacterium <i>Agrobacterium</i> sp. strain CP4 (tolerance to herbicide glyphosate)</li> <li>• ribonuclease (<i>barnase</i>) gene derived from the bacterium <i>Bacillus amyloliquefaciens</i> (confers male sterility)</li> <li>• ribonuclease inhibitor (<i>barstar</i>) gene derived from the bacterium <i>B. amyloliquefaciens</i> (restores fertility)</li> <li>• antibiotic resistance gene (<i>nptII</i>) from <i>E. coli</i> (antibiotic resistance for selection during initial development)</li> </ul>
Proposed locations	Australia-wide, in all canola growing areas
Primary purpose	Commercial release of the GM canola

<sup>1</sup> The title of the licence application submitted by Bayer is “Commercial release of InVigor® x TruFlex™ Roundup Ready® (*Brassica napus*) for use in the Australian cropping system”.

## ***Risk assessment***

The risk assessment concludes that there are negligible risks to the health and safety of people, or the environment, from the proposed release.

The risk assessment process considers how the genetic modification and activities conducted with the GMOs might lead to harm to people or the environment. Risks were characterised in relation to both the seriousness and likelihood of harm, taking into account information in the application, relevant previous approvals, current scientific knowledge and advice received from a wide range of experts, agencies and authorities consulted on the preparation of the RARMP. Both the short and long term impact were considered.

Credible pathways to potential harm that were considered included: toxic and allergenic properties of the GM canola; increased spread and persistence leading to increased weediness of the GM canola relative to unmodified plants; and vertical transfer of the introduced genetic material to other sexually compatible plants.

The principal reasons for the conclusion of negligible risks are: the introduced proteins are not considered toxic or allergenic to people and other desirable organisms; the parental GM canola lines and other GM crops containing the introduced genes have a history of safe use in Australia and overseas; the introduced genes and proteins are widespread in the environment; the GM canola lines and their progeny can be controlled using integrated weed management; the GM canola lines are susceptible to the biotic or abiotic stresses that normally restrict the geographic range and persistence of canola; and the limited capacity of the GM canola to spread and persist in undisturbed natural habitats. In addition, food made from the GM canola is approved by Food Standards Australia New Zealand as safe for human consumption.

## ***Risk management***

The risk management plan describes measures to protect the health and safety of people and to protect the environment by controlling or mitigating risk. The risk management plan is given effect through licence conditions.

As the level of risk is assessed as negligible, specific risk treatment is not required. However, the Regulator has imposed licence conditions to ensure that there is ongoing oversight of the release and to allow the collection of information to verify the findings of the RARMP. The licence also contains a number of general conditions relating to ongoing licence holder suitability, auditing and monitoring, and reporting requirements, which include an obligation to report any unintended effects.

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## Abbreviations

Act	<i>Gene Technology Act 2000</i>
AGSWG	Australian Glyphosate Sustainability Working Group
APVMA	Australian Pesticides and Veterinary Medicines Authority
<i>bar</i>	<i>bar</i> gene from <i>Streptomyces hygroscopicus</i>
CaMV	Cauliflower mosaic virus
CFIA	Canadian Food Inspection Agency
CMP	Crop Management Plan
<i>cp4 epsps</i>	<i>epsps</i> gene from <i>Agrobacterium</i> sp. strain CP4
CP4 EPSPS	EPSPS protein from <i>Agrobacterium</i> sp. strain CP4
CTP	Chloroplast transit peptide
<i>ctp2</i>	Chloroplast transit peptide coding region from the <i>epsps</i> gene of <i>A. thaliana</i>
dwt	Dry weight
DIR	Dealings involving Intentional Release
DNA	Deoxyribonucleic acid
EFSA	European Food Safety Authority
EPA	United States Environmental Protection Agency
EPSPS	5-enolpyruvylshikimate-3-phosphate synthase
FDA	United States Food and Drug Administration
FMV	Figwort mosaic virus
FSANZ	Food Standards Australia New Zealand (formerly ANZFA)
fw	Fresh weight
g	Gram
GM	Genetically Modified
GMO	Genetically Modified Organism
GTTAC	Gene Technology Technical Advisory Committee
kDa	Kilodalton
µg	Microgram
µmole	Micromole
mRNA	Messenger ribonucleic acid (RNA)
OGTR	Office of the Gene Technology Regulator
<i>pat</i>	<i>pat</i> gene from <i>Streptomyces viridochromogenes</i>
PAT	Phosphinothricin-acetyl transferase
PPT	Phosphinothricin
PRR	Post release review
RARMP	Risk Assessment and Risk Management Plan
Regulator	Gene Technology Regulator
RNA	Ribonucleic acid
RNase	Ribonuclease
USDA-APHIS	Animal and Plant Health Inspection Service of the United States Department of Agriculture

# Chapter 1 Risk assessment context

## Section 1 Background

1. An application has been made under the *Gene Technology Act 2000* (the Act) for Dealings involving the Intentional Release (DIR) of genetically modified organisms (GMOs) into the Australian environment.
2. The Act in conjunction with the Gene Technology Regulations 2001 (the Regulations), an inter-governmental agreement and corresponding legislation in States and Territories, comprise Australia's national regulatory system for gene technology. Its objective is to protect the health and safety of people, and to protect the environment, by identifying risks posed by or as a result of gene technology, and by managing those risks through regulating certain dealings with GMOs.
3. 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. The risk assessment context is established within the regulatory framework and considers application-specific parameters (Figure 1).

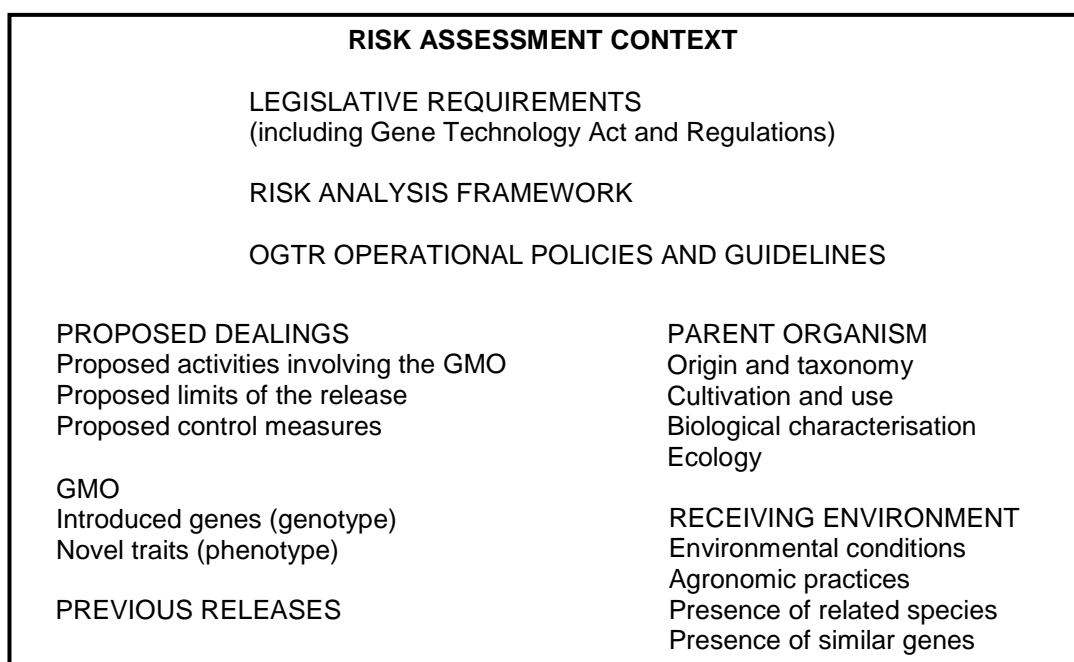


Figure 1 Summary of parameters used to establish the risk assessment context

## Section 2 Regulatory framework

4. Sections 50, 50A and 51 of the Act outline the matters which the Gene Technology Regulator (the Regulator) must take into account, and who must be consulted, in preparing the Risk Assessment and Risk Management Plans (RARMPs) that inform the decisions on licence applications. In addition, the Regulations outline further matters the Regulator must consider when preparing a RARMP.
5. Since this application is for commercial purposes, it cannot be considered as a limited and controlled release application under section 50A of the Act. Therefore, under section 50(3) of the Act, the Regulator was required to seek advice from prescribed experts, agencies and authorities on matters relevant to the preparation of the RARMP. This first round of consultation included the Gene Technology Technical Advisory Committee (GTTAC), State and Territory Governments, Australian Government authorities or agencies prescribed in the



Regulations, all Australian local councils<sup>2</sup> and the Minister for the Environment. A summary of issues contained in submissions received is given in Appendix A.

6. Section 52 of the Act requires the Regulator, in a second round of consultation, to seek comment on the RARMP from the experts, agencies and authorities outlined above, as well as the public. Advice from the prescribed experts, agencies and authorities for the second round of consultation, and how it was taken into account, is summarised in Appendix B. Eleven public submissions were received and their consideration is summarised in Appendix C.

7. The Risk Analysis Framework (2013) explains the Regulator's approach to the preparation of RARMPs in accordance with the legislative requirements. Additionally, there are a number of operational policies and guidelines developed by the Office of the Gene Technology Regulator (OGTR) that are relevant to DIR licences. These documents are available from the [OGTR website](#).

8. Any 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 and the Department of Agriculture and Water Resources. These dealings may also be subject to the operation of State legislation declaring areas to be GM, GM free, or both, for marketing purposes.

### **Section 3 The proposed release**

9. Bayer CropScience Pty Ltd (Bayer) proposes commercial cultivation of genetically modified (GM) InVigor® x TruFlex™ Roundup Ready® canola. The variety is the result of conventional breeding between GM InVigor® canola and GM TruFlex™ Roundup Ready® canola which are individually authorised for commercial release under licences DIR 021/2002 and DIR 127, respectively. InVigor® canola refers to GM canola lines MS1, MS8, RF1, RF2 and RF3 and their hybrids. DIR 021/2002 also authorised T45 and Topas 19/2 which only have glufosinate tolerance. MS1, RF1, RF2 and Topas 19/2 contain an antibiotic resistance marker gene. TruFlex™ Roundup Ready® canola is also known as GM canola line MON 88302. MS8 x RF3 x MON88302 is the subject of this application. Bayer also proposes to release the double stacks MS8 x MON 88302 and RF3 x MON 88302, created through conventional breeding, as these would be used in the seed production process for MS8 x RF3 x MON 88302. TruFlex™ Roundup Ready® canola hybrids with lines MS1, RF1, RF2, T45 and Topas 19/2 may be present and are implicitly included in all considerations of this RARMP.

10. The applicant is seeking approval for the release to occur Australia-wide, subject to any moratoria imposed by States and Territories for marketing purposes. The GM canola may be grown in all commercial canola growing areas, and products derived from the GM plants would enter general commerce, including use in human food and animal feed.

11. The dealings involved in the proposed intentional release are all dealings, ie

- conducting experiments with the GMOs
- making, developing, producing or manufacturing the GMOs
- breeding the GMOs with other canola cultivars
- propagating the GMOs

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<sup>2</sup> Bayer is seeking approval for unrestricted commercial release of the GM canola in all canola growing areas of Australia. Canola may be grown over a significant proportion of Australian agricultural land, including areas in all States. Therefore, the Regulator decided to consult with all of the local councils in Australia, except for those that have requested not to be consulted on such matters.

- using the GMO in the course of manufacture of a thing that is not the GMOs
- growing, raising or culturing the GMOs
- transporting the GMOs
- disposing of the GMOs
- importing the GMOs

and the possession, supply or use of the GMOs for the purposes of, or in the course of, any of the above.

## **Section 4 Previous releases of the GM canola proposed for release and other relevant GM canola**

### **4.1 Australian approvals**

#### **4.1.1 GMOs proposed for release**

12. InVigor® x TruFlex™ Roundup Ready® canola has been approved by the Regulator for limited and controlled release under licence DIR 104, but has not been grown in Australia.

#### **4.1.2 Parental GM canola lines**

##### GM parent InVigor® canola

13. Field trials of the parental GM InVigor® canola began in Australia in 1996. The first field trials were overseen by the Genetic Manipulation Advisory Committee (GMAC) as Planned Releases (PR) PR-62, PR-63 and their respective extensions. Under the current regulatory system, trials were approved by the Regulator under licence [DIR 010/2001](#). Commercial release of InVigor® Hybrid canola was approved by the Regulator in 2003 under licence [DIR 021/2002](#). As yet, InVigor® Hybrid canola has not been commercially grown in Australia.

##### GM parent TruFlex Roundup Ready ® canola

14. Field trials of TruFlex™ Roundup Ready® canola have been conducted in Australia since 2011 under licence [DIR 105](#). Commercial release of TruFlex™ Roundup Ready® canola was approved by the Regulator in November 2014 under licence [DIR 127](#). As yet TruFlex™ Roundup Ready® canola has not been grown on a commercial scale in Australia.

##### GM Roundup Ready canola

15. Field trials of the parental GM Roundup Ready® canola, which contains the same *cp4 epsps* gene as TruFlex™ Roundup Ready® canola, began in Australia in 1997. The trials were overseen by GMAC as PR-77 and associated extensions and were approved by the Regulator under licence [DIR 011/2001](#). Commercial release of Roundup Ready® canola was approved by the Regulator in 2003 under licence [DIR 020/2002](#). Commercial production began in NSW and Vic in 2008 and in WA in 2010. Currently, Roundup Ready® canola comprises about 20% of the Australian canola crop.

#### **4.1.3 Other relevant GM canola lines**

16. InVigor® x Roundup Ready® canola, which is a cross between the GM parental lines authorised for commercial release under licences DIR 021/2002 and DIR 020/2002, has been approved by the Regulator for limited and controlled release (field trials) under licences [DIR 069/2006](#) and [DIR 104](#), and for commercial release under [DIR 108](#).

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

## 4.2 Approvals by other Australian agencies

18. 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 FSANZ and APVMA.

19. FSANZ is responsible for human food safety assessment and food labelling, including GM food. FSANZ has approved the use of food derived from InVigor® canola and the other GM canola lines approved under licence DIR 021/2002, Roundup Ready® canola approved under licence DIR 020/2002 and TruFlex™ Roundup Ready® canola approved under licence DIR 127. These approvals are listed in the Schedule to Standard 1.5.2 of the Australia New Zealand Food Standards Code under Items 1.1 (RoundupReady®), 1.2 (InVigor®) and 1.4 (TruFlex™ Roundup Ready®). FSANZ has determined that food derived from these GM lines of canola is as safe for human consumption as food derived from conventional (non-GM) canola varieties. These approvals also cover InVigor® x Roundup Ready® canola and InVigor® x TruFlex™ Roundup Ready® canola.

20. APVMA has regulatory responsibility for the supply of agricultural chemicals, including herbicides and insecticidal products. Bayer has indicated they will need to make an application to the APVMA to change the current Liberty® and Roundup Ready® herbicide labels to include InVigor® x TruFlex™ Roundup Ready® canola. Bayer has been granted registration of glufosinate containing products for use on InVigor® canola (Liberty®). Glyphosate is the active constituent of a range of proprietary herbicides registered by the APVMA, including those for use on Roundup Ready® canola crops.

21. In addition, dealings authorised by the Regulator may be subject to the operation of State and Territory legislation declaring areas to be GM, GM free, or both, for marketing purposes. The Act allows for areas to be designated under State and Territory law for the purpose of preserving the identity of non-GM or GM crops for marketing purposes. Following the Regulator's approval in 2003 of GM InVigor® canola and GM Roundup Ready® canola on human health and environmental safety grounds, all jurisdictions except QLD and the NT enacted legislation to delay the commercial release of GM crops, including GM canola, until marketability, agricultural trade and segregation issues were better understood. Subsequently, GM canola approved by the Regulator has been allowed to be commercially cultivated in NSW, Vic and WA.

## 4.3 International approvals

### 4.3.1 GMOs proposed for release

22. InVigor® x TruFlex™ Roundup Ready® canola was grown in Canada and the USA to generate data for this application. As the parental GM canola lines (InVigor® and TruFlex™ Roundup Ready®) have been individually approved in Canada and the USA, stacking of the GM traits through conventional breeding did not require separate or additional regulatory approval. InVigor® x TruFlex™ Roundup Ready® canola has been approved for food and/or feed use in Japan (2015), Mexico (2015) and South Korea (2014 & 2015).

### 4.3.2 Parental GM canola lines

23. The parental GM canola lines MS8, RF3, MS8 x RF3 InVigor® (MS8 x RF3) and TruFlex™ Roundup Ready® have been approved for commercial (or environmental) release and/or for food and feed use in many countries. GM InVigor® canola has been grown commercially in North America since 1995; GM Roundup Ready® canola since 1996. They have been approved for food and/or feed use in countries such as Canada, USA, China, Japan and Mexico.

24. MS1, RF1 and RF2 have been approved in the USA for environmental release and food and feed use, and in Mexico for food, import and processing.

25. MS1xRF1 and MS1xRF2 have been approved in Canada and the USA for environmental release; in Canada, the Republic of Korea and South Africa for food and feed use; and in China, Japan and the European Union for food, feed, import and processing.

26. T45 and Topas 19/2 have been approved in Canada, Japan and the USA for environmental release and food and feed use; in the Republic of Korea for food and feed use; in China for food, feed, import and processing. T45 has also been approved in Mexico for food, import and processing and in the European Union for food, feed, import and processing (industrial use only). Topas 19/2 has also been approved in the European Union for food, feed, import and processing; and in South Africa for food and feed use.

## **Section 5 The parent organism**

27. The parent organism is *Brassica napus* L., which is commonly known as canola, rapeseed or oilseed rape. Canola is exotic to Australia and is grown as an agricultural crop mainly in WA, NSW, Vic and SA. It is Australia's third largest broad acre crop (ABARES 2015). Canola is primarily grown for its seed oil, which is used as a cooking oil and for other food and industrial applications. The seed meal which remains after oil extraction is used as animal feed (OECD 2011). Information on the weediness of the parent organism is summarised below and information on the use of the parent organism in agriculture is summarised in Section 8 (the receiving environment). More detailed information can be found in *The Biology of Brassica napus L. (canola)* (OGTR 2011), which was produced to inform the risk assessment process for licence applications involving GM canola plants and is available from the [OGTR Risk Assessment References page](#).

28. The Standards Australia *National Post-Border Weed Risk Management Protocol* rates the weed risk potential of plants according to properties that strongly correlate with weediness for each relevant land use (Standards Australia Ltd et al. 2006). These properties relate to the plants' potential to cause harm (impact), to its invasiveness (spread and persistence) and to its potential distribution (scale). The weed risk potential of volunteer canola has been assessed using methodology based on the *National Post-Border Weed Risk Management Protocol* (see Appendix 1, OGTR 2011). It is summarised below. Please note that, because canola has been grown in Australia over several decades, its actual rather than potential distribution is addressed.

### **5.1 Potential to cause harm**

29. In summary, as a volunteer (rather than as a crop), non-GM canola is considered to exhibit the following potential to cause harm:

- low potential to negatively affect the health of animals and/or people
- limited ability to reduce the establishment or yield of desired plants
- low ability to reduce the quality of products or services obtained from land uses
- limited potential to act as a reservoir for plant pests, pathogens or diseases.

30. *B. napus* seeds contain two natural toxicants: erucic acid and glucosinolates. Erucic acid is found in the oil, and animal feeding studies have shown that traditional rapeseed oil with high levels of erucic acid can have detrimental health effects. Glucosinolates are found in the seed meal, which is used exclusively as livestock feed. The products of glucosinolate hydrolysis have negative effects on animal production (OECD 2011).

31. The term canola refers to varieties of *B. napus* that contain less than 2% erucic acid in the oil and less than 30 µmoles/g of glucosinolates in the seed meal, so are considered suitable for

human and animal consumption (OECD 2011). The Australian canola crop grown in 2014 contained on average less than 0.1% erucic acid in the oil and approximately 12  $\mu\text{moles/g}$  of glucosinolates in the meal (Seberry et al. 2015).

## 5.2 Invasiveness

32. With regard to invasiveness, non-GM canola volunteers have:

- the ability to reproduce by seed, but not by vegetative means
- short time to seeding
- high annual seed production
- low ability to establish amongst existing plants
- low tolerance to average weed management practices
- low ability to undergo long distance spread by natural means
- high potential for long distance spread by people from cropping areas and low potential for long distance spread by people from intensive land uses such as roadsides.

## 5.3 Actual distribution

33. In canola growing areas, volunteer canola is considered to be a major problem warranting control in agricultural settings (Groves et al. 2003). Canola volunteers requiring weed management are likely to be found in fields for up to three years after growing a canola crop (Salisbury 2002; Australian Oilseeds Federation 2014). Canola volunteers produce allelopathic compounds that reduce germination of other crops, in addition to directly competing with crop plants (Asaduzzaman et al. 2014; Gulden et al. 2008).

34. Due to its primary colonising nature, canola can take advantage of disturbed habitats such as roadside verges [typically within 5 m from the edge of the road (Norton 2003; Agrisearch 2001)], field margins, wastelands and along railway lines. However, canola is a poor competitor with weed species and will be displaced unless the habitats are disturbed on a regular basis (Salisbury 2002; OECD 2012). Roadside canola populations are usually transient, and are thought to be reliant on re-supply of seed through spillages (Crawley & Brown 2004; Gulden et al. 2008; Baker & Preston 2004).

35. Canola is not considered a significant weed in natural undisturbed habitats in Australia (Dignam 2001; Groves et al. 2003).

## **Section 6 The parental GM canola lines and other relevant GM canola**

36. The GM canola proposed for release is the result of conventional breeding between GM InVigor® canola and GM TruFlex™ Roundup Ready® canola. The parental GM canola lines were evaluated and authorised for commercial release under licences [DIR 021/2002](#) and [DIR 127](#), respectively. The original RARMPs provide detail of all relevant aspects of the parental GM canolas, particularly with respect to molecular characterisation, toxicity, allergenicity, weediness and the potential for adverse effects upon outcrossing.

37. The five InVigor® canola lines authorised for commercial release under licence [DIR 021/2002](#) contain genes comprising a hybrid breeding system. Topas 19/2, MS1, RF1 and RF 2 contain a gene conferring resistance to certain antibiotics. All lines authorised under [DIR 021/2002](#) contain a gene conferring tolerance to the herbicide glufosinate.

38. TruFlex™ Roundup Ready® canola contains a gene conferring tolerance to the herbicide glyphosate.

39. The RARMP for [DIR 108](#), which assessed and authorised InVigor® x Roundup Ready® canola, also includes information on InVigor® canola, Roundup Ready canola (with the same herbicide tolerance gene as TruFlex™ Roundup Ready® canola) and the hybrid thereof.

40. A summary of the genes and traits, including any additional information is provided below.

## 6.1 The introduced genetic material and its effects

41. The introduced genetic material, source organisms and traits are summarised in Tables 1 and 2.

**Table 1 The traits and genes introduced into the parental GM canola lines**

Parental GM canola line	Glufosinate tolerance	Glyphosate tolerance	Hybrid breeding system	Antibiotic resistance
<i>MON 88302</i>	-	<i>cp4 epsps</i>	-	
<i>MS1</i>	<i>bar</i>	-	<i>barnase</i>	<i>nptII</i>
<i>MS8</i>	<i>bar</i>	-	<i>barnase</i>	-
<i>RF1</i>	<i>bar</i>	-	<i>barstar</i>	<i>nptII</i>
<i>RF2</i>	<i>bar</i>	-	<i>barstar</i>	<i>nptII</i>
<i>RF3</i>	<i>bar</i>	-	<i>barstar (2 copies)</i>	-
<i>T45</i>	<i>pat</i>	-	-	-
<i>Topas 19/2</i>	<i>pat</i>	-	-	<i>nptII</i>

**Table 2 Genetic elements and their origin**

Gene (source)	Protein produced	Protein function	Promoter (source)	Terminator (source)	Additional elements (source)
<i>bar</i> ( <i>S. hygroscopicus</i> )	PAT (phosphinothricin acetyl transferase)	glufosinate tolerance	<i>PSsuAra</i> ( <i>A. thaliana</i> )	<i>3' g7</i> ( <i>A. tumefaciens</i> )	In RF1, RF2 and MS1 only: Ctp/S1A (chloroplast transit peptide) ( <i>A. thaliana</i> )
<i>barnase</i> ( <i>B. amyloliquefaciens</i> )	BARNASE (RNase)	male sterility	<i>PTa29</i> ( <i>N. tabacum</i> )	<i>3'-nos</i> ( <i>A. tumefaciens</i> )	-
<i>barstar</i> ( <i>B. amyloliquefaciens</i> )	BARSTAR (RNase inhibitor)	restoration of fertility	<i>PTa29</i> ( <i>N. tabacum</i> )	<i>3'-nos</i> ( <i>A. tumefaciens</i> )	-
<i>cp4 epsps</i> ( <i>Agrobacterium sp. strain CP4</i> )	CP4 EPSPS (5-enolpyruvylshikimate-3-phosphate synthase)	glyphosate tolerance	<i>P-FMV/Tsf-1</i> ( <i>FMV</i> and <i>A. thaliana</i> )	<i>E9 3'</i> ( <i>P. sativum</i> )	L-Tsf1 (leader sequence) & I-Tsf1 (intron) Ctp2 (chloroplast transit peptide) ( <i>A. thaliana</i> )
<i>nptII</i> ( <i>E. coli</i> )	neomycin phosphotransferase	resistance to certain antibiotics	<i>P-nos</i> <i>A. tumefaciens</i>	<i>3'-ocs</i> <i>A. tumefaciens</i>	-
<i>pat</i> ( <i>S. viridochromogenes</i> )	PAT	glufosinate tolerance	<i>P-35S</i> ( <i>CaMV</i> )	<i>T-35S</i> ( <i>CaMV</i> )	-

### 6.1.1 Hybrid breeding system

42. Traditional plant breeding selects for plants with agronomically valuable characteristics. However, repetitive self-pollination of desirable lines can produce progeny that display lowered fitness or vigour when compared to their out-crossing counterparts, a phenomenon termed inbreeding depression. By contrast, when crosses are made between genetically distinct parents, the progeny often outperform the parental lines and are said to display hybrid vigour. Hybrid vigour is commercially advantageous, but ensuring a hybrid cross is technically difficult to achieve, especially when working with species that have both male and female floral organs borne on the same flower and are predominantly self-fertilising, such as canola.

43. To facilitate the production of hybrid canola plants, Bayer has developed a hybrid breeding system that is conferred by expression of the *barnase* and *barstar* genes derived from the common soil bacterium *Bacillus amyloliquefaciens*. *Barnase* encodes a ~12kDa (kilodaltons) ribonuclease (RNase) called BARNASE, and *barstar* encodes a ~10kDa RNase inhibitor protein, BARSTAR, which specifically binds to BARNASE and suppresses its activity (Hartley 1988; Hartley 1989).

44. RNases are commonly found in nature and collectively their function is to degrade the messenger ribonucleic acid (mRNA) that allows genetic information to be translated into protein production. This turnover of mRNA is important for regulating the activity of genes. In *B. amyloliquefaciens*, the BARNASE enzyme is secreted extracellularly as a defence mechanism where it degrades the ribonucleic acid of competing organisms. BARSTAR accumulates intracellularly to protect the host cell from the destructive properties of its own ribonuclease enzyme.

#### MS lines

45. In the MS lines, *barnase* is controlled by the *PTa29* promoter from tobacco (*Nicotiana tabacum*) that directs gene expression solely within the tapetal cell layer of the anthers. This results in localised degradation of ribonucleic acid within the tapetal cells prior to microspore development and prevents the production of pollen (De Block & De Bouwer 1993; Mariani et al. 1990). The resulting plants are male-sterile (MS) and can only be fertilised by the pollen of another plant, thereby ensuring the production of hybrid progeny. The mRNA polyadenylation signals, which are required for gene expression in plants, are provided by the 3' non-translated region of the nopaline synthase gene (3'-nos) from *Agrobacterium tumefaciens* (Depicker et al. 1982).

#### RF lines

46. To reverse the effects of *barnase* expression, GM canola lines have also been generated that contain the *barstar* gene. The introduced *barstar* gene in the RF lines is under the control of the same regulatory sequences as the *barnase* gene in the MS lines. Expression of *barstar* has no effect on pollen development and GM canola plants have a normal appearance and viable pollen (Mariani et al. 1992). When a GM line containing *barnase* (eg RF3) is crossed with a GM line containing *barstar* (eg MS8), progeny that inherit both genes display completely normal fertility due to the specific inhibition of BARNASE activity by BARSTAR (Mariani et al. 1992). For this reason, the GM lines modified with the *barstar* gene are designated as restorers of fertility (RF).

### **6.1.2 Herbicide tolerance**

#### Glufosinate tolerance

47. Glufosinate is the active ingredient in a number of proprietary broad-spectrum herbicides that have been registered for use in Australia. These herbicides function by inhibiting the plant enzyme glutamine synthase, which is a key enzyme involved in plant nitrogen metabolism. In the absence of glutamine synthase activity, ammonia accumulates in plant tissues causing inhibition of amino acid biosynthesis, inhibition of photosynthesis and rapid death of the plant (Evstigneeva et al. 2003).

48. The herbicidal component of glufosinate is the L-isoform of phosphinothricin (PPT). PPT is a component of the antibiotic bialaphos, which is produced naturally by the soil bacteria *Streptomyces hygroscopicus* and *S. viridochromogenes*. To avoid the toxicity associated with bialaphos production, these bacteria express the bialaphos resistance gene *bar* (Murakami et al. 1986; Thompson et al. 1987; Wohlleben et al. 1988) or *pat* (Strauch et al. 1988; Wohlleben et al. 1988), respectively. The *bar* and *pat* genes encode phosphinothricin acetyl transferase

(PAT), an enzyme that acetylates the free amino groups of PPT with high affinity and specificity to render it inactive (Wohlleben et al. 1988; Dröge-Laser et al. 1994; OECD 1999b). The PAT protein comprises 183 amino acids and has a molecular weight of ~22 kDa (Wehrmann et al. 1996).

49. GM canola lines RF1, RF2, RF3, MS1 and MS8 contain the *bar* gene and lines T45 and Topas 19/2 the *pat* gene.

50. The *bar* and *pat* genes share an overall identity of 87% at the nucleotide sequence level, and both encode PAT proteins of 183 amino acids with 85% sequence identity at amino acid level, comparable molecular weights (~22kD) and similar substrate affinity and biochemical activity (Wehrmann et al. 1996). The DNA sequence of both these genes was modified for plant-preferred codon usage to ensure optimal expression in *Brassica napus*.

51. The *bar* gene introduced into MS8 and RF3 was modified by a substitution of the two 3' codons of the original bacterial gene (see RARMP for DIR 021/2002; Thompson et al. 1987).

52. The PAT protein produced from the *bar* gene in GM canola lines RF1, RF2, RF3, MS1 and MS8 has the same amino acid sequence as the native protein from *S. hygrosopicus*, except for the first two amino acids. The amino acid sequence of the PAT protein in T45 and Topas 19/2 is identical to that of the native protein from *S. viridochromogenes*.

53. Expression of the *bar* gene in the GM canola lines RF1, RF2, RF3, MS1 and MS8 is controlled by the plant promoter PSSuAra from the S1A ribulose-1,5-bisphosphate carboxylase (RubisCO) small subunit gene from *Arabidopsis thaliana* (Krebbers et al. 1988). This promoter directs gene expression in green plant tissues (Krebbers et al. 1988). The mRNA polyadenylation signal for the *bar* gene in GM canola lines RF1, RF2, RF3, MS1 and MS8 is 3'g7, derived from the 3' non-translated region from gene 7 of *A. tumefaciens* found in octopine tumours of tobacco after bacterial infection (Dhaese et al. 1983; Velten & Schell 1985).

54. In lines RF1, RF2 and MS1, post-translational targeting of the *bar* gene product (PAT) to the chloroplast is accomplished by fusion of the 5' terminal coding sequence of *bar* with the chloroplast transit peptide coding sequence of the S1A RubisCO gene from *A. thaliana* (Krebbers et al. 1988).

55. In lines T45 and Topas 19/2, the *pat* gene is controlled by the constitutive 35S promoter and 35S mRNA polyadenylation signals from cauliflower mosaic virus (CaMV) (Odell et al. 1985).

### Glyphosate tolerance

56. Glyphosate (N-phosphonomethyl glycine) is the active ingredient in a number of broad-spectrum systemic herbicides that have been approved for use in Australia. The herbicidal activity of glyphosate is derived from its ability to inhibit the function of 5-enolpyruvylshikimate-3-phosphate synthase (EPSPS), a key enzyme involved in the shikimate biosynthetic pathway present in all plants, bacteria and fungi. Glyphosate competes with phosphoenolpyruvate for binding to the complex formed between EPSPS and shikimate 3-phosphate. Upon glyphosate binding, the EPSPS:shikimate 3-phosphate complex is highly 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).

57. The CP4 EPSPS protein encoded by the *cp4 epsps* gene from *Agrobacterium* sp. is largely insensitive to the effects of glyphosate (Padgett et al. 1993), as are a number of other microbial EPSPS enzymes (Schulz et al. 1985; Eschenburg et al. 2002; Funke et al. 2006).



Consequently, in GM plant cells with the *Agrobacterium cp4 epsps* gene, biosynthesis of aromatic amino acids is not inhibited in the presence of glyphosate. Therefore, no new metabolic products are formed in these GM plants as the only difference from the native EPSPS enzyme is the reduced affinity for glyphosate (OECD 1999a).

58. TruFlex™ Roundup Ready® canola was modified by the insertion of the *cp4 epsps* gene, which encodes EPSPS, a 47.6 kDa protein consisting of a polypeptide of 455 amino acids (Padgett et al. 1996). EPSPS is a key enzyme in plants, bacteria, algae and fungi but is absent from mammals, birds, reptiles and fish which are not able to synthesize these aromatic amino acids (Padgett et al. 1993; Bentley 1990; Gasser et al. 1988).

59. The nucleotide sequences of the *cp4 epsps* gene was modified by Monsanto for plant-preferred codon usage but these nucleotide substitutions did not alter the sequence of the encoded proteins. Roundup Ready® canola contains the same *cp4 epsps* gene as TruFlex™ Roundup Ready® canola. The expression of *cp4 epsps* is under the control of a chimeric constitutive promoter, P-FMV/Tsf1. This promoter contains enhancer sequences from the Figwort mosaic virus (FMV) 35S promoter and 479 bp of DNA from the promoter region of the *A. thaliana Tsf1* gene, which encodes elongation factor EF-1 alpha (Axelos et al. 1989; Richins et al. 1987). A leader and intron sequence derived from the Tsf1 gene are also included (Axelos et al. 1989). The inclusion of these sequences ensures strong and reliable constitutive expression of *cp4 epsps*.

60. In plants, aromatic amino acid synthesis occurs in the chloroplast (reviewed in Herrmann 1995; Tzin & Galili 2010). Plant EPSPS enzymes are synthesised by free cytoplasmic ribosomes as protein precursors, each containing a chloroplast transit peptide (CTP) at its N-terminal. 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). The bacterial *cp4 epsps* coding sequence in the GM canola line is engineered to be preceded by a CTP coding region, *ctp2*, from the *epsps* gene of *A. thaliana*. The *ctp2* sequence present in MON 88302 canola is the same as that used in Roundup Ready® Flex cotton and Roundup Ready® 2 Yield soybean.

61. The E9 3' mRNA terminator for *cp4 epsps* is the 3' non-translated region of the RubisCO small subunit *E9* gene derived from pea (*Pisum sativum*) (Coruzzi et al. 1984).

### Antibiotic resistance

62. The *nptII* gene has been transferred into lines Topas 19/2, MS1, RF1 and RF2. It is derived from transposon Tn5 from the bacterium *E. coli* (as described in detail by Beck et al. 1982) and codes for the ~29kD enzyme neomycin phosphotransferase (NPTII) conferring resistance to aminoglycoside antibiotics, such as kanamycin and neomycin. It was used as a selectable marker in the initial laboratory stages of development of the GM plants.

63. Expression of *nptII* is controlled by the nopaline synthase promoter (P-nos) from *A. tumefaciens* (Bevan et al. 1983) and the mRNA polyadenylation signals derived from the 3' non-translated region of the octapine synthase gene (3'-ocs) from *A. tumefaciens* (Dhaese et al. 1983).

### **6.1.3 Molecular characterisation of the GM parental lines MS8, RF3 and MON88302**

64. Molecular characterisation of the parental GM canola lines included Southern blot and PCR analyses, as well as molecular cloning and sequencing of the site of insertion. Stable integration and inheritance of the inserted DNA was demonstrated in all of the parental lines. DNA sequencing was used to verify the inserted genes and to determine the regions flanking all of the insertions sites.

65. In lines MS8 and MON 88302, a single insertion event occurred resulting in transfer of a single copy of the T-DNA. In line RF3, a single insertion event occurred that resulted in the

integration of one complete copy and a second, incomplete T-DNA copy that included a second copy of the *barstar* gene.

66. In the multiple field trials, breeding programs and seed production, there have been no reports of aberrant segregation and instability for either MS8, RF3 or TruFlex™ Roundup Ready® canola.

#### **6.1.4 Toxicity/allergenicity of the proteins encoded by the introduced genes**

##### BARNASE and BARSTAR proteins

67. The parental GM InVigor® canola lines have been approved for food and feed use as well as environmental release in Australia and overseas with no credible reports of adverse effects (Section 4).

68. The *barnase* and *barstar* genes were obtained from *Bacillus amyloliquefaciens*. *B. amyloliquefaciens* is used commercially as a source of industrial enzyme production, particularly  $\alpha$ -amylase, and is also used in the food industry for brewing and bread-making. Although some *Bacillus* species have been implicated as the causal agents of human diseases, *B. amyloliquefaciens* is not known to be allergenic or pathogenic towards humans.

69. BARNASE degrades ribonucleic acid into its component ribonucleotides. Ribonucleotides are ubiquitous in nature and are not considered toxic or allergenic. BARSTAR does not possess enzymatic activity but, instead, exerts its action by binding to the BARNASE enzyme to form an inactive complex. Therefore, the products of the enzymatic reactions catalysed by the novel proteins are also unlikely to be toxic or allergenic.

70. No sequence homology was found between BARNASE or BARSTAR and known toxins or allergens (EFSA 2009a; Rascle 2014b; Rascle 2014a; Rascle 2014b). BARNASE and BARSTAR do not have characteristics typical of known protein allergens (Van den Bulcke 1997) and no matches with known immunoglobulin E epitopes were found (Kleter & Peijnenburg 2002; Rascle 2014a; Rascle 2014b). Both proteins are rapidly degraded in simulated gastric juices (0.32% pepsin and acidic pH) with complete protein degradation within five minutes (Van den Bulcke 1997), showing that these proteins would not easily survive in the digestive tract.

##### PAT protein

71. The *bar* and *pat* genes have both been used extensively in the production of GM plants as selectable markers in the laboratory or to provide herbicide tolerance in the field.

72. The *bar* gene was obtained from the common soil bacteria *S. hygroscopicus*, the *pat* gene from *S. viridochromogenes*, both saprophytic, soil-borne microbes that are not considered pathogens of plants, humans or other animals (OECD 1999b).

73. PAT proteins have been previously assessed by the Regulator and they have been found to pose no substantial risk to people or the environment.

74. No sequence homology has been found between PAT and any known toxic or allergenic proteins (H rouet et al. 2005; Van den Bulcke 1997; EFSA 2009a; Pecoraro-Mercier 2014). The PAT proteins do not possess any of the characteristics associated with food allergens and they are not stable in simulated gastric or intestinal fluid conditions (Wehrmann et al. 1996; H rouet et al. 2005; ANZFA 2001; OECD 1999b) hence the potential for the PAT protein to be a food allergen is minimal (EPA 1997). In addition, PAT proteins are inactivated by heat, low pH and during processing of canola (European Scientific Committee on Plants 1998; EPA 1997; OECD 1999b; Wehrmann et al. 1996).

### CP4 EPSPS protein

75. A number of Australian and international regulatory bodies have assessed and authorised Roundup Ready canola for food and feed use (Section 4). The *cp4 epsps* gene is derived from the common soil bacteria, *Agrobacterium* sp. strain CP4 (Padgett et al. 1995), which is widespread in the environment and can be found on plant produce, especially raw vegetables. The CP4 EPSPS protein is functionally and structurally similar to EPSPS proteins naturally present in canola and in human food and animal feed derived from other plant and microbial sources (Nair et al. 2002).

76. The amino acid sequence CP4 EPSPS was compared to the amino acid sequences of known protein toxins and allergens and no significant homology was found (Harrison et al. 1996; Mitsky 1993). Further bioinformatic studies using updated databases have confirmed that the CP4 EPSPS protein does not share any similarity with any known toxins or allergens (EFSA 2009b; EFSA 2013). The CP4 EPSPS protein is readily inactivated by heat and rapidly degraded by simulated mammalian digestive conditions (OECD 1999a; Harrison et al. 1996; Chang et al. 2003).

### The NPTII protein

77. The *nptII* gene is used extensively as selectable markers in the production of GM plants (Miki & McHugh 2004). As discussed in previous DIR RARMPs, regulatory agencies in Australia and in other countries have assessed the use of the *nptII* gene in GMOs as not posing a risk to human or animal health or to the environment. An evaluation of NPTII by the European Food Safety Authority was in agreement with this conclusion (EFSA 2007).

#### **6.1.5 Toxicity of herbicide metabolites**

78. The potential toxicity of herbicide metabolites is considered by the Australian Pesticides and Veterinary Medicines Authority (APVMA) in its assessment of a new use pattern for particular herbicides, in this case glyphosate and glufosinate on InVigor® x TruFlex™ Roundup Ready® canola.

### Glufosinate metabolites

79. The herbicide glufosinate comprises a racemic (equal) mixture of the L- and D-enantiomers. The L-enantiomer is the active constituent and acts by inhibiting the enzyme glutamine synthase. D-glufosinate does not exhibit herbicidal activity and is not metabolised by plants (Ruhland et al. 2002).

80. The PAT enzyme, encoded by the *bar* gene, inactivates the L-isomer of glufosinate by acetylating it to N-acetyl- L- glufosinate (NAG), which does not inhibit glutamine synthase (Dröge-Laser et al. 1994; OECD 2002). This metabolite is not found in non-GM plants.

81. The metabolism of glufosinate in tolerant GM plants and in non-GM (non-tolerant) plants has been reviewed (OECD 2002; FAO & WHO 1998). In non-GM plants the metabolism of glufosinate is low to non-existent because of plant death due to the herbicidal activity. However, some metabolism does occur (Müller et al. 2001) and is different to that in GM plants expressing the PAT protein (Dröge et al. 1992).

82. Two pathways for the metabolism of glufosinate in non-GM plants have been identified. The first step, common to both pathways, is the rapid deamination of L-phosphinothricin to the unstable intermediate 4-methylphosphonico-2-oxo-butanoic acid, which is then metabolised to either:

- 3-methyl-phosphinico-propionic acid (MPP, sometimes referred to as 3-hydroxy-methyl phosphinoyl-propionic acid) which may be further converted to 2-methyl-phosphinico-acetic acid (MPA); or

- 4-methylphosphonico-2-hydroxy-butanoic acid (MHB), which may be further converted to 4-methylphosphonico-butanoic acid (MPB), a final and stable product (Dröge-Laser et al. 1994; Ruhland et al. 2002; Ruhland et al. 2004).

The main metabolite in non-GM plants is MPP (Müller et al. 2001; OECD 2002).

83. The metabolism of glufosinate has been investigated in GM herbicide-tolerant canola, maize, tomato, soybean and sugar beet (OECD 2002; FAO & WHO 1998). The major residue present in the GM crops after glufosinate herbicide application was *N*-acetyl-glufosinate (NAG), with lower concentrations of glufosinate and MPP. Studies using cell cultures of GM canola gave similar results, with NAG being the major metabolite (Ruhland et al. 2002).

84. Both NAG and MPP are less toxic than glufosinate, which itself has low toxicity (EFSA 2005; OECD 2002; OECD 1999b).

### Glyphosate metabolites

85. There is no expected difference in the metabolic fate of glyphosate in non-GM canola and in GM canola expressing the *cp4 epsps* gene. The CP4 EPSPS protein encoded by the *cp4 epsps* gene is naturally insensitive to the effects of glyphosate (Padgett et al. 1993), as are a number of other microbial EPSPS enzymes (Schulz et al. 1985; Eschenburg et al. 2002). Consequently, in GM plant cells with the *Agrobacterium cp4 epsps* gene, biosynthesis of aromatic amino acids is not inhibited in the presence of glyphosate. Therefore, no new metabolic products are formed in these GM plants as the only difference from the native EPSPS enzyme is the reduced affinity for glyphosate (OECD 1999a).

## **6.2 Toxicity/allergenicity of the parental GM canola lines**

86. The Regulator concluded in the RARMPs for the parental GM canola lines that they are as safe as non-GM canola. New or updated information since the original RARMPs is provided here.

87. Since the approval of these GM canola lines, there have been no credible reports of adverse effects to humans, livestock or other organisms (Section 4).

### **6.2.1 Toxicity/allergenicity to humans**

88. Canola oil is the only food product consumed by people, and oil from all GM parental lines has been approved for human consumption in Australia (ANZFA 2000; ANZFA 2001; FSANZ 2013) and other countries (Section 4).

89. People are exposed to canola pollen in the environment. Expression levels of the introduced proteins in pollen vary from undetectable for the PAT protein in RF1 and RF2 and the BARNASE and BARSTAR proteins in RF3, to 8 µg per g fwt for the CP4 EPSPS protein in TruFlex™ Roundup Ready® canola.

### **6.2.2 Toxicity to animals including livestock**

90. Canola meal is produced as a by-product during the extraction of oil from canola seed. It is a significant component and a rich source of protein in livestock feed in Australia. Unprocessed canola seed can also be used directly as animal feed. In addition, canola can be used as a dual-purpose crop in Australia, whereby it is used for forage prior to seed production (Kirkegaard et al. 2008).

91. Toasted canola meal is the most common fraction used as animal feed, although some meal (20%) is physically extracted without added heat. A small amount (5%) of canola meal available in Australia is from cold-pressed seed (Mailer 2004).

92. Glucosinolates and erucic acid are naturally occurring toxicants in canola seed. Glucosinolates remain in the canola meal after oil extraction while erucic acid is removed with

the oil fraction during processing of the seed. Previous compositional analyses demonstrated that the levels of erucic acid and glucosinolates in TruFlex™ Roundup Ready® canola and InVigor® canola lines were below the industry standard of 30 µmoles of glucosinolates per g and do not vary significantly from their parental cultivars or other commercially available canola.

93. The parental GM canola lines are compositionally equivalent to non-GM canola varieties, with no meaningful differences other than the presence of the introduced proteins, and feeding studies on a range of organisms demonstrate that there are no anti-nutritional effects of the genetic modifications in the parental GM canola lines (FSANZ 2013; ANZFA 2001).

### **6.2.3 Toxicity to other organisms**

94. A number of overseas regulatory agencies have assessed whether the parental GM canola lines have any increased toxicity to non-target organisms as a result of the genetic modifications. In its assessments of InVigor® canola lines MS8 and RF3, the USDA-APHIS determined that the GM canola lines would not harm threatened or endangered species or other organisms, such as bees, that are beneficial to agriculture (USDA-APHIS 1999c; USDA-APHIS 1999b; USDA-APHIS 1999a). The Canadian Food Inspection Agency (CFIA) concluded that the unconfined release of lines MS8 and RF3 would not result in altered impacts on interacting organisms, and that their potential impact on biodiversity is equivalent to that of currently commercialised canola varieties (Canadian Food Inspection Agency 1995; Canadian Food Inspection Agency 1996).

95. Regulatory assessments of GM canola and GM cotton plants that express the CP4 EPSPS protein have concluded that those plants would not harm arthropods. In its assessment of Roundup Ready Flex® cotton and Roundup Ready® canola, the USDA-APHIS determined that these GM plants would not harm threatened or endangered species, or other species (such as bees) that are beneficial to agriculture due to the lack of known toxicity of the CP4 EPSPS protein (USDA-APHIS 2004a; USDA-APHIS 1999b; USDA-APHIS 1999d; USDA-APHIS 2004b). One of these assessments notes that there are no reports of the CP4 EPSPS protein possessing any toxic properties, and exposure of a range of arthropods (eg bees, springtails, greenbugs, aphids) to tissues from a number of Roundup Ready® crops has not resulted in negative consequences (USDA-APHIS 2004b).

96. No significant differences were observed in a study evaluated in the [DIR 127](#) RARMP, between TruFlex™ Roundup Ready® canola and non-GM canola crops for the abundance of beneficial arthropods: chironomid midge, lacewings (Chrysopidae), ladybird beetles (Coccinellidae), micro- and macro-parasitic hymenoptera, miniature pirate bug (*Orius* spp.), spiders (Aranea) and sphecid wasps (Sphecidae).

97. The BARNASE and BARSTAR proteins are only expressed in the tapetal cell layer during anther development, so exposure to residues of these proteins from the GM plants is expected to be low.

98. Several studies investigated the effects of growing GM glyphosate tolerant canola or GM glufosinate tolerant canola on soil microbes. Slightly altered microbial communities in the rhizosphere of GM canola plants were reported, but these differences were minor and generally not sustained after removal of the GM plants (Dunfield & Germida 2001; Dunfield & Germida 2003; Gyamfi et al. 2002). In a review of more than 20 studies of the impact of GM plants on soil microbial communities, Dunfield and Germida (2004) concluded that impacts of GM plants on soil microbes were relatively variable and transient in comparison to other well-accepted agricultural practices such as crop rotation, tillage, herbicide usage and irrigation. Further, a number of authors have commented on the technical difficulties in measuring,

assessing and interpreting such effects of GM plants on soil microorganisms (O'Callaghan et al. 2005; Bruinsma et al. 2003; Weinert et al. 2010)

### 6.3 Method of genetic modification of the parental GM canola lines

99. InVigor® canola is derived from conventional breeding between GM canola lines which were developed using *Agrobacterium tumefaciens*-mediated transformation.

100. TruFlex™ Roundup Ready® canola was also developed using *A. tumefaciens*-mediated transformation.

101. Details regarding *A. tumefaciens*-mediated transformation are provided in the RARMPs for licence applications DIR 021/2002 and DIR 127, and also in the risk assessment reference document *Methods of plant genetic modification* which is available from the OGTR [Risk Assessment References](#) page.

### 6.4 Weediness of the parental GM canola lines

102. The weediness of the GM parental canola lines was assessed in the [DIR 021/2002](#) and [DIR 127](#) RARMPs as posing negligible risk, and no credible reports of adverse outcomes as a result of the authorised releases have been received (Section 4).

103. Multiple-herbicide tolerant individuals are as susceptible to alternative herbicides as single-herbicide tolerant canola plants or their non-GM counterparts (Beckie et al. 2004).

104. InVigor® canola hybrids have displayed yield increases of 10-20% over non-GM open pollinated varieties in Australia and greater than 20% in Canada (Clayton et al. 1999; Harker et al. 2003; Zand & Beckie 2002). However, the superior seedling emergence and increased seed numbers (Harker et al. 2003; Clayton et al. 1999) does not lead to the expected increase in volunteers in commercial fields in Canada (Beckie & Owen 2007) or in trials in the UK, due to greater uniformity in ripening (Crawley et al. 1993; MacDonald & Kuntz 2000; Sweet 1999). Data obtained in Australia indicate that the vigour exhibited by InVigor® canola hybrids falls within the range of vigour exhibited by non-GM hybrid and open pollinated varieties of canola grown commercially ([DIR 021/2002](#)).

105. The Conservation Council of Western Australia published a survey of roadside canola plants conducted by the Conservation Council (WA) Citizen Science Program, Esperance Local Environmental Action Forum and GM Cropwatch<sup>3</sup>. The survey was conducted in September 2011 to determine the frequency and distribution of GM Roundup Ready® canola plants in the Esperance region of WA after one year of commercial production. Among the 190 canola plants collected and tested, two GM positive plants were detected, representing ~1%. The area sown to GM canola was around 8% of the total canola crop in WA in 2010 (DAFWA 2010).

#### 6.4.1 Herbicide resistance

106. There is some potential for development of herbicide-resistant weeds if the parental GM canola lines and their corresponding herbicides are used inappropriately. The repetitious use of a single herbicide, or herbicide group<sup>4</sup>, increases the likelihood of selecting weeds that have developed herbicide resistance through natural mechanisms (Gressel 2002). Integrated weed management practices help to avoid selection of resistant weed biotypes (CropLife Australia 2011).

<sup>3</sup> Source: [Conservation Council of Western Australia](#) website; accessed 10 November 2015; page subsequently removed.

<sup>4</sup> Herbicides are classified into groups based on their mode of action. All herbicide product labels must display the mode of action group. This enables users to rotate among herbicides with different modes of action to delay the development of herbicide resistance in weeds.

107. Herbicide resistance comes under the regulatory oversight of the APVMA. The APVMA has primary regulatory responsibility for agricultural chemicals in Australia and operates the national system that evaluates, registers and regulates agricultural and veterinary chemical products. Any changes to a product that is already on the market must also be referred to the APVMA.

108. At least 37 weed species from around the world are reported to have resistance to glyphosate<sup>5</sup>. Glufosinate resistance has been reported for two weeds, ie *Eleusine indica* in Malaysia and *Lolium perenne* ssp *multiflorum* in the USA<sup>5</sup>.

109. Crop Management Plans (CMPs) have been developed separately by Bayer CropScience and Monsanto for InVigor® and Roundup Ready® canola, respectively (see also Section 8.1). These CMPs are required to be followed by canola growers when growing either InVigor® canola, Roundup Ready® canola or InVigor® x Roundup Ready® canola. The CMPs address issues such as minimising and managing canola volunteers in rotation crops following GM herbicide tolerant canola, and minimising the development of herbicide resistant weeds.

## Section 7 The GMOs proposed for release

### 7.1 Introduction to the GMOs

110. The main line proposed for release, InVigor® x TruFlex™ Roundup Ready® canola, is derived from conventional breeding between InVigor® canola lines MS8 and RF3 and TruFlex™ Roundup Ready® canola line MON 88302.

111. Bayer has indicated that the double stacks MS8 x MON 88302 and RF3 x MON 88302, created through conventional breeding, would be part of the commercial release, as these would be used in the seed production process. Crossing between the double stacks would yield InVigor® x TruFlex™ Roundup Ready® canola (MS8 x RF3 x MON 88302). Bayer has also indicated that the double stack RF3 x MON 88302 may be sold as a commercial product.

112. TruFlex™ Roundup Ready® canola hybrids or double stacks with lines MS1, RF1, RF2, T45 and Topas 19/2 may also be present. The focus of this evaluation is the MS8 x RF3 x MON 88302 canola. It will be described below.

113. The InVigor® x TruFlex™ Roundup Ready® canola will contain the *barnase* and *barstar* genes that comprise a hybrid breeding system; two copies of the *bar* gene conferring tolerance to glufosinate; the *cp4 epsps* gene that confers tolerance to glyphosate (Table 3); and the regulatory sequences associated with those genes.

**Table 3 The introduced genes present in the main GM canola hybrids proposed for release**

GM canola	Hybrid breeding system	Glufosinate tolerance	Glyphosate tolerance
MS8 x RF3 x MON 88302 (InVigor® x TruFlex™ Roundup Ready® canola)	<i>barnase</i> and <i>barstar</i> (2 copies)	<i>bar</i> (2 copies)	<i>cp4 epsps</i>
MS8 x MON 88302	<i>barnase</i>	<i>bar</i>	<i>cp4 epsps</i>
RF3 x MON 88302	<i>barstar</i> (2 copies)	<i>bar</i>	<i>cp4 epsps</i>

<sup>5</sup> Sources: [International Survey of Herbicide Resistant Weeds website](#), accessed 10 November 2015; Green et al. (2008).

## 7.2 Characterisation of the GMOs

114. The GMOs proposed for release were authorised for a field trial under licence [DIR 104](#); however, as application DIR 104 proposed strict limits and controls, detailed phenotypic data were not provided at the time. No planting occurred under the DIR 104 field trial licence.

115. Extensive data characterising the parental GM canola lines were provided with licence applications [DIR 021/2002](#) and [DIR 127](#). More information on the lines authorised under DIR 021/2002 was provided with licence application [DIR 108](#). Licence DIR 108 authorises the commercial release of GM InVigor® x Roundup Ready® canola. In addition, Bayer has provided nine reports characterising the MS8 x RF3 x MON 88302 canola proposed for commercial release. Relevant reports are described below.

### 7.2.1 Stability and molecular characterisation

116. Southern blot analysis was used to demonstrate the molecular equivalence of the MS8, RF3 and MON 88302 events in InVigor® x TruFlex™ Roundup Ready® canola to the same events in the individual parental lines. These confirm the intactness of the GM loci and their flanking regions in InVigor® x TruFlex™ Roundup Ready® canola, indicating that no rearrangement occurred during conventional breeding (Skottke et al. 2015).

### 7.2.2 Levels of the introduced proteins in the GM canola

117. The applicant has supplied two studies regarding the expression levels of CP4 EPSPS, PAT and BARNASE proteins and the BARSTAR proteins, respectively. Expression levels were determined by enzyme-linked immunosorbent assays from MON 88302 x MS8 x RF3, MON 88302 x RF3, MON 88302 x MS8, MON 88302, MS8 and RF3 canola plants (New 2013; New 2014). For each study, the plants were grown in two field sites in Chile (2011-2012) and four field sites North America (2012). Expression levels were determined in leaves at two different developmental stages, roots, grain (seed), forage, immature inflorescence and pollen. The applicant provided the data as average protein level on a fresh weight and dry weight basis; the data on a fresh weight basis for CP4 EPSPS and PAT are provided in Table 4.

118. The average expression of BARNASE in MON 88302 x MS8 x RF3 canola pollen was  $0.138 \pm 0.017 \mu\text{g/g}$  fwt. The *barnase* gene is driven by the *PTa29* promoter that restricts gene expression to the tapetum cells during anther development. As expected, the expression of BARNASE in all plant parts tested except pollen was either below the lower limit of quantitation or below the limit of detection.

119. Similarly, the *barstar* gene was only expressed in immature inflorescences with  $0.0983 \pm 0.026$  (ranging from 0.0500 to 0.145) in RF3,  $0.0379 \pm 0.0088$  (ranging from 0.0263 to 0.0561) in MON 88302 x MS8 x RF3 and  $0.104 \pm 0.022$  (ranging from 0.0566 to 0.131) in MON 88302 x RF3. This is consistent with a previous study of the parental GM canola line RF3, and the two highly similar lines RF1 and RF2, where expression of the *barstar* gene was confirmed by the phenotype of the RF x MS crosses, ie the plants were fully fertile with normal anther development. The three RF lines were investigated by Northern blot analysis and *barstar* mRNA was detected in flower buds, but not in leaves, pollen or dry seed (Appendix 1, Section 6.3, RARMP for DIR 021/2002).

**Table 4 Average fresh weight and range for the introduced CP4 EPSPS and PAT proteins**

Tissue	Line/stack	CP4 EPSPS protein in $\mu\text{g/g}$ fwt $\pm$ SD (range)	PAT protein in $\mu\text{g/g}$ fwt $\pm$ SD (range)
Leaf (3 to 4 unfolded leaf stage)	MS8	Not applicable	$9.00 \pm 1.9$ (6.51 – 12.7)
	RF3	Not applicable	$17.8 \pm 4.6$ (3.49 – 24.7)
	MON 88302	$20.1 \pm 3.8$ (13.2 – 29.3)	Not applicable



Tissue	Line/stack	CP4 EPSPS protein in $\mu\text{g/g fwt} \pm \text{SD}$ (range)	PAT protein in $\mu\text{g/g fwt} \pm \text{SD}$ (range)
	MON 88302 x MS8 x RF3	$17.4 \pm 3.9$ (11.7 – 24.9)	$12.7 \pm 3.5$ (8.53 – 21.2)
	MON 88302 x MS8	$12.1 \pm 2.4$ (8.55 – 16.3)	$9.50 \pm 2.1$ (6.00 – 13.2)
	MON 88302 x RF3	$31.7 \pm 6.6$ (24.3 – 45.9)	$15.0 \pm 3.4$ (11.2 – 22.9)
Leaf (7 to 9 unfolded leaf stage)	MS8	Not applicable	$7.53 \pm 2.7$ (1.84 – 13.5)
	RF3	Not applicable	$14.5 \pm 2.9$ (9.93 – 20.5)
	MON 88302	$31.7 \pm 9.5$ (11.9 – 53.8)	Not applicable
	MON 88302 x MS8 x RF3	$18.7 \pm 6.1$ (5.69 – 28.7)	$9.40 \pm 4.3$ (3.30 – 18.0)
	MON 88302 x MS8	$15.3 \pm 3.4$ (9.19 – 20.9)	$8.00 \pm 1.8$ (4.15 – 12.1)
	MON 88302 x RF3	$41.9 \pm 14$ (12.8 – 76.4)	$14.9 \pm 4.1$ (7.98 – 25.8)
Root	MS8	Not applicable	Not determined
	RF3	Not applicable	$0.415 \pm 0.12$ (0.263 – 0.669)
	MON 88302	$14.0 \pm 2.9$ (8.93 – 19.5)	Not applicable
	MON 88302 x MS8 x RF3	$8.18 \pm 1.9$ (4.57 – 11.3)	$0.241 \pm 0.060$ (0.115 – 0.355)
	MON 88302 x MS8	$7.46 \pm 1.3$ (4.52 – 9.63)	Not determined
	MON 88302 x RF3	$14.2 \pm 3.2$ (9.50 – 21.5)	$0.408 \pm 0.095$ (0.263 – 0.579)
Forage (above ground portion of the plant)	MS8	Not applicable	$3.42 \pm 0.68$ (2.31 – 4.49)
	RF3	Not applicable	$7.30 \pm 1.4$ (5.05 – 9.31)
	MON 88302	$16.9 \pm 2.3$ (13.7 – 23.5)	Not applicable
	MON 88302 x MS8 x RF3	$10.9 \pm 1.5$ (8.28 – 13.5)	$4.67 \pm 1.2$ (2.75 – 7.14)
	MON 88302 x MS8	$9.09 \pm 1.1$ (7.47 – 10.7)	$3.21 \pm 0.71$ (2.10 – 4.69)
	MON 88302 x RF3	$21.2 \pm 2.3$ (17.6 – 25.8)	$6.33 \pm 1.1$ (4.34 – 9.00)
Grain	MS8	Not applicable	$0.301 \pm 0.092$ (0.206 – 0.464)
	RF3	Not applicable	$1.08 \pm 0.18$ (0.808 – 1.38)
	MON 88302	$33.5 \pm 3.3$ (28.4 – 40.0)	Not applicable
	MON 88302 x MS8 x RF3	$27.4 \pm 2.4$ (21.8 – 32.6)	$0.708 \pm 0.15$ (0.441 – 0.924)
	MON 88302 x MS8	$15.5 \pm 3.3$ (10.5 – 19.4)	$0.361 \pm 0.085$ (0.237 – 0.495)
	MON 88302 x RF3	$30.0 \pm 3.0$ (25.0 – 36.9)	$0.796 \pm 0.17$ (0.517 – 1.10)
Raceme (immature inflorescence)	MS8	Not applicable	$4.87 \pm 1.1$ (3.26 – 7.21)
	RF3	Not applicable	$10.9 \pm 1.6$ (8.54 – 13.8)
	MON 88302	$15.5 \pm 2.4$	Not applicable

Tissue	Line/stack	CP4 EPSPS protein in $\mu\text{g/g fwt} \pm \text{SD}$ (range)	PAT protein in $\mu\text{g/g fwt} \pm \text{SD}$ (range)
		(9.35 – 19.3)	
	MON 88302 x MS8 x RF3	$30.1 \pm 3.7$ (23.7 – 38.2)	$7.41 \pm 1.3$ (5.21 – 10.0)
	MON 88302 x MS8	$32.5 \pm 3.9$ (25.1 – 40.8)	$4.59 \pm 1.4$ (2.72 – 7.03)
	MON 88302 x RF3	$16.2 \pm 1.8$ (13.4 – 19.7)	$10.3 \pm 1.3$ (7.87 – 12.7)
Pollen*	MS8	Not applicable	Not applicable
	RF3	Not applicable	Not included
	MON 88302	Not included	Not applicable
	MON 88302 x MS8 x RF3	$6.86 \pm 0.55$ (6.42 – 7.47)	$0.0913 \pm 0.00060$ (<LOD – 0.102)
	MON 88302 x MS8	Not applicable	Not applicable
	MON 88302 x RF3	$10.4 \pm 4.3$ (7.19 – 15.3)	$0.302 \pm 0.28$ (<LOD – 0.501)

SD: standard deviation; <LOD: value below the limit of detection; Not determined: most raw data values were below the lower limit of quantitation or below the limit of detection; Not included: sample was not included in the experiment. \*Note that MS8 lines that have not been crossed with an RF line cannot produce pollen.

### 7.2.3 Phenotypic characterisation and environmental interaction

120. Phenotypic characterisation (including agronomic characters) and environmental interaction data were collected from field trials conducted in 2012 at three sites in Canada and three in the USA. These studies are relevant to the Australian environment as they demonstrate how the GM canola lines behaved in the field compared to non-GM canola. The trial sites provided a range of environmental and agronomic conditions representative of those commercial canola production regions. The MS8 and RF3 lines have been backcrossed into the non-GM canola variety Ebony. Therefore, the non-GM canola variety Ebony was included in the studies regarding the phenotypic characterisation and environmental interaction discussed below. InVigor® x TruFlex™ Roundup Ready® canola, the non-GM canola variety Ebony and four additional commercial non-GM reference varieties were evaluated at each site. Across the sites, 14 different non-GM reference varieties were evaluated.

121. InVigor® x TruFlex™ Roundup Ready® canola was compared to the non-GM canola variety Ebony across sites (combined-site analyses) and within each site (individual-site analyses). The applicant has indicated that the assessment of the overall field observations and dataset indicate that the phenotypic characteristics and environmental interactions of InVigor® x TruFlex™ Roundup Ready® canola were typical for canola grown in the USA and Canada (Moon et al. 2013). Summaries of these studies are provided below.

#### Phenotypic characterisation

122. Eleven phenotypic characteristics were assessed using analysis of variance (ANOVA). An additional characteristic, plant vigour, was assessed and summarised within each site (individual-site analyses) to provide a general assessment of field conditions, but not statistically analysed.

123. In the combined-site analyses, there were no statistically significant differences between InVigor® x TruFlex™ Roundup Ready® canola and Ebony for the characteristics early stand count, days to first flowering, male fertility, plant height, seed maturity pre-harvest, lodging, pod shattering, seed moisture, seed quality and yield. There was significant difference between InVigor® x TruFlex™ Roundup Ready® canola and Ebony in the combined-site analysis for final stand count (18.0 vs. 15.7 plants per linear metre, respectively). However, as the mean

value of InVigor® x TruFlex™ Roundup Ready® canola was within the non-GM reference range for final stand count (10.9 – 24.0 plants per linear metre), it is unlikely the difference in final plant stand would contribute to increased weed risk potential for InVigor® x TruFlex™ Roundup Ready® canola compared to Ebony or the other non-GM reference varieties.

124. Although statistical differences were detected in the individual-site analyses for days to first flower, plant height, seed maturity pre-harvest, lodging, pod shattering and yield (Table 5), these differences were not detected in the combined-site analysis. Thus, these differences at individual sites do not indicate a consistent response associated with the trait and are unlikely to be biologically meaningful in terms of increased weed risk potential of the GM canola compared to Ebony and the conventional reference varieties.

**Table 5. Significant differences in phenotypic characters at individual sites.**

Characteristic (site code)	Ebony (non-GM canola)	InVigor® x TruFlex™ Roundup Ready® canola
Days to first flower (NDGR)	54.8 days	50.0 days
Plant height (NDGR)	100.5 cm	122.4 cm
Seed maturity pre-harvest (NDVA)	94.8%	98.3%
Lodging (MBPL)	3.3 rating	1.5 rating
Pod shattering (MBPL)	1.0 rating	3.5 rating
Yield (MBPL)	0.9 t/ha	0.6 t/ha
Final stand count (MBPL)	12.3 plants per linear metre	15.4 plants per linear metre
Final stand count (NDGR)	10.4 plants per linear metre	15.2 plants per linear metre

125. Statistical differences were also detected for final stand count in two individual sites. However, as discussed above, the mean value of InVigor® x TruFlex™ Roundup Ready® canola for final stand count in the combined-site analysis was within the range of values for the commercial reference varieties. Thus, the difference in final stand count is unlikely to be biologically meaningful in terms of increased weed risk potential of InVigor® x TruFlex™ Roundup Ready® canola compared to Ebony and the other non-GM reference varieties.

### Environmental interaction

126. Environmental interaction refers to the interaction between the crop plants and their receiving environment. The environmental interaction data collected included plant response to abiotic stressors, disease and arthropod damage. At least three abiotic stressors, three diseases and three arthropod pests were evaluated at four intervals during the growing season. The four intervals were the seedling to rosette stage, bud to first flowering stage, full flower to flower completion stage and pod development stage.

127. As the collected environmental interaction data was categorical, it was not subject to statistical analysis. For the qualitative assessment of the abiotic stress response, disease damage and arthropod damage, the GM canola and Ebony were considered different in susceptibility or tolerance if the range of injury of each did not overlap across all four replications within a site. Observed differences were then assessed for biological significance in the context of the range of the commercial non-GM reference varieties and for consistency in other observation times

and sites. Differences that were not consistently observed in multiple environments were considered not biologically meaningful in terms of weed risk potential.

#### Abiotic stress tolerance

128. Canola plants were scored for their response to the following abiotic stresses: cold, drought, frost, hail, heat, nutrient deficiency, soil compaction, wet soil and wind, with a total of 72 observations made across all sites.

129. In individual-site assessments, there were no differences observed between InVigor® x TruFlex™ Roundup Ready® canola and Ebony for 71 of the 72 comparisons. The only difference observed was for drought response at one site during the bud to first flowering stage (none vs. slight-moderate for the GM canola and Ebony, respectively). However, the rating for InVigor® x TruFlex™ Roundup Ready® canola was within the range of the non-GM reference varieties (none to moderate) at this site. Additionally, this difference was not observed in any of the other 13 observations across the sites. Thus, this observation is unlikely to be biologically meaningful in terms of increased weed risk potential of InVigor® x TruFlex™ Roundup Ready® canola compared to Ebony and the other non-GM reference varieties.

#### Disease damage

130. Canola plants were scored for damage from the following diseases: *Alternaria* black spot, aster yellows, blackleg, clubroot, damping-off, downey mildew, *Fusarium* wilt, powdery mildew, root rot complex, *Sclerotinia* stem rot, seedling blight, seedling disease complex and white leaf spot. A total of 72 observations were made across all sites. Individual-site analysis showed no differences between InVigor® x TruFlex™ Roundup Ready® canola compared to Ebony in their response to disease damage.

#### Arthropod damage

131. Canola plants were scored for damage from the following insects: arthropods, including aphids, bertha armyworms, cabbage seedpod, weevils, cabbage worms, crucifer flea beetles, cutworms, diamondback moths, grasshoppers, loopers, lygus bugs, red turnip beetles, slugs, swede midges, and thrips. A total of 70 observations were made across all sites. Individual-site analysis showed no differences between InVigor® x TruFlex™ Roundup Ready® canola compared to Ebony in their response to arthropod damage.

132. Of the 214 environmental interaction comparisons between InVigor® x TruFlex™ Roundup Ready® canola and Ebony described above, only one difference was observed (ie one observation on drought tolerance at one site). This one observation was unlikely to be biologically meaningful, thus InVigor® x TruFlex™ Roundup Ready® canola is unlikely to have an increased weed risk potential compared to Ebony and the conventional reference varieties.

#### **7.2.4 Compositional analysis**

133. The composition of InVigor® x TruFlex™ Roundup Ready® canola (treated with herbicides glufosinate and glyphosate) was compared to Ebony (an untreated non-GM variety) with a similar genetic background (Breeze et al. 2013). Analysis was conducted on seed of the GM canola, Ebony and a total of 14 different non-GM reference varieties grown at six sites in the USA and Canada during 2012. The 14 non-GM reference varieties were included in the analysis to provide a reference on the natural variability for each compositional component. The canola was grown under normal agronomic field conditions for their respective geographic regions, these areas being typical for canola cultivation in the USA and Canada.

134. Compositional analysis of the canola seed samples were conducted for nutrients including proximates (ash, fat, moisture and protein), carbohydrates by calculation, acid

detergent fibre, neutral detergent fibre, crude fibre, amino acids, fatty acids (C8-C24, including erucic acid), vitamin E ( $\alpha$ -tocopherol), vitamin K<sub>1</sub> (phylloquinone) and minerals (calcium, chloride, copper, iron, magnesium, manganese, molybdenum, phosphorus, potassium, sodium, sulfur, and zinc). The anti-nutrients assessed in canola seeds included glucosinolates, phytic acid, sinapine and tannins. In all, 71 different analytical components were measured in canola seeds. Of these, ten had more than 50% of the observations below the assay limit of quantitation and as a result, were excluded from the statistical analyses. Moisture values were measured for conversion of component values to dry weight basis and thus were not statistically analysed. Therefore, 60 compositional components were included in the statistical analyses, which are summarised below.

#### Seed protein and amino acids

135. There were no significant differences in seed protein and amino acid content (18 amino acids measured) between InVigor® x TruFlex™ Roundup Ready® canola and Ebony, suggesting that the genetic modification was not a major contributor to variation in protein and amino acid levels in canola seed and confirmed the similarity of the GM canola to Ebony for these components.

#### Total fat and fatty acids

136. There were no significant differences in seed total fat and fatty acid content between InVigor® x TruFlex™ Roundup Ready® canola and Ebony. The fatty acids included in the analysis were: myristic, palmitic, palmitoleic, heptadecanoic (17:0), heptadecenoic (17:1), stearic, oleic, linoleic, linolenic, arachidic, eicosenoic, eicosadienoic, behenic, lignoceric and nervonic.

137. The above data suggests that the genetic modification was not a major contributor to variation in protein and amino acid levels in canola seed and confirmed the similarity of the GM canola to Ebony for these components.

#### Carbohydrates by calculation and fibre

138. In addition to protein and fat, carbohydrates by calculation and fibre (acid detergent fibre, neutral detergent fibre and crude fibre) comprise the major biomass components of the canola seed. These values are measures of most of the structural plant cell components of the forage (in this case seed or seed meal) such as cellulose, hemicellulose and lignin, which are important determinants in the ability of an animal to digest the forage. There were no significant differences in carbohydrate and fibre content between InVigor® x TruFlex™ Roundup Ready® canola and Ebony.

#### Ash and minerals

139. The major mineral elements in canola are calcium, phosphorus, magnesium, potassium and sodium; and trace elements include chloride, iron, manganese, sulphur, molybdenum, zinc and copper. All of these major and trace elements are constituents of ash. There were no significant differences in the major and minor mineral content between InVigor® x TruFlex™ Roundup Ready® canola and Ebony. However, there was a significant difference between the GM canola and Ebony for overall ash content (4.08% vs. 3.84% on a dry weight (dwt) basis, respectively).

140. The difference in mean ash content (0.25%) between the GM canola and Ebony is considerably less than the mean range for Ebony, which was 1.18% (ranging from 3.20 to 4.38%). This suggests that the genetic modification has much less of an impact on ash levels than natural variation for Ebony grown at multiple locations. The mean ash content falls within both the 99% tolerance interval of the conventional reference canola varieties (3.20 to 4.78%)

and the historical range from the literature (3.36 to 6.02%). It can, therefore, be concluded that the observed difference in ash content between InVigor® x TruFlex™ Roundup Ready® canola and Ebony is not compositionally meaningful from a food and feed perspective.

### Vitamins

141. Canola oil contains mainly alpha- and gamma-tocopherols (Vitamin E) which are natural antioxidants. Canola, soybean and olive oils are good sources of vitamin K<sub>1</sub> (phyloquinone), the second most substantial contributors of vitamin K<sub>1</sub> to the human diet after leafy green vegetables (OECD 2011). There was no significant difference observed for vitamin K<sub>1</sub>, but there was a significant difference between InVigor® x TruFlex™ Roundup Ready® canola and Ebony for vitamin E (only alpha-tocopherol levels were measured).

142. The mean value for vitamin E was 0.10 mg/g dwt for InVigor® x TruFlex™ Roundup Ready® canola and 0.094 mg/g dwt for Ebony, a difference of 0.0093 mg/g dwt. In the context of Ebony (range from 0.083 to 0.10 mg/g dwt, a span of 0.02 mg/g dwt<sup>6</sup>), the mean difference between the GM canola and Ebony was less than the range of values for Ebony at multiple locations. This suggests the genetic modification has less of an impact on vitamin E levels than natural variation for Ebony. The mean difference in vitamin E values was also less than the variability observed in the conventional reference varieties (range from 0.058 to 0.18 mg/g dwt, a span of 0.122 mg/g dwt). The mean vitamin E value for InVigor® x TruFlex™ Roundup Ready® canola was also within the 99% tolerance interval of the conventional reference varieties (0.014 to 0.20 mg/g dwt). It can, therefore, be concluded that the observed difference in vitamin E content between InVigor® x TruFlex™ Roundup Ready® canola and Ebony is not compositionally meaningful from a food and feed perspective.

### Anti-nutrient levels

143. Anti-nutrients assessed in the canola seed were glucosinolates, phytic acid, sinapine and tannins (total).

#### Glucosinolates

144. Industry standards require canola meal to be low in glucosinolates (total glucosinolates of 30 µmoles g<sup>-1</sup>) in toasted oil free meal (OECD 2001). Metabolites of glucosinolate can affect animal performance and can be toxic to the liver and kidneys (OECD 2011). There was no significant difference observed for glucosinolate levels between InVigor® x TruFlex™ Roundup Ready® canola and Ebony.

#### Phytic acid

145. Phytic acid (or phytate in salt form) is the main storage form of phosphorus in many plant tissues. The binding capabilities of phytic acid results in less bio-availability of phosphorus for monogastric animals because they lack the digestive enzyme phytase, required to cleave phosphorus from the phytate molecule. Strong binding affinity between phytic acid and minerals such as calcium, magnesium, iron and zinc can also reduce the absorption of these minerals (OECD 2011).

146. The mean value for phytic acid was 1.82% dwt for InVigor® x TruFlex™ Roundup Ready® canola, which was significantly different from Ebony (1.57% dwt), a difference of 0.25% dwt. In the context of the phytic acid for Ebony (range from 1.04 to 2.27%, a span of 1.23% dwt), the mean difference in phytic acid is less than the range of values for Ebony grown at multiple locations. This suggests the genetic modification has less of an impact on phytic acid than natural variation for Ebony. The mean difference in phytic acid values was

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<sup>6</sup>The data provided rounded the mean difference of 0.017 to two decimal points (ie 0.02).

also less than the variability observed in the other non-GM reference varieties (range from 0.94 to 2.27%, a span of 1.33% dwt). The mean phytic acid value for InVigor® x TruFlex™ Roundup Ready® canola was also within the 99% tolerance interval of the other non-GM reference varieties (0.76 to 2.41% dwt).

### Sinapine

147. Sinapine is the principal phenolic compound in canola. Most animals have the ability to convert sinapine into an excretable compound, trimethylamine oxide. However, some animals such as laying hens, are not readily able to catabolise trimethylamine, resulting in a fishy odour and flavour in the eggs (OECD 2011).

148. A statistically significant difference (0.053% dwt) was found between the mean values for sinapine in InVigor® x TruFlex™ Roundup Ready® canola (1.03% dwt) compared to Ebony (0.97% dwt). However, in the context of the sinapine value for Ebony (range from 0.80 to 1.10% dwt, a span of 0.30% dwt), the mean difference for sinapine is less than the range of values for Ebony grown at multiple locations. This suggests the genetic modification has less of an impact on sinapine than the natural variation within Ebony. The mean difference in sinapine was also less than the variability seen in the conventional reference varieties (range from 0.47 to 1.28% dwt, a span of 0.81% dwt). The mean sinapine value for InVigor® x TruFlex™ Roundup Ready® canola was also within the 99% tolerance interval of the conventional reference varieties (0.32 to 1.50% dwt) and values reported in the literature (0.772 to 1.153% dwt).

### Tannins

149. Tannins are complex phenolic compounds that can reduce digestibility by binding to proteins and some complex carbohydrates (OECD 2011).

150. The mean value for total tannins was 0.55% dwt for InVigor® x TruFlex™ Roundup Ready® canola and 0.66% dwt for Ebony. This difference (0.11% dwt) was statistically significant. However, in the context of the total tannins value for Ebony (range from 0.32 to 1.00% dwt, a span of values, 0.68% dwt), the mean difference for total tannins is less than the range of values for Ebony grown at multiple locations. This suggests the genetic modification has less of an impact on total tannins than the natural variation for Ebony. The mean difference in total tannins was also less than the variability seen in the reference canola varieties (range 0.23 to 0.96% dwt, a span of 0.73% dwt). The InVigor® x TruFlex™ Roundup Ready® canola mean total tannin value was also within the 99% tolerance interval of the reference varieties (0.060 to 0.98% dwt).

151. For the above anti-nutrients, the observed differences in phytic acid, sinapine and total tannins content between InVigor® x TruFlex™ Roundup Ready® canola and Ebony is small relative to the variation observed in the values for Ebony grown at multiple locations. Further, the mean values for these components were within the 99% tolerance interval of the conventional reference varieties. Thus, the observed differences are not compositionally meaningful from a food and feed perspective.

## **Section 8 The receiving environment**

152. The receiving environment forms part of the context in which the risks associated with dealings involving the GMOs are assessed. Relevant information about the receiving environment includes abiotic and biotic interactions of the crop with the environment where the release would occur; agronomic practices for the crop; presence of plants that are sexually compatible with the GMO; and background presence of the gene(s) used in the genetic modification (OGTR 2013).

153. The applicant has proposed to release InVigor® x TruFlex™ Roundup Ready® canola in all commercial canola growing areas, Australia-wide. Therefore, for this licence application, it is considered that the receiving environment is all of Australia but in particular agricultural areas that are suitable to cultivate canola. Canola growing areas are mainly in the Australian winter cereal belt of NSW, Vic, SA and WA. Small quantities of canola are grown in southern QLD and Tas (OGTR 2011). The actual locations, number of sites and area of land used in the proposed release would depend on factors such as field conditions, grower demand and seed availability.

### 8.1 Relevant agronomic practices

154. In Australia, canola is commonly grown in rotation with wheat as the following crop. Canola is 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 in cool regions with high water availability. Canola has higher requirements for nitrogen, phosphorus and sulphur than most other crops so fertiliser application is important. Canola is harvested either by windrowing (swathing) or less commonly by direct harvesting. Windrowing involves cutting the crop and placing it in rows to dry. After 1-2 weeks, when most of the seed has matured and the moisture content is under 9%, the windrow is picked up by the harvester. Standard cultivation practices for canola are discussed in more detail in the OGTR canola biology document (OGTR 2011) and the Canola best practice management guide for south-eastern Australia (GRDC 2009).

155. It is anticipated that agronomic practices for the cultivation of the GMOs proposed for release would not differ from standard industry practices. Glyphosate and/or glufosinate may be applied over the top of the GM canola crop to control weeds, in the same manner that herbicides are applied over other herbicide tolerant canola varieties grown in Australia. Herbicides would be applied according to label directions approved by the APVMA. The APVMA assesses all herbicides used in Australia and sets their conditions of use. It should be noted that the Regulator will not consider issues relating to efficacy of the herbicide or resistance management as these issues most appropriately fall under the Agricultural and Veterinary Chemicals Code Act 1994, and as such are the responsibility of the APVMA.

156. Crop Management Plans (CMP) have been developed separately for InVigor® and TruFlex™ Roundup Ready® canola that farmers growing the GM canola would be required to follow. Bayer has indicated they will need to make an application to the APVMA to change the current Liberty® and Roundup® herbicide labels to include use on InVigor® x TruFlex™ Roundup Ready® canola.

### 8.2 Relevant abiotic factors

157. The geographical distribution of commercial canola cultivation in Australia is limited by a number of abiotic factors, the most important being water availability. Canola is generally grown as a winter crop in dominant winter rainfall environments that receive more than 400 mm rainfall per year. It can be grown in lower-rainfall zones as an opportunistic crop when there is good subsoil moisture, or at low plant population densities to reduce water requirements. Germination of seed will only occur if there is sufficient soil moisture, and drought stress after anthesis can significantly reduce yield due to abortion of seed and reduced pod numbers. Canola is also sensitive to waterlogging, which restricts root development (GRDC 2009; Walton et al. 1999).

158. Other abiotic stresses that can reduce canola yields include frost, particularly during early pod development, and heat stress (GRDC 2009).



## 8.3 Relevant biotic factors

### 8.3.1 Presence of related plants in the receiving environment

159. Canola is predominantly self-pollinating, with an average of approximately 70% of canola seeds resulting from self-fertilisation. However, outcrossing between canola plants can be mediated by insects, wind or physical contact. Outcrossing frequencies between immediately adjacent fields of canola are highest in the first 10 m of the recipient fields, with rates averaging about 1.8% over this area, and rates decline with distance (Husken & Dietz-Pfeilstetter 2007). Under Australian conditions, a large study found that outcrossing rates between neighbouring commercial canola fields were less than 0.1% averaged over whole fields (Rieger et al. 2002).

160. Canola can cross with other *B. napus* subspecies including forage rape and vegetables such as swedes if there is synchronicity of flowering. Brassica vegetables are generally harvested prior to flowering unless they are grown for seed production, in which case precautions would usually be taken to avoid crossing with oilseed canola (OGTR 2011).

161. Canola can spontaneously cross with the related crop species *B. juncea* (Indian mustard) and *B. rapa* (including turnips) (Liu et al. 2010; Warwick et al. 2003), and there is one report of field crosses with the crop species *B. oleracea* (including cabbage, cauliflower and broccoli) (Ford et al. 2006). Of these, Juncea canola (*B. juncea*) is grown in Australia as a broad-acre crop similar to canola, though at much smaller scale, and typically in low rainfall regions that are marginally suitable for canola (GRDC 2009). Horticultural crops that are variants or subspecies of *B. napus*, *B. juncea*, *B. rapa* or *B. oleracea* are also commercially grown in Australia.

162. Under open pollination conditions, naturally occurring hybrids between *B. napus* and the related weedy species *Raphanus raphanistrum* and *Hirschfeldia incana* have been reported at very low frequencies (Darmency et al. 1998; Darmency & Fleury 2000). *R. raphanistrum* (wild radish) is a serious agricultural weed widespread in all states and territories except the NT. *H. incana* (Buchan weed) is a common roadside weed found in QLD, NSW, Vic, Tas and SA<sup>7</sup>.

163. Canola is widely grown as a commercial crop in Australia. Most of the canola crop is herbicide tolerant with one of three different herbicide tolerance traits. In 2015, the Australia canola crop comprised approximately 60% triazine tolerant (TT), 15% imidazolinone tolerant (Clearfield®), 20% Roundup Ready® and 5% non-herbicide tolerant canola varieties (Nick Goddard, Australian Oilseeds Federation, personal communication, 2015). The amount of each type of canola would vary from state to state, eg in 2014 the WA canola crop comprised approximately 83% TT canola, 3% Clearfield®, 1% non-herbicide tolerant and 13% Roundup Ready® varieties (Bucat 2014).

164. TT canola varieties were obtained by conventional breeding (they are not GM) and have resistance to Group C triazine herbicides. TT canola was the first type of herbicide tolerant canola introduced to Australia, and became very popular despite a significant yield penalty associated with the trait (Pritchard 2014).

165. Clearfield® canola varieties are conventionally bred and have resistance to Group B imidazolinone herbicides. The Clearfield® trait is also available in Juncea canola (*Brassica juncea* or Indian mustard, discussed below) (DPI NSW 2013).

166. Roundup Ready® canola varieties are genetically modified and were approved for commercial release by the Regulator (DIR 020/2002). They have tolerance to glyphosate herbicide (Group M). Dual herbicide tolerant RT® canola, which is a cross between Roundup Ready® and TT canola, was released in 2015 ([Pacific Seeds website](#)). TruFlex™ Roundup Ready® canola, a variant of Roundup Ready® canola with a longer spray window, has been

<sup>7</sup> Source: Department of the Environment – [National weeds lists website](#); accessed on 12 November 2015.

approved for commercial release by the Regulator ([DIR 127](#)), but has not yet entered commercial production in Australia.

167. GM InVigor® canola, which has tolerance to Group N glufosinate herbicide, was approved for commercial release by the Regulator either alone (DIR 021/2003) or combined with Roundup Ready® canola ([DIR 108](#)). However, these canola varieties have only been grown on a limited scale for breeding work and not yet entered commercial production in Australia.

### **8.3.2 Presence of other biotic factors**

168. A number of diseases have the potential to significantly reduce the yield of canola. Blackleg disease caused by the fungal pathogen *Leptosphaeria maculans* is the most devastating disease affecting commercial canola production in Australia. Blackleg is managed by choosing cultivars with high blackleg resistance ratings and by planting canola at least 500 m from the previous year's stubble, which carries blackleg spores. Other damaging diseases of canola include stem rot caused by the fungus *Sclerotinia sclerotiorum* and damping-off caused mainly by the fungus *Rhizoctonia solani* (Howlett et al. 1999; GRDC 2009).

169. Canola is most susceptible to insect pests during establishment of the crop, at which time earth mites, lucerne flea and false wireworms cause the greatest damage. Damage can also be caused by aphids, native budworm and Rutherglen bug during flowering and podding (Miles & McDonald 1999; Oilseeds W.A. 2006).

170. Canola is highly susceptible to weed competition during the early stages of growth. The most problematic weeds include annual ryegrass, members of the *Fescue* genus, volunteer cereals and a large number of *Brassicaceous* weeds. The most detrimental *Brassicaceous* weeds are wild radish (*Raphanus raphanistrum*), Indian hedgemustard (*Sisymbrium orientale*), Shepherd's purse (*Capsella bursa-pastoris*), wild turnip (*Brassica tournefortii*), turnip weed (*R. rugosum*), charlock (*Sinapis arvensis*), musk weed (*Myagrimum perfoliatum*) and Buchan weed (*Hirschfeldia incana*) (Sutherland 1999), some of which are sexually compatible with canola.

## **8.4 Presence of the introduced or similar genes and proteins in the receiving environment**

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

172. The *bar* and *pat* genes were obtained from common soil bacteria, ie *S. hygroscopicus* and *S. viridochromogenes*, respectively. These are saprophytic, soil-borne microbes that are not considered pathogens of plants, humans or other animals (OECD 1999b). Genes encoding PAT or similar enzymes are present in a wide variety of bacteria. Acetyltransferases, the class of enzymes to which PAT belongs, are common enzymes in all microorganisms, plants and animals.

173. The bacterium *B. amyloliquefaciens*, from which the *barnase* and *barstar* genes were obtained, is a commonly occurring soil bacterium that is widespread in nature and is frequently used in industry (see Section 6.1.4) (ANZFA 2001). BARNASE is a ribonuclease enzyme that is secreted by *B. amyloliquefaciens* into the soil and BARSTAR is a ribonuclease inhibitor protein which specifically inhibits BARNASE enzyme function. Ribonuclease enzymes and ribonuclease inhibitor proteins are ubiquitous in nature and can be found in plants, animals and microorganisms. Therefore, both the source organism (*B. amyloliquefaciens*) and the classes of protein encoded by the introduced genes (ribonuclease and ribonuclease inhibitor) would be commonly encountered by other organisms in the environment.

174. The introduced *cp4 epsps* gene was isolated from the CP4 strain of the common soil bacterium *Agrobacterium* sp. The CP4 EPSPS protein is produced naturally by this strain (Padgett et al. 1995). This bacterium can also be found on plants and fresh plant produce. Genes coding for closely related EPSPS proteins are present in plants, bacteria and fungi (Gasser et al. 1988). The CP4 EPSPS protein expressed in the GM canola plants is functionally equivalent to endogenous plant EPSPS with the exception that CP4 EPSPS is less sensitive to glyphosate inhibition (Franz et al. 1997). CP4 EPSPS protein is also expressed in commercial varieties of GM canola and cotton grown in Australia.

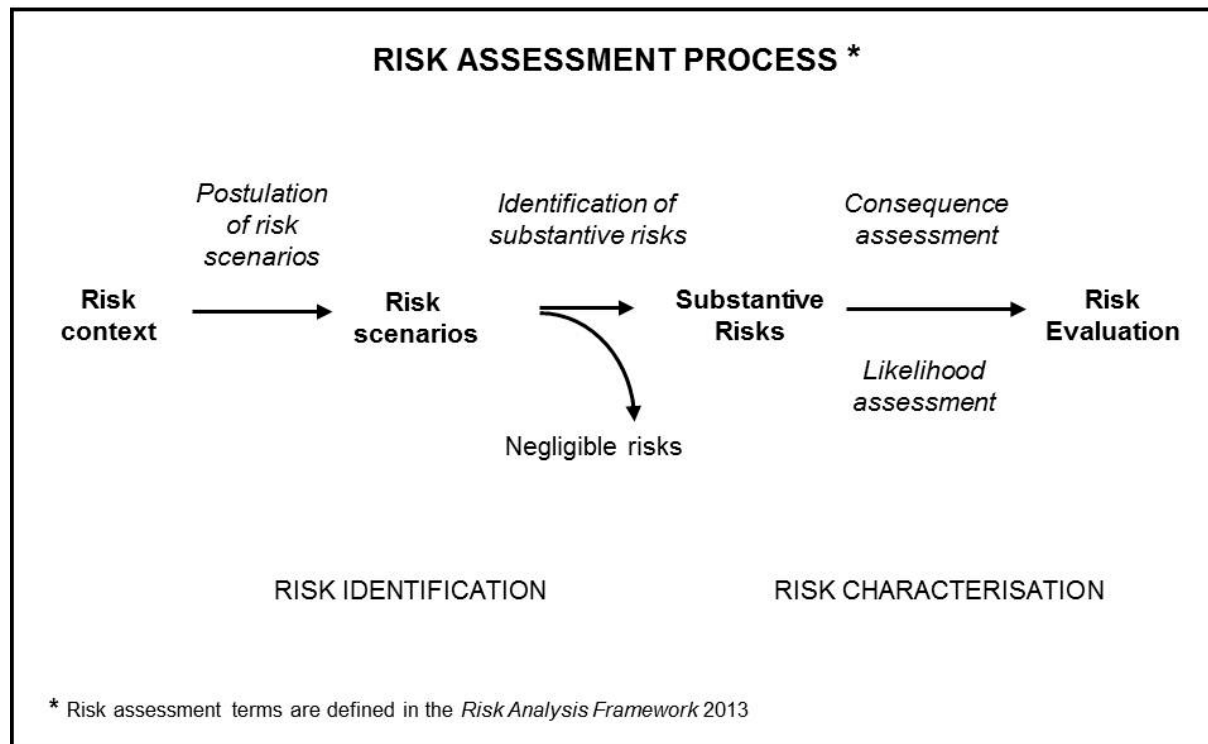
175. The *nptII* gene was derived from the common gut bacteria *E. coli*. This gene is present in other GM plants authorised for release, including the parental GM canola lines authorised under DIR 021/2002 and a number of GM cotton cultivars, such as Bollgard II<sup>®</sup>, Bollgard III<sup>®</sup>, Roundup Ready Flex<sup>®</sup>/ Bollgard II<sup>®</sup> and Roundup Ready Flex<sup>®</sup>/ Bollgard III<sup>®</sup>.

176. Short regulatory sequences are derived from the bacterium *A. tumefaciens*, the plants *A. thaliana* (thale cress), *N. tabacum* (tobacco) and *Pisum sativum* (pea) and the plant viruses CMV and FMV. Although *A. tumefaciens*, CMV and FMV are plant pathogens, and tobacco produces toxins and carcinogens, the regulatory sequences comprise a small part of their total genome, and in themselves have no pathogenic, toxic or carcinogenic properties. With the exception of tobacco, which is no longer grown commercially in Australia, all the source organisms for the introduced genetic elements are widespread and prevalent in the Australian environment and thus humans and other organisms would commonly encounter their genes, encoded proteins and regulatory sequences.

## Chapter 2 Risk assessment

### Section 1 Introduction

177. 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 a 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**

178. 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 in the short and long term. These are called risk scenarios.

179. A number of risk identification techniques are used by the Regulator and staff of the OGTR, including checklists, brainstorming, reported international experience and consultation (OGTR 2013). A weed risk assessment approach is used to identify traits that may contribute to risks from GM plants, as this approach addresses the full range of potential adverse outcomes associated with plants. In particular, novel traits that may increase the potential of the GMO to spread and persist in the environment or increase the level of potential harm compared with the parental plant(s) are considered in postulating risk scenarios (Keese et al. 2013). Risk scenarios postulated in previous RARMPs prepared for licence applications of the same and similar GMOs are also considered.

180. Postulated risk scenarios are screened to identify those that are 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.

181. Substantive risks (ie those identified for further assessment) are characterised in terms of the potential seriousness of harm (Consequence assessment) and the likelihood of harm

(Likelihood assessment). Risk evaluation then combines the Consequence and Likelihood assessments to determine the level of risk and whether risk treatment measures are required. The potential for interactions between risks is also considered.

## **Section 2 Risk Identification**

182. Postulated risk scenarios are comprised of three components:

- i. The source of potential harm (risk source).
- ii. A plausible causal linkage to potential harm (causal pathway).
- iii. Potential harm to an object of value, people or the environment.

183. When postulating relevant risk scenarios, the risk context is taken into account, including the following factors::

- 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
- any proposed limits including the extent and scale of the proposed dealings
- any proposed controls to restrict the spread and persistence of the GMOs
- the characteristics of the parent organism(s).

### **2.1 Risk source**

184. The source of potential harms can be intended novel GM traits associated with one or more introduced genetic elements, or unintended effects/traits arising from the use of gene technology.

185. As discussed in Chapter 1, the GM canola lines proposed for release are the result of conventional breeding between InVigor® and TruFlex™ Roundup Ready® (MON 88302) canola. These lines have been modified by the introduction of separate genes for tolerance to the herbicides glufosinate and glyphosate, as well as for a hybrid breeding system comprising genes for male sterility and fertility restoration. The introduced genes are considered further as potential sources of risk.

186. The introduced genes are controlled by introduced regulatory sequences. These regulatory sequences are derived from plants, a bacterium and plant viruses (see Table 2). Regulatory sequences are naturally present in plants, and the introduced elements are expected to operate in similar ways to endogenous elements. The regulatory sequences are DNA that is not expressed as a protein, and dietary DNA has no toxicity (Society of Toxicology 2003). Hence, potential harms from the regulatory elements will not be considered further. However, the introduced regulatory sequences, especially the promoters, control gene expression and hence the distribution and concentration of the derived proteins in the GM plants. The effects of protein and their levels, especially in relation to toxicity and allergenicity, will be considered below.

187. The genetic modifications have the potential to cause unintended effects in several ways, including altered expression of endogenous genes by random insertion of introduced DNA in the genome, increased metabolic burden due to expression of the introduced proteins, novel traits arising out of interactions with non-target proteins and secondary effects arising from altered substrate or product levels in biochemical pathways. However, these types of effects also occur spontaneously and in plants generated by conventional breeding (Bradford et al. 2005; Ladics et al. 2015; Schnell et al. 2015). Accepted conventional breeding techniques such as hybridisation, mutagenesis and somaclonal variation can have a much larger impact on the plant genome than genetic engineering (Schnell et al. 2015). Plants generated by conventional

breeding have a long history of safe use, and there are no documented cases where conventional breeding has resulted in the production of a novel toxin or allergen in a crop (Bradford et al. 2005; Steiner et al. 2013). Therefore, unintended effects resulting from the process of genetic modification will not be considered further.

188. Five of the GM canola lines and their potential hybrids contain the *nptII* antibiotic resistance selectable marker gene. This gene and its product have already been extensively characterised and assessed as posing negligible risk to human or animal health or to the environment by the Regulator as well as by other regulatory agencies in Australia and overseas. Further information about this gene can be found in the document *Marker genes in GM plants* available from the OGTR [Risk Assessment References](#) page. As this gene and its product has not been found to pose a substantive risk to either people or the environment, its potential effects will not be considered further.

189. The InVigor® canola hybrids are created to possess improved growth characteristics due to their hybrid vigour. This is not a function of the genetic modification that can be transferred as a single trait, but is a result of breeding two genetically distinct parents. In general, hybrid vigour manifested in the F1 generation declines in subsequent generations (Falconer & Mackay 1996). The GM male sterile canola lines cannot fertilise other plants as they are unable to develop functional pollen. The GM RF lines will only have an effect when outcrossing to MS lines, where they restore fertility. When they transfer pollen to other plants, the resulting offspring will be similar to the MS lines themselves. The potential for the introduced genes of the hybrid breeding system to increase the weed risk potential of InVigor® canola was assessed as negligible in the RARMPs for [DIR 021/2002](#) and [DIR 108](#) and will not be considered further.

## 2.2 Causal pathway

190. The following factors are taken into account when postulating plausible causal pathways to potential harm:

- routes of exposure to the GMOs, the introduced gene(s) and gene product(s)
- 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
- spread and persistence of the GM plants (eg reproductive characteristics, dispersal pathways and establishment potential)
- tolerance to abiotic conditions (eg climate, soil and rainfall patterns)
- tolerance to biotic stressors (eg pest, pathogens and weeds)
- tolerance to cultivation management practices
- gene transfer to sexually compatible organism
- gene transfer by horizontal gene transfer
- unauthorised activities.

191. Although all of these factors are taken into account, some are not included in risk scenarios because they are regulated by other agencies or have been considered in previous RARMPs (see sections 2.2.1 to 2.2.5 below).

### 2.2.1 Tolerance to abiotic factors

192. The geographic range of non-GM canola in Australia is limited by a number of abiotic factors, including water and nutrient availability, as well as climate and soil compatibility (OGTR 2011). The introduced genes are unlikely to make the GM canola plants more tolerant to abiotic stresses that are naturally encountered in the environment, and are therefore unlikely

to alter the potential distribution of the GM canola plants. As discussed in Chapter 1 (Section 7), there was no significant difference between InVigor® x TruFlex™ Roundup Ready® canola and other non-GM canola varieties in their response to a number of abiotic factors. Therefore, tolerance to abiotic stresses will not be assessed further.

### **2.2.2 Agronomic management and development of herbicide resistance**

193. There is some potential for development of herbicide resistant weeds if a herbicide tolerant canola and its corresponding herbicide are used inappropriately. The repetitious use of a single herbicide, or herbicide group<sup>8</sup>, increases the likelihood of selecting weeds that have developed herbicide resistance through natural mechanisms (Gressel 2002). This is not a novel issue associated with the GMOs, as most canola currently grown in Australia is herbicide tolerant, by either non-GM or GM mechanisms (see Chapter 1, Section 8.3.1).

194. Stacking of multiple herbicide tolerant traits, such as in the InVigor® x TruFlex™ Roundup Ready® canola proposed for release, increases the number of herbicide mixture options with multiple modes of action (Green et al. 2008). This could reduce the selective pressure on weed populations that occurs when a single herbicide is used exclusively. The development of resistance to glufosinate and glyphosate herbicides would have implications for the choice of herbicide(s) available for weed control operations in agriculture and elsewhere.

195. The genetic modifications to the GM canolas proposed for release confer tolerance to glyphosate, which is a widely used herbicide in Australia. A number of glyphosate resistant weed populations have already been identified in Australia. The weed species reported include *Brachiaria eruciformis*, *Bromus diandrus*, *Bromus rubens*, *Chloris truncata*, *Conyza bonariensis*, *Echinochloa colona*, *Lolium rigidum*, *Raphanus raphanistrum*, *Sonchus oleraceus* and *Urochloa panicoides*<sup>9</sup>. It also confers tolerance to glufosinate. Two glufosinate resistant species have been identified overseas (see Chapter 1, Section 5.4.1).

196. The risk of development of herbicide resistant weeds through selective pressure comes under the regulatory oversight of the APVMA, which has primary regulatory responsibility for agricultural chemicals in Australia. The APVMA assesses all herbicides used in Australia and sets their conditions of use. Bayer has indicated they will need to make an application to the APVMA to change the current Liberty® and Roundup® herbicide labels to include use on InVigor® x TruFlex™ Roundup Ready® canola. The APVMA will consider appropriate use patterns for the herbicides in order to minimise the potential for development of herbicide resistance prior to changing the relevant product labels for use of glyphosate or glufosinate on the GM canolas. Therefore, the issue of development of herbicide resistant weeds through selective pressure will not be further considered in this risk assessment. The development of herbicide tolerant weeds through gene transfer will be considered below.

### **2.2.3 Gene transfer by horizontal gene transfer**

197. The potential for horizontal gene transfer and any possible adverse outcomes has been reviewed in the scientific literature (Keese 2008) as well as assessed in many previous RARMPs. Horizontal gene transfer was most recently considered in detail in the RARMP for [DIR 108](#). No risk greater than negligible was identified due to the rarity of these events and because the gene sequences are already present in the environment and available for transfer via demonstrated natural mechanisms. Therefore, horizontal gene transfer will not be assessed further.

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<sup>8</sup> Herbicides are classified into groups based on their mode of action. All herbicide product labels must display the mode of action group. This enables users to rotate among herbicides with different modes of action to delay the development of herbicide tolerance in weeds.

<sup>9</sup> Source: [The international survey of herbicide resistant weeds](#) website; accessed on 12 November 2015.

### 2.2.4 Unauthorised activities

198. The potential for unauthorised activities to lead to harm has been considered in previous RARMPs. The Act provides for substantial penalties for non-compliance and unauthorised dealings with GMOs. The Act also requires the Regulator to have regard to 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, and no risk greater than negligible was identified in previous RARMPs. Therefore, unauthorised activities will not be considered further.

### 2.3 Potential harm

199. Potential harms from GM plants include:

- harm to the health of people or desirable organisms, including toxicity/allergenicity
- reduced biodiversity through harm to other organisms or ecosystems
- reduced establishment of desirable plants, including having an advantage in comparison to related plants
- reduced products or services from the land use
- restricted movement of people, animals, vehicles, machinery and/or water
- reduced quality of the biotic environment (eg providing food or shelter for pests or pathogens) or abiotic environment (eg negative effects on fire regimes, nutrient levels, soil salinity, soil stability or soil water table).

200. These harms are based on those used to assess risk from weeds (Standards Australia Ltd et al. 2006; Keese et al. 2013). Judgements of what is considered harm depend on the management objectives of the land where the GM plant may be present. A plant species may have different weed risk potential in different land uses such as dryland cropping or nature conservation.

### 2.4 Postulated risk scenarios

201. Five risk scenarios were postulated and screened to identify substantive risk. These scenarios are summarised in Table 6, and discussed individually below. Postulation of risk scenarios considers impacts of the GM canola or its products on people undertaking the dealings, as well as impacts on people and the environment exposed to the GM canola or its products as the result of the commercial use or the spread and persistence of plant material.

202. In the context of the activities proposed by the applicant and considering both the short and long term, none of the five risk scenarios gave rise to any substantive risks that could be greater than negligible.

**Table 6 Summary of risk scenarios from the proposed dealings**

Risk scenario	Risk source	Causal pathway	Potential harm	Substantive risk?	Reason
1	Introduced genes for dual herbicide tolerance and hybrid breeding system	Commercial cultivation of GM canola lines expressing these introduced genes ↓ Exposure of people via consumption of oil derived from GM canola, inhalation of GM canola pollen, or occupational contact with GM canola plants or products. Exposure of other organisms through contact or consumption of the GM plants or products	Increased toxicity or allergenicity for people or Increased toxicity for other desirable organisms	No	<ul style="list-style-type: none"> <li>• The introduced proteins are not considered toxic or allergenic to people and other desirable organisms.</li> <li>• The parental GM canola lines and other GM crops containing the introduced genes have a history of safe use.</li> <li>• The introduced genes and proteins are widespread in the environment.</li> </ul>



Risk scenario	Risk source	Causal pathway	Potential harm	Substantive risk?	Reason
2	Introduced genes for dual herbicide tolerance	Commercial cultivation of GM canola lines expressing these introduced genes ↓ Establishment of volunteer GM canola plants in agricultural areas ↓ Reduced effectiveness of weed management measures to control the volunteer GM canola plants	Reduced establishment or yield of desirable agricultural crops or Increased reservoir for pathogens	No	<ul style="list-style-type: none"> <li>The genetic modification will only give an advantage to the GM canola plants in managed environments, where glyphosate and/or glufosinate herbicide is applied.</li> <li>The GM canola lines can be controlled using alternative weed management.</li> </ul>
3	Introduced genes for dual herbicide tolerance	Commercial cultivation of GM canola lines expressing these introduced genes ↓ Dispersal of GM canola seed to nature reserves or intensive use areas ↓ Establishment of GM plants in nature reserves or intensive use areas ↓ Reduced effectiveness of weed management measures to control the feral plants	Reduced establishment of desirable native vegetation or Reduced services from the land use	No	<ul style="list-style-type: none"> <li>The GM canola lines are similar to non-GM canola with respect to the intrinsic characteristics contributing to spread and persistence of canola.</li> <li>The GM canola lines are susceptible to the biotic or abiotic stresses that normally restrict the geographic range and persistence of canola.</li> <li>The GM canola lines can be controlled using alternative weed management.</li> </ul>
4	Introduced genes for dual herbicide tolerance	Commercial cultivation of GM canola in agricultural areas ↓ Cross-pollination with other canola, including canola with other herbicide tolerance traits ↓ Establishment of hybrid GM canola plants expressing the herbicide tolerance gene as volunteers ↓ Reduced effectiveness of weed management measures to control the hybrid plants	Reduced establishment or yield of desirable agricultural crops or Increased reservoir for pathogens	No	<ul style="list-style-type: none"> <li>Hybrids between the GMOs and other canola would be generated at low levels.</li> <li>Multiple-herbicide tolerant hybrids can be controlled using integrated weed management.</li> </ul>
5	Introduced genes for dual herbicide tolerance	Commercial cultivation of GM canola in agricultural areas ↓ Cross-pollination with sexually compatible Brassica crops or agricultural weeds ↓ Establishment of hybrid GM Brassica plants expressing the herbicide tolerance gene/s as volunteers or Introgression of the introduced herbicide tolerance gene/s into agricultural weed populations ↓ Reduced effectiveness of weed	Reduced establishment or yield of desirable agricultural crops	No	<ul style="list-style-type: none"> <li>Hybridisation between GM canola and Brassica crop species would occur at very low levels.</li> <li>Hybrids between GM canola and Brassica crop species could be controlled by integrated weed management.</li> <li>It is highly unlikely that GM herbicide tolerance gene/s would introgress into Brassicaceae weed species.</li> </ul>

Risk scenario	Risk source	Causal pathway	Potential harm	Substantive risk?	Reason
		management measures to control hybrid volunteers or weeds expressing the herbicide tolerance gene/s			

**2.4.1 Risk scenario 1**

<i>Risk source</i>	Introduced genes for dual herbicide tolerance and hybrid breeding system
<i>Causal pathway</i>	<p style="text-align: center;">↓</p> Commercial cultivation of GM canola lines expressing these introduced genes <p style="text-align: center;">↓</p> Exposure of people via consumption of oil derived from GM canola, inhalation of GM canola pollen, or occupational contact with GM canola plants or products. Exposure of other organisms through contact or consumption of the GM plants or products <p style="text-align: center;">↓</p>
<i>Potential harm</i>	Increased toxicity or allergenicity for people or Increased toxicity for other desirable organisms

**Risk source**

203. The source of potential harm for this postulated risk scenario is the introduced genes for dual herbicide tolerance and hybrid breeding system (male sterility and fertility restoration).

**Causal pathway**

204. The applicant proposes that the GM canola lines would be cultivated on a commercial scale in all Australian canola growing areas. The herbicide tolerance genes *cp4 epsps* and *bar* are expressed in all parts of the GM canola plant at all developmental stages including leaf, stem, root, pollen and seed, whereas expression of the *barnase* and *barstar* genes, comprising the hybrid breeding system, is restricted to the pollen (Chapter 1, Section 7.2). Herbicide metabolites would be present if the GM canola had been treated with glyphosate or glufosinate.

205. The GM canola would enter general commerce and be used in the same ways as non-GM canola. The general public could be exposed to oil from the GM canola, which would be sold for human consumption.

206. People could be exposed to wind-borne GM canola pollen by inhalation. The vast majority of wind-dispersed canola pollen travels less than 10 m from the pollen source (Husken & Dietz-Pfeilstetter 2007 and references therein), so this route of exposure would mainly apply to people who enter or pass close to GM canola fields during flowering.

207. People involved in cultivating or processing the GM canola, or using GM canola meal as animal feed, could be exposed to plant parts or products through contact.

208. Livestock would be exposed when consuming the GM canola lines as forage, whole seed or seed meal.

209. Wild animals and birds could enter canola fields and feed on GM canola seed or other plant parts. Pollinators such as honeybees would be exposed to nectar and pollen from the GM canola. Soil organisms such as earthworms would contact root exudates or decomposing plant material after harvest. Therefore, these desirable organisms would be exposed to the GM canola and plant material derived from it.

**Potential harm**

210. 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). 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).

211. The *cp4 epsps*, *bar*, *pat*, *barnase* and *barstar* genes introduced into the GM canola lines encode proteins that are well characterised. Based on all available information, these proteins are not known to be toxic or allergenic, do not share relevant sequence homology with known toxins or allergens, and are not involved in biochemical pathways that produce toxic or allergenic products (Chapter 1, Section 5.3).

212. FSANZ has determined that food derived from the parental GM lines of canola, InVigor® and TruFlex™ Roundup Ready® canola, is as safe for human consumption as food derived from conventional (non-GM) canola varieties. These approvals also cover the stacked InVigor® x TruFlex™ Roundup Ready® canola. The parental GM lines and the stack have also been approved as food and/or animal feed in other countries, including Canada, Japan, Korea, Mexico and the USA (Chapter 1, Section 4.3).

213. The parental GM canola lines and other GM crops containing the same introduced genes have been approved for use as animal feed in Australia and many other countries (Chapter 1, Section 4). Although InVigor® canola was approved for commercial release in Australia in 2002, it has not been grown on commercial scale. Roundup Ready® canola, containing the same *cp4 epsps* gene as TruFlex™ Roundup Ready® canola, was approved by the Regulator for commercial release and has been grown since 2008 in NSW and Vic, and since 2010 in WA.

214. Some countries, such as Canada and the USA do not require a separate authorisation for the stacking of these previously approved parental GM canola lines. Other countries, such as Japan and South Korea have specifically approved the stack InVigor® x TruFlex™ Roundup Ready® canola for use in animal feed (Chapter 1, Section 4.3). Both InVigor® canola and Roundup Ready® canola have been grown commercially in Canada for nearly 20 years.

215. There have been no reported adverse effects on human or animal health from these GM canola lines or other commercial GM crops with the same introduced genes (Chapter 1, Section 4).

216. The introduced genes were all isolated from common soil bacteria that are widespread and prevalent in the environment. Homologous EPSPS proteins that perform the identical biochemical reaction to the introduced CP4 EPSPS protein occur in all plants and many other microorganisms (Chapter 1, Section 8.4). Thus it is expected that desirable soil organisms are regularly exposed to the introduced proteins or their degradation products.

217. The GM canola has dual herbicide tolerance and the potential toxicity of the metabolites of the two herbicides, glyphosate and glufosinate, is summarised in Chapter 1, Section 5.1. Ultimately, the APVMA has regulatory responsibility for the supply of agricultural chemicals, including herbicide products, in Australia.

### **Conclusion**

218. Risk scenario 1 is not identified as a substantive risk because the introduced proteins are not considered toxic or allergenic to people and other desirable organisms, there is a history of safe use of the GM parental lines and other GM crops containing the introduced genes in Australia and overseas, and the introduced genes and proteins are widespread in the environment. Therefore, this risk could not be greater than negligible and does not warrant further detailed assessment.

**2.4.2 Risk Scenario 2**

<i>Risk source</i>	Introduced genes for dual herbicide tolerance
<i>Causal pathway</i>	<p style="text-align: center;">↓</p> <p style="text-align: center;">Commercial cultivation of GM canola lines expressing these introduced genes</p> <p style="text-align: center;">↓</p> <p style="text-align: center;">Establishment of volunteer GM canola plants in agricultural areas</p> <p style="text-align: center;">↓</p> <p style="text-align: center;">Reduced effectiveness of weed management measures to control the volunteer GM canola plants</p> <p style="text-align: center;">↓</p>
<i>Potential harm</i>	<p style="text-align: center;">Reduced establishment or yield of desirable agricultural crops</p> <p style="text-align: center;">or</p> <p style="text-align: center;">Increased reservoir for pathogens</p>

**Risk source**

219. The source of potential harm for this postulated risk scenario is the introduced genes for dual herbicide tolerance.

**Causal pathway**

220. The applicant proposes that the GM canola lines would be cultivated on a commercial scale. Studies in the USA indicated no meaningful differences between InVigor® x TruFlex™ Roundup Ready® canola and non-GM canola with respect to the intrinsic characteristics contributing to spread and persistence (eg seed production, pod shattering and competitiveness; Chapter 1, Section 7.2), it would be expected to produce similar numbers of volunteers as other canola. This expectation is also consistent with the finding of low levels of GM Roundup Ready® volunteer canola along road sides in the Esperance region of WA after one year of commercial production (see Chapter 1, Section 6.4).

221. Volunteer canola plants are also likely to occur following dispersal of GM canola seeds within agricultural areas. Short-range dispersal of canola seed into field margins or adjacent fields could occur due to pod shattering or transport of canola plant material from windrows by strong winds. Short to medium-range dispersal of canola seed within agricultural areas could be mediated by human activities such as movement of agricultural machinery used during canola sowing or harvest or movement of livestock after grazing on canola (OGTR 2011). Dispersal of viable canola seed by endozoochory (consumption and excretion of seed) by wild mammals or birds is also possible at very low levels (Twigg et al. 2008).

222. InVigor® x TruFlex™ Roundup Ready® canola only has a survival advantage in the presence of glyphosate or glufosinate or both herbicides. Glyphosate is widely used for weed control in broad-acre agriculture, horticulture and other weed management situations, whereas glufosinate is not widely used in broad-acre cropping or management along roadsides. Neither herbicide would be effective in controlling canola volunteers in situations where InVigor® x TruFlex™ Roundup Ready® canola had been grown previously. The presence of InVigor® x TruFlex™ Roundup Ready® canola volunteers in agricultural areas has implications for the choice of herbicide(s) in situations where glyphosate is the principal weed control strategy. Crop Management Plans have been developed separately by Bayer CropScience and Monsanto for InVigor® and TruFlex™ Roundup Ready® canola, respectively (see also Section 5.4.1). These CMPs are to be followed by canola growers when growing InVigor® canola, TruFlex™ Roundup Ready® canola or InVigor® x TruFlex™ Roundup Ready® canola. The CMPs address issues such as minimising and managing canola volunteers in crops following GM herbicide tolerant canola in a rotation, and minimising the development of herbicide resistant weeds.

223. All herbicides sold in Australia are grouped by mode of action for the purpose of resistance management. The mode of action is indicated by a letter code on the product label (CropLife Australia 2011). Glyphosate is a mode of action Group M herbicide and glufosinate

is in Group N. Herbicides from different mode of action groups or products with multiple mode of action groups could be used to control InVigor® x TruFlex™ Roundup Ready® canola volunteers. Specifically, herbicides from Groups B, C, F, G, I, L and Q are registered for use on canola in various crop and non-crop situations by the APVMA. In addition, several herbicides with multiple modes of action groups (eg groups C + F, C + H, C + I, F + I, H + I and L + Q) are registered for use on canola volunteers (Australian Oilseeds Federation 2014). Further details of registered herbicide products are available on the [APVMA website](#).

224. InVigor® x TruFlex™ Roundup Ready® canola is as susceptible as non-GM canola to all herbicides other than glyphosate and glufosinate. The GM canola volunteers could therefore be controlled using integrated weed management practices, which include using a variety of other herbicides assessed and approved by the APVMA as well as non-chemical management methods currently used to control non-GM canola, such as mowing, grazing or grading (Australian Oilseeds Federation 2014).

### ***Potential harm***

225. Volunteer canola (non-GM and GM) is a weed of agricultural production systems (Simard et al. 2002; Groves et al. 2003). If left uncontrolled, volunteer canola plants could establish and compete with other crops but their ability to reduce the establishment or yield of desired crops is limited. As discussed above, there are alternative methods to control the GM volunteers and, therefore, the number of volunteers persisting in agricultural areas is likely to be low, further minimising the likelihood of reduced establishment or yield of crops.

226. Volunteer canola could act as a reservoir for canola pests, pathogens or diseases. For example, blackleg is the most serious disease of canola in Australia, and over 95% of blackleg spores originate from the previous year's canola stubble (GRDC 2009). Canola volunteers emerging in fields or field margins the year after a canola crop could be infected with blackleg from stubble, then in turn infect a canola crop planted in the following year. However, there is no difference in disease incidence for a number of diseases between the GM canola lines proposed for release and non-GM canola (Chapter 1, Section 7.2). Effective control of canola volunteers (both GM and non-GM) will lead to reduced potential for those volunteers to act as disease reservoirs.

### ***Conclusion***

227. Risk scenario 2 is not identified as a substantive risk because the genetic modification would only give an advantage to the GM canola plants in managed environments, where glyphosate and/or glufosinate herbicide is applied and because integrated weed management practices would control GM canola volunteers in agricultural areas. Therefore, this risk could not be greater than negligible and does not warrant further detailed assessment.

### 2.4.3 Risk Scenario 3

<i>Risk source</i>	Introduced genes for dual herbicide tolerance
<i>Causal pathway</i>	<p style="text-align: center;">↓</p> <p style="text-align: center;">Commercial cultivation of GM canola lines expressing these introduced genes</p> <p style="text-align: center;">↓</p> <p style="text-align: center;">Dispersal of GM canola seed to nature reserves or intensive use areas</p> <p style="text-align: center;">↓</p> <p style="text-align: center;">Establishment of GM plants in nature reserves or intensive use areas</p> <p style="text-align: center;">↓</p> <p style="text-align: center;">Reduced effectiveness of weed management measures to control the feral plants</p> <p style="text-align: center;">↓</p>
<i>Potential harm</i>	<p style="text-align: center;">Reduced establishment of desirable native vegetation</p> <p style="text-align: center;">or</p> <p style="text-align: center;">Reduced services from the land use</p>

#### **Risk source**

228. The source of potential harm for this postulated risk scenario is the introduced genes for dual herbicide tolerance.

#### **Causal pathway**

229. The applicant proposes that the GM canola would be cultivated for commercial purposes. After harvest, the GM canola seed would usually be transported for processing or export. Seed spillages could lead to establishment of feral canola populations in intensive use areas, eg along transport routes or near processing or storage sites. Whole seeds could be used as livestock feed and feral GM canola could potentially establish in and around animal feeding areas, which are also included in the intensive use areas.

230. If transport routes passed through or were near nature reserves, dispersal of canola seeds into the nature reserves could occur due to spillages or GM canola could spread into nature reserves after establishing along transport routes. However, surveys of roadside canola typically only found feral canola plants within 5 m of the edge of the road (Norton 2003; Agrisearch 2001). Dispersal of viable canola seed into nature reserves by endozoochory (consumption and excretion of seed) by wild animals or birds is also possible at very low levels (Twiggs et al. 2008).

231. Dispersal of viable seed to intensive use areas and nature reserves could also occur via extremes of weather such as flooding or high winds.

232. As discussed in Chapter 1, Section 5.3, feral canola plants are often observed growing on roadsides or railway easements in Australia. These canola populations are thought to be reliant on re-supply of seed from spillages rather than forming self-sustaining weed populations. The GM canola lines proposed for release are similar to non-GM canola with respect to the intrinsic characteristics contributing to spread and persistence, such as seed production, pod shattering and competitiveness (Chapter 1, Section 7.2), and, therefore, the level of volunteers is expected to be similar to non-GM canola. The genetic modification is also not expected to alter the tolerance of GM plants to biotic or abiotic stresses that normally restrict the geographic range and persistence of canola (Chapter 1, Sections 7.2 and 7.3). Therefore, feral GM canola is not expected to be more persistent than non-GM canola.

233. The traits of glyphosate and glufosinate tolerance could affect the plant's tolerance to standard weed management practices in any areas where either or both of these herbicides are used. Glyphosate is widely used for weed control in intensive use areas such as roadsides (Storrie 2012). Glyphosate would not be effective in controlling feral GM canola populations due to the expression of the introduced *cp4 epsps* gene. Broad application of glyphosate in intensive use areas could potentially promote the establishment of feral GM canola due to reduction of competition. A recent Australian study found that under favourable climatic

conditions, and in circumstances where other roadside weeds are controlled by glyphosate, roadside populations of glyphosate tolerant GM canola could persist for at least three years (Busi & Powles 2016).

234. As there are currently increasing numbers of glyphosate resistant weeds such as annual ryegrass, fleabane and windmill grass present on roadsides and along railway lines, the Australian Glyphosate Sustainability Working Group recommends dealing with glyphosate resistant weeds in non-agricultural areas by using integrated weed management, including alternative herbicide modes of action, double knock, physical control practices aimed at weed seed set prevention, and planting or managing other species to compete with weeds<sup>10</sup>. These strategies would also be effective in controlling feral GM canola.

235. In nature reserves where glyphosate or glufosinate are not used for weed control, the GM canola would not be expected to have any survival advantage over non-GM canola. A recent Australian study found that when glyphosate tolerant GM canola seeds were dispersed into two natural areas, feral canola populations persisted for 0 and 3 years, respectively, prior to extinction (Busi & Powles 2016). Similarly, non-GM canola is not a persistent weed in natural undisturbed habitats in Australia (Dignam 2001; Groves et al. 2003).

### **Potential harm**

236. If the GM canola lines expressing the introduced genes for dual herbicide tolerance were able to establish and persist in nature reserves, this could reduce the establishment of desirable native vegetation. It could give rise to lower abundance of desirable species, reduced species richness, or undesirable changes in species composition. Feral canola could also potentially reduce services from the land use by decreasing the amenity of nature reserves for nature-based tourism. Canola can grow to a height of 1.5 m (OGTR 2011) and is highly visible when in flower. Feral canola on roadsides or along railway lines could reduce services from the land use by obstructing lines of sight around corners and signs.

237. None of these potential harms are increased in the GM canola lines proposed for release compared to non-GM canola and the GM parental canola lines.

### **Conclusion**

238. Risk scenario 3 is not identified as a substantive risk because the GM canola lines are: similar to non-GM canola with respect to the intrinsic characteristics contributing to spread and persistence of canola; susceptible to the biotic or abiotic stresses that normally restrict the geographic range and persistence of canola; and can be controlled using integrated weed management. Therefore, this risk could not be greater than negligible and does not warrant further detailed assessment.

#### **2.4.4 Risk Scenario 4**

<i>Risk source</i>	Introduced genes for dual herbicide tolerance
<i>Causal pathway</i>	↓
	Commercial cultivation of GM canola in agricultural areas
	↓
	Cross-pollination with other canola, including canola with other herbicide tolerance traits
	↓
	Establishment of hybrid GM canola plants expressing the herbicide tolerance gene as volunteers
	↓
	Reduced effectiveness of weed management measures to control the hybrid plants
	↓
<i>Potential harm</i>	Reduced establishment or yield of desirable agricultural crops or Increased reservoir for pathogens

<sup>10</sup> Source: [Australian Glyphosate Sustainability Working Group website](#); accessed 10 November 2015.

### ***Risk source***

239. The source of potential harm for this postulated risk scenario is the introduced genes for dual herbicide tolerance.

### ***Causal pathway***

240. The herbicide tolerance gene could potentially be transferred by pollen flow to other canola, including other herbicide tolerant non-GM and GM canola plants. This may lead to reduced effectiveness of weed management measures used to control volunteers.

241. The applicant proposes that the GM canola be cultivated on a commercial scale in all canola growing areas. Cross pollination between the GM canola proposed for release and other canola would most likely occur when different canola crops are grown in adjacent paddocks and flower synchronously. Cross pollination may also occur at a smaller scale with volunteer or feral canola populations.

242. Outcrossing rates between neighbouring commercial canola fields in Australia are less than 0.1% averaged over whole fields (Rieger et al. 2002). Correspondingly low levels of hybridisation are expected between the GMOs and other canola.

243. Hybrid seed with the GM trait could disperse within agricultural areas, to intensive use areas, or to nature reserves, by the same mechanisms as described in Risk Scenario 3. In addition, if a field that is adjacent to GMOs is planted with an open pollinating canola variety, the farmer may retain seed, including a proportion of GM hybrid seed, for future planting.

244. Crossing between the GMOs and non-GM, non-herbicide tolerant canola varieties would result in hybrid plants highly similar to the GMOs proposed for release. Therefore, the progeny would not be expected to pose any greater risks than the GM canola lines proposed for release.

245. There are currently three herbicide-tolerant canola varieties widely grown in Australia: two were conventionally bred, ie TT and Clearfield<sup>®</sup> canola; and one GM canola, ie GM Roundup Ready<sup>®</sup> canola. Where canola varieties that are tolerant to different herbicides are in close proximity, the production of multiple-herbicide tolerant volunteers has been noted (Beckie et al. 2003; Hall et al. 2000; Schafer et al. 2011; Knispel et al. 2008). If the GM canola lines proposed for release were to cross with the TT and Clearfield<sup>®</sup> canola this could result in a canola with tolerance to four herbicides. This has been a possible outcome since the approval of InVigor<sup>®</sup> canola and Roundup Ready<sup>®</sup> canola in 2003. InVigor<sup>®</sup> ([DIR 021/2002](#)) and InVigor<sup>®</sup> x Roundup Ready<sup>®</sup> canola ([DIR 108](#)) have not yet been cultivated widely. However, approval of the GM canola lines for commercial release would not add a new trait in terms of combinations of herbicide tolerance in canola volunteers.

246. If the dual herbicide tolerant GM canola lines were widely grown, this could increase the likelihood of multiple-herbicide tolerant volunteers, particularly by crossing with TT canola, which is over half of the current Australian canola crop<sup>11</sup>. However, this would depend on the uptake of the GM canola.

247. However, multiple-herbicide tolerant individuals are as susceptible to alternative herbicides as single-herbicide tolerant canola plants or their non-GM counterparts (Beckie et al. 2004). Therefore, if multiple-herbicide tolerant canola plants were to occur, they could be controlled by other herbicides or other (non-chemical) agricultural practices. As discussed in Risk Scenario 3, there are a range of other herbicide products available with alternative or multiple modes of action. Also, CMPs have been developed separately by Bayer and Monsanto for InVigor<sup>®</sup> and TruFlex<sup>™</sup> Roundup Ready<sup>®</sup> canola, respectively (Chapter 1, Section 7). These CMPs are to be followed by canola growers when growing InVigor<sup>®</sup>, TruFlex<sup>™</sup> Roundup Ready<sup>®</sup> canola or InVigor<sup>®</sup> x TruFlex<sup>™</sup> Roundup Ready<sup>®</sup> canola. These include

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<sup>11</sup> Source: [Pacific Seeds website](#); accessed on 10 November 2015.



management strategies that aim to control canola volunteers, minimise gene flow, and prevent or delay the development of herbicide resistant weeds.

248. Intensive use areas such as roadsides may also be subject to weed management (eg appropriate herbicide treatment or slashing/mowing) for aesthetic and practical purposes, and/or grazed by livestock, thereby limiting the reproduction or survival of volunteers.

**Potential harm**

249. If left uncontrolled, volunteer canola plants could establish and compete with other crops. If hybrid progeny with multiple herbicide tolerance were to establish in agricultural areas, the effectiveness of existing weed management measures to control volunteer canola could be compromised. As a result, the establishment and yield of desirable agricultural crops might be reduced. In addition, surviving volunteer canola could act as a reservoir for canola pests, pathogens or diseases, as described in Risk Scenario 3.

**Conclusion**

250. Risk scenario 4 is not identified as a substantive risk because hybrids between the GMOs and other canola would be generated at low levels, and multiple-herbicide tolerant hybrids can be controlled using integrated weed management. Therefore, this risk could not be greater than negligible and does not warrant further detailed assessment.

**2.4.5 Risk scenario 5**

<i>Risk source</i>	Introduced genes for dual herbicide tolerance
<i>Causal pathway</i>	<p style="text-align: center;">↓</p> <p style="text-align: center;">Commercial cultivation of GM canola in agricultural areas</p> <p style="text-align: center;">↓</p> <p style="text-align: center;">Cross-pollination with sexually compatible Brassica crops or agricultural weeds</p> <p style="text-align: center;">↓</p> <p style="text-align: center;">Establishment of hybrid GM Brassica plants expressing the herbicide tolerance gene/s as volunteers or Introgression of the introduced herbicide tolerance gene/s into agricultural weed populations</p> <p style="text-align: center;">↓</p> <p style="text-align: center;">Reduced effectiveness of weed management measures to control hybrid volunteers or weeds expressing the herbicide tolerance gene/s</p> <p style="text-align: center;">↓</p>
<i>Potential harm</i>	Reduced establishment or yield of desirable agricultural crops

**Risk source**

The source of potential harm for this postulated risk scenario is the introduced herbicide tolerance genes.

**Causal pathway**

251. The applicant proposes that the GM canola be cultivated on a commercial scale in all canola growing areas. This could bring it into proximity to other Brassica crop species such as vegetables, forage crops and Indian mustard as well as related weeds.

Interactions with Brassica crop species

252. Pollen flow between the GM canola proposed for release and other Brassica crop species could occur if the Brassica crops were grown in proximity to the GM canola and flowered synchronously. Brassica vegetable crops are generally harvested prior to flowering unless they are grown for seed production, in which case precautions would usually be taken to avoid crossing with oilseed canola (OGTR 2011). Brassica forage crops rarely flower due to heavy grazing. *B. juncea* (Indian mustard) crops, which are grown as oilseeds or for condiment mustard, could plausibly cross-pollinate with the GM canola. Cross pollination could also conceivably occur with volunteer populations of Brassica plants.

253. Hybrids between *B. napus* and *B. juncea* have been observed in the field, are fertile, and often have high fitness (Liu et al. 2010). Cross-pollination between *B. napus* and *B. rapa* occurs frequently in the field if plants of the two species are in proximity, and the hybrids are vigorous and fertile, although with reduced pollen viability (Warwick et al. 2003). Hybrids between *B. napus* and *B. oleracea* have been detected at low levels in wild populations (Ford et al. 2006).

254. Based on the data above, hybridisation between GM canola and other Brassica crop species is expected to occur if the GM canola is released. However, the frequency of inter-species crossing would be lower than the frequency of crossing between the GM canola and other canola plants, both because there is greater sexual compatibility between *B. napus* plants than between *B. napus* and other species, and because canola is far more widely grown than other Brassica crops (ABARES 2015). In Risk Scenario 4, it was considered that hybridisation between GM canola and other canola would occur at low levels, so hybridisation between GM canola and other Brassica crop species is likely to occur at very low levels.

255. Volunteer plants that are hybrids between GM canola and other Brassica crop species would not be controlled by the application of glyphosate or glufosinate herbicides. However, the hybrid volunteers could be controlled by integrated weed management practices, which would include using a variety of other herbicides approved by the APVMA for use on Brassica volunteers, as well as non-chemical management methods currently used to control non-GM Brassica plants. As discussed in previous risk scenarios, the presence of the herbicide tolerance gene/s are not expected to alter intrinsic characteristics contributing to spread and persistence, or to alter the tolerance of GM plants to biotic or abiotic stresses. Therefore, GM hybrid volunteers would not be expected to be more invasive or persistent than hybrids between non-GM canola and other Brassica crop species.

#### Interactions with Brassicaceae weeds

256. Brassicaceae agricultural weeds are expected to be present in fields or field margins where GM canola would be grown. Cross-pollination could occur if weeds are not destroyed prior to flowering, if there is synchronous flowering of weeds and the crop and if the weed species is sexually compatible with *B. napus*.

257. Cross-pollination between *B. napus* and wild radish (*R. raphanistrum*) has been observed in the field at very low levels. The hybrids are smaller than either parent and are close to sterile (Darmency et al. 1998; Warwick et al. 2003). Cross-pollination between *B. napus* and Buchan weed (*H. incana*) has been observed in the field at low levels. The hybrids were close to almost sterile, had very low fertility, and by the fifth generation of back-crossing, the progeny produced no viable seed (Darmency & Fleury 2000). Thus, introgression of the herbicide genes from GM canola into wild radish or Buchan weed populations is highly unlikely. Although GM Roundup Ready® canola has been grown commercially in North America since 1996, and wild radish and Buchan weed are both agricultural weeds in North America, there are no reports of glyphosate tolerant wild radish or Buchan weed populations there<sup>12</sup>.

258. *B. napus* has been reported to cross with other Brassicaceae weeds with human intervention, but not in open-pollination field conditions. Therefore, hybridisation between the GM canola and other Brassicaceae weeds would be highly unlikely.

259. In the highly unlikely event that herbicide tolerance gene/s were introgressed into populations of wild radish or Buchan weed, which retained the vigour of the recurrent weedy parent, these plants could establish as weeds. The GM weeds would not be controlled by the application of glyphosate or glufosinate herbicides. However, other weed management practices would be as effective on the GM weeds as they are on the parent non-GM weeds.

<sup>12</sup> Source: [The international survey of herbicide resistant weeds](#) website; accessed on 12 November 2015.

## ***Potential harm***

### Interactions with Brassica crop species

260. Both volunteer canola and other Brassica crop species are weeds of agricultural production systems (Groves et al. 2003). Any hybrids between the GM canola and other Brassica species could also potentially become volunteers. If left uncontrolled, GM hybrid volunteers could reduce the establishment or yield of desired crops. However, if appropriate weed management is used, GM hybrid volunteers would not cause more harm than hybrids between non-GM canola and other Brassica crop species.

### Interactions with Brassicaceae weeds

261. Wild radish and Buchan weed are both declared weeds in canola growing states and are not easily controlled in agricultural areas<sup>13</sup>. If GM herbicide tolerance traits were introgressed into populations of these weeds, it would increase the difficulty of weed management, particularly where herbicide tolerance traits were not anticipated. These GM weeds could impact the agricultural environment by reducing the establishment or yield of desired crops.

262. It should be noted that weeds can evolve herbicide resistance through natural mechanisms due to selective pressure. There are reports of wild radish populations in Australia that have acquired resistance to one or more of five classes of herbicides, including glyphosate<sup>14</sup>. If wild radish did acquire herbicide tolerance genes from GM canola, it would be no more difficult to control than wild radish that had naturally evolved herbicide resistance.

## ***Conclusion***

263. Risk scenario 5 is not identified as a substantive risk because hybridisation between GM canola and Brassica crop species would occur at very low levels, hybrids between GM canola and Brassica crop species could be controlled by integrated weed management, and it is highly unlikely that GM herbicide tolerance gene/s would introgress into Brassicaceae weed species. Therefore, this risk could not be greater than negligible and does not warrant further detailed assessment.

## ***Section 3 Uncertainty***

264. Uncertainty is an intrinsic property of risk and is present in all aspects of risk analysis<sup>15</sup>.

265. There are several types of uncertainty in risk analysis (Bammer & Smithson 2008; Clark & Brinkley 2001; Hayes 2004). These include:

- uncertainty about facts:
  - knowledge – data gaps, errors, small sample size, use of surrogate data
  - variability – inherent fluctuations or differences over time, space or group, associated with diversity and heterogeneity
- uncertainty about ideas:
  - description – expression of ideas with symbols, language or models can be subject to vagueness, ambiguity, context dependence, indeterminacy or under-specificity

<sup>13</sup> Source: Department of the Environment – [National weeds lists websites](#); accessed 12 November 2015.

<sup>14</sup> The reported wild radish populations with glyphosate resistance did not acquire their trait from glyphosate tolerant GM canola. The glyphosate resistant wild radish populations were found in Western Australia in 2010 (Ashworth et al. 2014), and GM canola was first commercially grown in Western Australia in 2010, so there was no opportunity for introgression to have occurred.

<sup>15</sup> A more detailed discussion is contained in the Regulator's *Risk Analysis Framework* available from the [OGTR website](#) or via Free call 1800 181 030.

- perception – processing and interpreting risk is shaped by our mental processes and social/cultural circumstances, which vary between individuals and over time.

266. Uncertainty is addressed by approaches such as balance of evidence, conservative assumptions, and applying risk management measures that reduce the potential for risk scenarios involving uncertainty to lead to harm. If there is residual uncertainty that is important to estimating the level of risk the Regulator will take this uncertainty into account in making decisions.

267. InVigor® x TruFlex™ Roundup Ready® canola has been approved by the Regulator for limited and controlled release (field trials) under licence DIR 104. The RARMP for DIR 104 identified additional information that may be required for a large scale or commercial release of InVigor® x TruFlex™ Roundup Ready® canola. This includes the uncertainty associated with the potential for any unintended effects as a result of changes in biochemistry, physiology or ecology of the GM canola plants, particularly noting further characterisation related to enhanced tolerance to abiotic or biotic stress. Information provided by the applicant addressing these areas of uncertainty is presented and discussed in Chapter 1, Section 7.2.

268. Uncertainty can arise from a lack of experience with the GMO itself. The GMOs proposed for release have never been grown in Australia and, although approved for commercial release, neither of the GM parental lines InVigor® and TruFlex™ Roundup Ready® have been grown in Australia on a commercial scale. However, the level of uncertainty is considered to be low given that the GM canolas have been grown in the United States and Canada to generate data for this application, and the GM parental line InVigor® has been grown in the Canada for ~20 years. In addition, Roundup Ready® canola, which contains the same *cp4 epsps* gene as TruFlex™ Roundup Ready® canola, has been commercially grown in Australia, Canada and the USA for many years without adverse effects for human health and safety or the environment. The uncertainty has been taken into account in assessment of risk scenarios, and is not sufficient to affect the conclusions on the overall level of risk.

269. For commercial releases of GMOs, which typically do not have limited duration, uncertainty regarding any future changes to knowledge about the GMO is addressed through post release review (Chapter 3, Section 4).

## **Section 4 Risk evaluation**

270. Risk is evaluated against the objective of protecting the health and safety of people and the environment to determine the level of concern and, subsequently, the need for controls to mitigate or reduce risk. Risk evaluation may also aid consideration of whether the proposed dealings should be authorised, need further assessment, or require collection of additional information.

271. Factors used to determine which risks need treatment may include:

- risk criteria
- level of risk
- uncertainty associated with risk characterisation
- interactions between substantive risks.

272. Five risk scenarios were postulated whereby the proposed dealings might give rise to harm to people or the environment. The level of risk for each scenario was considered negligible in relation to both the seriousness and likelihood of harm, and by considering both the short and long term. The principal reasons for these conclusions are summarised in Table 6.

273. The *Risk Analysis Framework* (OGTR 2013), which guides the risk assessment and risk management process, defines negligible risks as insubstantial with no present need to invoke actions for their mitigation. Therefore, no controls are required to treat these negligible risks.

Hence, the Regulator considers that the dealings involved in this proposed release do not pose a significant risk to either people or the environment.

## Chapter 3 Risk management plan

### Section 1 Background

274. 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 addresses risks evaluated as requiring treatment and considers limits and controls proposed by the applicant, as well as general risk management measures. The risk management plan informs the Regulator's decision-making process and is given effect through licence conditions.

275. 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.

276. 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 allow the Regulator to maintain oversight of licensed dealings: section 64 requires the licence holder to allow the Regulator, or a person authorised by the Regulator, to enter premises 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.

277. The licence is also subject to any conditions imposed by the Regulator. Examples of the matters to which conditions may relate are listed in section 62 of the Act. Licence conditions can be imposed to limit and control the scope of the dealings and to manage risk to people or the environment. 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 substantive risks

278. The risk assessment of risk scenarios listed in Chapter 2 concluded that there are negligible risks to people and the environment from the proposed release. These risk scenarios were considered in the context of the large scale of the proposed release and the receiving environment. The risk evaluation concluded that no containment measures are required to treat these negligible risks.

### Section 3 General risk management

279. 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
- testing methodology
- identification of the persons or classes of persons covered by the licence
- reporting structures
- access for the purpose of monitoring for compliance.

#### 3.1 Applicant suitability

280. 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 capacity of the applicant to meet the conditions of the licence.

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

282. The licence includes a requirement for the licence holder to inform the Regulator of any circumstances that would affect their suitability.

283. In addition, any applicant organisation must have access to a properly constituted Institutional Biosafety Committee and be an accredited organisation under the Act.

### **3.2 Testing methodology**

284. Bayer is required to provide a method to the Regulator for the reliable detection of the GMOs, and the presence of the introduced genetic materials in a recipient organism. This instrument is required prior to conducting any dealings with the GMOs.

### **3.3 Identification of the persons or classes of persons covered by the licence**

285. Any person, including the licence holder, may conduct any permitted dealing with the GMOs.

### **3.4 Reporting requirements**

286. 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 dealings
- any contraventions of the licence by persons covered by the licence
- any unintended effects of the release.

287. The licence holder is also obliged to submit an Annual Report containing any information required by the licence.

288. There are also provisions that enable the Regulator to obtain information from the licence holder relating to the progress of the commercial release (see Section 4, below).

### **3.5 Monitoring for compliance**

289. 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 the Regulator, or a person authorised by the Regulator to enter premises where a dealing is being undertaken for the purpose of monitoring or auditing the dealing.

290. 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 the health and safety of people or the environment could result.

## **Section 4 Post release review**

291. Regulation 10 requires the Regulator to consider the short and the long term when assessing risks. The Regulator takes account of the likelihood and impact of an adverse outcome over the foreseeable future, and does not disregard a risk on the basis that an adverse outcome might only occur in the longer term. However, as with any predictive process, accuracy is often greater in the shorter rather than longer term.

292. For the current application for a DIR licence, the Regulator has incorporated a requirement in the licence for ongoing oversight to provide feedback on the findings of the RARMP and ensure the outcomes remain valid for future findings or changes in circumstances. This ongoing oversight will be achieved through post release review (PRR) activities. The three components of PRR are:

- adverse effects reporting system (Section 4.1)
- requirement to monitor specific indicators of harm (Section 4.2)
- review of the RARMP (Section 4.3).

293. The outcomes of these PRR activities may result in no change to the licence or could result in the variation, cancellation or suspension of the licence.

#### **4.1 Adverse effects reporting system**

294. Any member of the public can report adverse experiences/effects resulting from an intentional release of a GMO to the OGTR through the Free-call number (1800 181 030), fax (02 6271 4202), mail (MDP 54 – GPO Box 9848, Canberra ACT 2601) or via email to the OGTR inbox (ogtr@health.gov.au). Reports can be made at any time on any DIR licence. Credible information would form the basis of further investigation and may be used to inform a review of a RARMP (see Section 4.3 below) as well as the risk assessment of future applications involving similar GMOs.

#### **4.2 Requirement to monitor specific indicators of harm**

295. Collection of additional specific information on an intentional release provides a mechanism for ‘closing the loop’ in the risk analysis process and for verifying findings of the RARMP, by monitoring the specific indicators of harm that have been identified in the risk assessment.

296. The term ‘specific indicators of harm’ does not mean that it is expected that harm would necessarily occur if a licence was issued. Instead, it refers to measurement endpoints which are expected to change should the authorised dealings result in harm. Should a licence be issued, the licence holder would be required to monitor these specific indicators of harm as mandated by the licence.

297. The triggers for this component of PRR may include risk estimates greater than negligible or significant uncertainty in the risk assessment.

298. The characterisation of the risk scenarios discussed in Chapter 2 did not identify any risks greater than negligible. Therefore, they were not considered substantive risks that warranted further detailed assessment. Uncertainty is considered to be low. No specific indicators of harm have been identified in this RARMP for application DIR 138. However, specific indicators of harm may also be identified during later stages, eg through either of the other components of PRR.

299. Conditions have been included in the licence to allow the Regulator to request further information from the licence holder about any matter to do with the progress of the release, including research to verify predictions of the risk assessment.

#### **4.3 Review of the RARMP**

300. The third component of PRR is the review of RARMPs after a commercial/general release licence is issued. Such a review would take into account any relevant new information, including any changes in the context of the release, to determine if the findings of the RARMP remained current. The timing of the review would be determined on a case-by-case basis and may be triggered by findings from either of the other components of PRR or be undertaken after the authorised dealings have been conducted for some time. If the review findings justified either an increase or decrease in the initial risk estimate(s), or identified new risks to



people or to the environment that require management, this could lead to changes to the risk management plan and licence conditions.

## **Section 5 Conclusions of the RARMP**

301. The risk assessment concludes that this proposed commercial release of GM canola poses negligible risks to the health and safety of people or the environment as a result of gene technology.

302. The risk management plan concludes that these negligible risks do not require specific risk treatment measures. However, general licence conditions have been imposed to ensure that there is ongoing oversight of the release.

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## Appendix A Summary of submissions from prescribed experts, agencies and authorities on RARMP preparation

Before commencing preparation of the RARMP, the Regulator requested submissions from prescribed experts, agencies and authorities on matters considered relevant to the preparation of the RARMP. All issues raised in submissions relating to risks to the health and safety of people and the environment were considered. The issues raised, and how they are addressed in the consultation RARMP, are summarised below.

Summary of issues raised	Comment
Wants to know on which property within the Shire the GM canola would be trialled.	The application is for commercial release and, if approved, the GM canola could be grown by any farmer in the shire, subject to state and territory law.
Raises concerns that if a Council has a policy of "no GM Canola" and if a local farmer wished to grow GM canola, but is not afforded the opportunity because of the "no GM canola policy", then Council is potentially exposed from a legal sense.	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. Marketing and trade issues, including segregation and coexistence regimes, are outside the matters to which the Regulator may have regard when deciding whether or not to issue a licence.
Asks for risk mitigation to be put in place to avoid the spread of canola seed into non-GM canola paddocks and roadsides. Explains that when this occurred in the past that roadside managers, such as Councils, were responsible for controlling this weed. States that the Council has areas of endangered habitat and environmental significance. These areas are protected by the EPBC Act and the Flora and Fauna Guarantee Act. Would like risk mitigation be put in place to control seed spreading into these areas.	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. Chapter 2 of the RARMP considered the risk of increased weediness compared to non-GM canola in agricultural areas, intensive use areas such as roadsides and in nature reserves. No substantive risks were identified because the same integrated weed management practices used for non-GM canola would be effective in managing the GM canola, with the exception of the choice of herbicide (glyphosate and glufosinate would not control the GM canola).
Has no comment on this application.	Noted.
Indicates that this does not fall under the Council's jurisdiction. Suggests contacting the Queensland Government's Department of Environment and Heritage Protection and the Department of Natural Resources and Mines.	Noted. Consultation on the application involved prescribed experts, Australian Government authorities and agencies, State and Territory Governments, relevant Australian local councils and the Minister for the Environment. The wider community, including all stakeholders consulted on the application will have the opportunity to comment on the consultation version of the RARMP. Submissions will be considered in finalising the RARMP, which will then inform the Regulator's decision on whether or not to issue a licence.
Has previously expressed concerns of the potential commercial release of GMOs. These concerns include: <ul style="list-style-type: none"> <li>the Government should preclude the release and use of GMOs until their safety has been demonstrated beyond doubt</li> <li>GM crops should be considered as part of an integrated regional natural resource management approach</li> <li>potential impact on organic or bio-dynamic producers, which could impact the regional community – GMOs could damage the clean and green reputation of the area, especially</li> </ul>	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. Chapter 2 of the RARMP considered the risk for increased toxicity, allergenicity or weediness compared to non-GM canola. The RARMP for this commercial release concludes that risks to human health and the environment are negligible. Issues of trade and marketing, such as potential impacts on: organic or biodynamic producers, a clean/green reputation and overseas markets, do not fall within the scope of the evaluation of the Regulator. These issues are the responsibility of the States, Territories and industry. Similarly, the consideration of an approved GM crop when developing an integrated regional natural resource management plan is a regional

Summary of issues raised	Comment
<p>impacting on the livelihood of organic or bio-dynamic producers</p> <ul style="list-style-type: none"> <li>potential for damage to overseas markets if consumers reject GM crops in other countries, as well as loss of market premiums.</li> </ul> <p>Strongly supports the current South Australian Government moratorium on GM crops.</p>	<p>issue.</p>
<p>Does not support the proposed field trial, including growing, storage and transport, of GM canola in their region. The region includes a Shire with the motto of 'pure' which is seen as providing marketing advantages. Not yet convinced that the release of GM products without significant direct benefits to public health should be permitted.</p> <p>States that without access to unbiased, expert data, scientific knowledge and a clear directive from the State Government of the proposed trial, a precautionary approach to any such trial must be taken and the risk of potential environmental and economic damage to the community and surrounding LGAs must be reduced.</p> <p>Mentions media articles which highlight the difficulties of treating roadside vegetation that is now immune to easy chemical treatment. States that it is suggested that this excessive vegetation is often from a GM product and that most roadsides and railway easements in this region now have fugitive canola growing with little or no treatment from the relevant authorities.</p> <p>If the trial is approved would expect safeguards put in place to:</p> <ul style="list-style-type: none"> <li>prevent escape of the GM canola from the trial sites</li> <li>ensure bees do not spread the GM canola to other areas.</li> </ul> <p>Considers canola a high risk crop for pollen mediated gene flow and recommends further research required to resolve that issue.</p> <p>Council would like to be informed of the exact location of the trials in order to provide a more meaningful response from people familiar with the area.</p> <p>Asks that any GM application receive a broad public notification and opportunity for comment so that informed choices can be made by more than just the regulators and the supporters for GM releases.</p>	<p>This application is for a commercial release of GM canola and, if approved, may be grown anywhere in Australia subject to state and territory law.</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. The RARMP for this commercial release concludes that risks to human health and the environment are negligible.</p> <p>Benefits, marketing and trade issues, including segregation and coexistence regimes, are outside the matters to which the Regulator may have regard when deciding whether or not to issue a licence. These matters are decided by individual States and Territories.</p> <p>The RARMP informs the Regulator when making a decision whether or not to issue a licence. Each RARMP includes a critical assessment of data supplied by the applicant, together with a review of other relevant national and international scientific literature and is finalised following an extensive consultation process as required by the Act.</p> <p>Risks related to gene flow and weediness of the GM canola are considered in Chapter 2 of the RARMP.</p> <p>The same integrated weed management practices as for non-GM canola would be effective in managing the GM canola, with the exception of the choice of herbicide (glyphosate and glufosinate would not control the GM canola).</p> <p>Consultation on the application was conducted in accordance with the Act, involving prescribed experts, Australian Government authorities and agencies, State and Territory Governments, relevant Australian local councils and the Minister for the Environment. The wider community, including all stakeholders consulted on the application now have the opportunity to comment on the consultation version of the RARMP. The public notification includes advertising in the widely circulated newspaper The Australian, rural press, the Australian Government Gazette and the OGTR website. The invitation to comment is also sent to interested parties who have registered on the OGTR mailing list and a tweet will be broadcast by the Health Department's Twitter account. Submissions will be considered in finalising the RARMP, which will then inform the Regulator's decision on whether or not to issue a licence.</p>
<p>The City would like to refer Regulator to the Northern Agricultural Council NARVSI site for natural resource information about the area.</p>	<p>The NARVSI website contains information about natural resource management for the Northern Agricultural region of WA. As this is an application for commercial release the Regulator considers all the areas in Australia where the GM canola may be grown, or may spread and persist.</p> <p>Chapter 2 of the RARMP considered the risk of increased weediness compared to non-GM canola in agricultural areas, intensive use areas such as roadsides and in nature reserves. No substantive risks were identified because the GM canola lines are similar to non-GM canola with respect to the intrinsic characteristics contributing to spread and persistence of canola, they are susceptible to the biotic or abiotic stresses that normally restrict the geographic range and persistence of canola and the same integrated weed management practices used for non-GM canola would be effective in managing the GM canola, with the</p>

Summary of issues raised	Comment
	exception of the choice of herbicide (glyphosate and glufosinate would not control the GM canola).
<p>Has not canvassed public opinion on this matter and we expect there would be opposition to use of GM crops in the area.</p> <p>Is not qualified to comment on the public health or indeed the economic impacts of this application; however, this application does not appear to impact the region.</p> <p>Has noted details regarding Dealings involving Intentional Release in general as well as regarding the current application.</p> <p>Acknowledges that canola is not grown in the Council's area as it is financially unviable.</p>	Noted.
<p>The RARMP should take into account:</p> <ul style="list-style-type: none"> <li>• any adverse effects of the parental GM canola lines</li> <li>• the rationale and conclusions from the RARMP for DIR 108 which should be broadly applicable, as the GMOs are highly similar</li> <li>• environmental issues arising from Hyola dual herbicide tolerant canola (Roundup Ready x Triazine tolerant) should be discussed.</li> <li>• gene flow from the GM canola to sexually compatible species, including <i>Brassica juncea</i>, radish, charlock and Buchan weed</li> <li>• dual herbicide tolerant canola volunteers are more difficult to control than single herbicide tolerant canola, leading to reduced establishment of native vegetation.</li> </ul> <p>Notes that there appears to be no plausible pathway for any potential of a novel adverse phenotype due to synergistic interactions between the introduced genes/proteins.</p> <p>The Department has identified one technical issue in the application summary and has suggested a more accurate description of the interaction between the CP4 EPSPS enzyme and the herbicide glyphosate.</p>	<p>The potential for adverse effects of the parental GM canola lines is discussed in Chapter 1, Section 5, which refers to the data, rationale and conclusions from the RARMPs for DIR 020/2002 (Roundup Ready® canola), DIR 021/2002 (InVigor® canola), DIR 127 (TruFlex™ Roundup Ready®) and DIR 108 (InVigor® x Roundup Ready® canola). Updated information is included.</p> <p>Gene flow from the GM canola to sexually compatible species, including amongst GM and non-GM herbicide tolerant canola and management of canola with multiple herbicide tolerance traits is considered in Chapter 2.</p> <p>The Application Summary for DIR 138 has been amended to improve the description of the CP4 EPSPS enzyme.</p>
<p>States that the region is a highly urban area and the proposed application would not have an impact in the area in the short term.</p> <p>States that there are examples of GM canola becoming a roadside weed in other states and urges caution as the GM canola proposed for release could pose a threat to the agricultural industry and natural bushland areas in the long term.</p> <p>Stresses the need for public consultation and education regarding this matter.</p>	<p>Risks related to weediness of the GM canola are considered in Risk Scenarios 2, 3, 4 and 5.</p> <p>Consultation on the application involved prescribed experts, Australian Government authorities and agencies, State and Territory Governments, relevant Australian local councils and the Minister for the Environment.</p> <p>The wider community, including all stakeholders consulted on the application will have the opportunity to comment on the consultation version of the RARMP. Submissions will be considered in finalising the RARMP, which will then inform the Regulator's decision on whether or not to issue a licence.</p>
<p>Does not support GM glyphosate tolerant crops for release in its local government area due to the:</p> <ul style="list-style-type: none"> <li>• potential damage to the clean green image currently used by producers to sell their product</li> <li>• potential environmental impact if these plants escape into the natural environment</li> <li>• individuals may grow GM glyphosate tolerant crops without consultation with Council or neighbours and this may impact negatively on</li> </ul>	<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. The RARMP for this commercial release concludes that risks to human health and the environment are negligible.</p> <p>Risks related to weediness of the GM canola are considered in Chapter 2 of the RARMP.</p> <p>The same integrated weed management practices used for non-GM canola would be effective in managing the GM canola, with the exception of the choice of herbicide (glyphosate and glufosinate would</p>

Summary of issues raised	Comment
<p>organic or non-GM producers.</p> <p>Notes that canola or GM crops are currently not grown in the Shire, but expresses concern regarding the potential for dryland cropping in the future.</p> <p>Looks forward to receiving the RARMP for comment.</p>	<p>not control the GM canola).</p> <p>Marketing and trade issues, including segregation and coexistence regimes, are outside the matters to which the Regulator may have regard when deciding whether or not to issue a licence. These matters are decided by individual States and Territories.</p> <p>Comments on the consultation RARMP are now sought.</p>
<p>Raised no issue for consideration in the preparation of the RARMP.</p> <p>Notes that the commercial release would extend to all states and territories, but that some jurisdictions restrict the cultivation of GM canola.</p> <p>Wishes to comment on the consultation RARMP when it has been developed.</p>	<p>Noted.</p> <p>Comments on the consultation RARMP are now sought.</p>
<p>Agrees that the RARMP should consider issues identified earlier, ie</p> <ul style="list-style-type: none"> <li>• the potential for the GM canola to be harmful to people through toxicity or allergenicity</li> <li>• the potential for the GM canola to be harmful to other desirable organisms through toxicity</li> <li>• whether the introduced hybrid breeding system and tolerance to two herbicides will increase the potential for InVigor® x TruFlex™ Roundup Ready® canola to spread and persist, leading to harm to the environment</li> <li>• the potential for gene flow to other canola, including other commercially approved GM canola and non-GM herbicide tolerant canola, and whether this could lead to harm to the environment</li> <li>• whether the commercial release is likely to result in changes to agricultural practices that may have an adverse environmental impact.</li> </ul>	<p>The items raised are addressed in Chapter 2, Risk Scenarios 1 – 5 in of the RARMP. The RARMP for this commercial release concludes that risks to human health and the environment are negligible.</p>
<p>Notes that as this is a conventional breeding cross of existing GM canola, then no additional concerns were raised.</p>	<p>Noted.</p>
<p>Notes that there were no recent publications on the incidence of GM canola volunteers on roadsides since 2001 and so there is a lack of information about the effect of commercial release of GM canola on incidence of roadside canola.</p>	<p>Chapter 1 of the RARMP presents information from a 2011 survey regarding canola growing as a volunteer along roadsides. The incidence of GM or non-GM canola along roadsides is dependent upon a number of factors such as spillage during transport, soil disturbance and the local council's desire or need to control plant growth along roadsides.</p>



## Appendix B Summary of advice from prescribed experts, agencies and authorities on the consultation RARMP

The Regulator received a number of submissions from prescribed experts, agencies and authorities<sup>16</sup> 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. Advice received is summarised below.

Summary of issues raised	Comment
Council does not have staff with the required expertise to comment on this matter.	Noted.
Concerned for non-GM growers who may be forced to farm alongside GM growers, whose crops may be subjected to GM pollen, the subsequent loss of their non-GM status, and potential prosecution from Bayer for having GM presence in a non-GM crop. Notes that the RARMP does not consider marketing and trade issues because such issues are covered by other agencies. Queries which agencies deal with such trade and marketing matters.	Marketing and trade issues, including segregation and coexistence regimes, are decided by individual States and Territories.
Requests confirmation that the release of GM canola will not occur in South Australia due to the current moratorium on GM crops.	This is correct. The licence does not authorise dealings with GM canola that are otherwise prohibited as a result of the operation of State legislation.
As Council does not have a specialist scientific expert to make an assessment no comment will be provided.	Noted.
Satisfied with the conclusions of the draft RARMP and has no additional comments.	Noted.
Agrees with the overall conclusion of the RARMP and raises no further issues.	Noted.
Supportive of the application as the consultation RARMP indicates that the proposed release poses negligible risks to people or the environment. Understands that a range of licence conditions would ensure there is ongoing oversight of the release. Notes that food made from this GM canola has been assessed and approved by FSANZ as safe for human consumption.	Noted.
Notes that FSANZ has assessed the food made from the GM canola and approved them to be safe for human consumption. Does not have any further comments on the licence application at this stage.	Noted.
Opposes the introduction of GM plants within the Northern Territory.	Individual States or Territories have the power to declare areas to be GM-free for marketing purposes. This does not fall within the remit of the Gene Technology Regulator. In the case of the current release of GM canola, it should be noted that canola plants are not commercially grown in the Northern Territory.
Notes that statements regarding unintended effects produced by genetic modification and by conventional breeding are supported solely on one reference each. Scientific rigour would be enhanced if additional references were cited.	Two additional relevant scientific references on unintended effects produced by genetic modification and conventional breeding have been added to the RARMP.

<sup>16</sup> Prescribed agencies include GTTAC, State and Territory Governments, relevant local governments, Australian Government agencies and the Minister for the Environment.

<b>Summary of issues raised</b>	<b>Comment</b>
Has no additional comments on DIR 138 and supports the Office of the Gene Technology Regulator's conclusion that DIR 138 poses negligible risk of harm to human health and the environment.	Noted.
Raises no issues to be considered in the preparation of the RARMP.	Noted.
Nil comment.	Noted.
Has no comments on DIR 138 and supports the science behind the risk assessment for commercial release of GM canola.	Noted.

## Appendix C Summary of submissions from the public on the consultation RARMP

The Regulator received eleven submissions from the public on the consultation RARMP. The issues raised in these submissions are summarised in the table below. All issues raised in the submissions that related to risks to the health and safety of people 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.

Sub. No.	Summary of issues raised	Comment
1	Objects to the GM canola being released to the public in regards to lack of independent third party (outside of Monsanto and Bayer self testing or linked paid testing) testing for human health safety.	The RARMP concludes that the commercial release of this GM canola poses negligible risks to the health and safety of people. The RARMP was prepared using a combination of critical assessment of data provided by the applicant, review of published scientific literature, information on relevant previous approvals and any adverse effects of these releases, and advice received from a range of Australian government authorities, agencies, experts and the public.
2	Does not like the path that Australia is heading down with using pesticides on our foods that we feed our children. When so many countries throughout the world are now turning away from the use of glyphosate cannot believe that Australia is still selling it and now wanting to change our crops to be tolerant of its use. This product is causing health problems as well as killing off the bees, which we need to pollinate our crops.	Issues relating to herbicide use are outside the scope of the Regulator’s assessments. The APVMA has regulatory responsibility for agricultural chemicals, including herbicides, in Australia. The APVMA considers risks to human health, animals and the environment in assessing agricultural chemicals for registration. Further information on the safety of glyphosate is available on the <a href="#">APVMA website</a> .
3	In the interest of Australian food and Australian food production, affecting both humans and animals, opposes the introduction of GM canola. “Feed the World” is a cliché of Big Pharma or Big Agriculture, when universally accepted ordinary food production could meet this need, if the distribution network around the world was improved. Sadly that doesn’t make money for Big Ag.	The Regulator is required to assess the risks of GMOs and cannot consider any benefits of gene technology. Therefore, no claims of benefits from GMOs have been taken into account when preparing the RARMP.
	Gene Technology is the scientific disruption and introduction of a foreign unknown entity into the DNA structure of the plant species. DNA and RNA should not be interrupted as the adverse effects on the human genome are not known and devastating.	The potential for unintended effects due to random insertion of introduced DNA into the canola genome is discussed in Chapter 2, Section 2.1 of the RARMP. These types of changes to the genome also occur in plants generated by conventional breeding, which have a long history of safe use.
	GM crops involve the insertion of modified virus and insect virus genes into crops. It is shown in the laboratory that genetic reconfiguration will create highly virulent new viruses from such configuration. The widely used cauliflower mosaic virus is a potentially dangerous gene. It is a pararetrovirus meaning that it multiplies by making DNA from RNA messages. It is very similar to the Hepatitis B virus and related to HIV. Modified viruses could cause famine by destroying crops and cause human and animal diseases.	This GM canola does not contain any introduced virus genes. As discussed in Chapter 1, Section 8.4, it contains short regulatory sequences derived from cauliflower mosaic virus and figwort mosaic virus. These regulatory sequences comprise a small part of the viral genomes and in themselves have no pathogenic properties. There are many known pararetroviruses and only a few are harmful to humans. Note that cauliflower mosaic virus is commonly found in vegetables including cauliflower, broccoli and cabbage. Its whole genome is consumed by humans with no ill effects, as plant viruses do not infect humans or animals.

Sub. No.	Summary of issues raised	Comment
	Toxins produced by Gene Technology could end up in products without anybody's knowledge.	The potential for the GM canola or its products to be toxic to people is considered in Risk Scenario 1 in Chapter 2 of the RARMP. The RARMP concludes that the commercial release of this GM canola poses negligible risks to the health and safety of people. FSANZ has regulatory responsibility for food safety assessments and food labelling in Australia, including GM food.
4	There is nothing new in gene technology corporations altering life-forms to suit industrial business interests. Tolerance to herbicides glufosinate and glyphosate and increased use of these is not sensible, for obvious reasons of human health and environmental sustainability.	Issues relating to herbicide use are outside the scope of the Regulator's assessments. The APVMA has regulatory responsibility for agricultural chemicals, including herbicides, in Australia. The APVMA considers risks to human health and the environment in assessing agricultural chemicals for registration and in setting maximum application rates. It is noted in Chapter 1, Section 8.3, of the RARMP that 95% of the current commercial non-GM and GM canola crop in Australia is tolerant to one or more herbicides. Thus, release of another herbicide tolerant canola may lead to a shift in herbicide use rather than an absolute increase.
5	The introduction of a new brassica variety with genes which currently don't exist in this species in the Australian environment potentially compromises future weed control options and enhances existing weed species that this species may cross with.	The potential for GM canola plants to become weedy due to reduced effectiveness of weed management is considered in Risk Scenarios 2 and 3 in Chapter 2 of the RARMP. These risks were assessed as negligible because the GM canola can be controlled using integrated weed management. The potential for crossing between the GM canola and brassica weeds is considered in Risk Scenario 5. This risk was assessed as negligible because it is highly unlikely that GM herbicide tolerance gene/s could introgress into brassica weed species.
	The introduction of new GM canola compromises Australia's ability to grow GM free canola given that pollinating organisms are likely to spread the genes from this species to adjoining crops and nearby naturalised specimens.	Marketing and trade issues, including segregation and coexistence regimes, are outside the matters to which the Regulator may have regard when deciding whether or not to issue a licence. These matters are decided by individual States and Territories.
6	It is impossible to prevent the generation of volunteer canola at test sites or within GMO crops. This finding was stated in previous OGTR monitoring reports. Therefore OGTR should have proof that the applicant will compensate the owners of neighbouring non-GM farms for the inevitable contamination of their crops with volunteer canola. Otherwise OGTR is also responsible for such contamination (and compensation) in that their approval was given to the applicant for the commercial release.	GM canola volunteers would be expected to grow following the cultivation of GM canola, in the same way as non-GM canola volunteers grow following cultivation of non-GM canola. Risk Scenario 2 in Chapter 2 of the RARMP considered potential harms from GM canola volunteers in agricultural areas and assessed that they pose no greater risks than non-GM canola volunteers. Marketing and trade issues, including segregation and coexistence regimes, are outside the matters to which the Regulator may have regard when deciding whether or not to issue a licence. These matters are decided by individual States and Territories.
	It is impossible to prevent long distance spreads of volunteer canola by transport of GM crops. The spread and persistence of volunteer canola causes degradation of areas such as parks or recreational areas, or native vegetation on roadsides. Then if removal of the weeds is attempted by herbicides, ecosystems are poisoned	GM canola seed could be dispersed by transport, in the same way as non-GM canola seed is dispersed by transport. Risk Scenario 3 in Chapter 2 of the RARMP considered potential harms from GM canola volunteers on roadsides or in nature reserves and assessed that they pose no greater risks than non-GM

Sub. No.	Summary of issues raised	Comment
	(insects, birds, waterways). Who is going to pay for spillages and clean-ups? Maybe OGTR as they granted the license for the commercial release.	canola volunteers.
	This new "breed" of GM canola will be just as herbicide-resistant as previous "breeds." OGTR is just as responsible for the super weeds and super bugs as the farmer growing the GM canola, as they approved the application.	Chapter 1, Section 8.3, of the RARMP explains that 95% of the current commercial canola crop in Australia is herbicide tolerant, either with a GM herbicide tolerance trait or one of two non-GM herbicide tolerance traits. The GM canola assessed by this RARMP is also herbicide tolerant.
7	As someone who is already highly sensitive to certain foods and the way they are processed, is concerned about the health implications of genetically modified foods entering the Australian food chain. There are serious moral and ethical questions that still need to be addressed concerning GM food and crops, this includes how GM food affects the human body in the long term. Australia is currently struggling to maintain its health care system. GM foods, and even trace GM processing, has the potential to make people sick and add even more unseen pressure to this system.	FSANZ has regulatory responsibility for food safety assessments in Australia. FSANZ has approved food derived from the GM canola for human consumption. It is noted that the two parental GM canola lines in this licence application have been grown commercially in North America since 1995 and 1996, respectively, without any evidence of adverse health effects.
8	Concerned regarding: <ul style="list-style-type: none"> <li>- Lack of long term independent research on the health effects of the consumption of GM canola</li> <li>- A growing national concern about the safety of GM crops</li> </ul>	FSANZ has regulatory responsibility for food safety assessments in Australia. FSANZ has approved food derived from the GM canola for human consumption. It is noted that the two parental GM canola lines in this licence application have been grown commercially in North America since 1995 and 1996, respectively, without any evidence of adverse health effects.
	<ul style="list-style-type: none"> <li>- The recent statement from the World Health Organisation on the likely carcinogenic properties of glyphosate, a key components in the advertised 'benefits' of GM canola</li> <li>- The growing number of countries banning the use of glyphosate</li> </ul>	Issues relating to herbicide use are outside the scope of the Regulator's assessments. The APVMA has regulatory responsibility for agricultural chemicals, including herbicides, in Australia. The APVMA considers risks to human health, animals and the environment in assessing agricultural chemicals for registration. Further information on the safety of glyphosate is available on the <a href="#">APVMA website</a> .
	<ul style="list-style-type: none"> <li>- Unclear labelling laws in Australia. If GM canola or any GM foods are to be allowed in the food chain then clear and mandatory labelling of their GM status should be implemented</li> </ul>	Labelling of food, including GM foods, is the responsibility of FSANZ. Labelling of GM status is legally required for GM foods that contain novel DNA or protein or have altered characteristics.
	<ul style="list-style-type: none"> <li>- Growing global sentiment against GM crops by many of Australia's trading partners</li> <li>- The significant risk to Australia's export markets with GM contamination of conventional crops potentially cutting some export markets</li> <li>- Litigation laws surrounding the patent holders of GM technologies, growers of GM crops and the growers of conventional and organic crops. Conventional and organic farming being the established technology, the rights, interests and markets for conventional growers must be protected and take precedence over the rights and interests of GM growers.</li> </ul>	Marketing and trade issues, including segregation and coexistence regimes, are outside the matters to which the Regulator may have regard when deciding whether or not to issue a licence. These matters are decided by individual States and Territories.

Sub. No.	Summary of issues raised	Comment
9	<p>GM canola is currently being grown in WA, but the public is not aware where, if and how it is finding its way into the food chain. Current labelling laws are inadequate. The GM industry tells the public that we are eating GM canola, yet we are unaware because there are few, if any, items on the supermarket shelf that carry a GM label.</p>	<p>Labelling of food, including GM foods, is the responsibility of FSANZ. Labelling of GM status is legally required for GM foods that contain novel DNA or protein or have altered characteristics.</p>
	<p>It is evident that there has been no public health studies on the effects of the GM canola already released. Until that is done, looking for both acute and chronic effects, it cannot be concluded that GM canola is negligible risk. The American Academy of Environmental Medicine (AAEM) position statement on GMOs in 2009 included a recommendation that regulators would be negligent to ignore: "because GM foods have not been properly tested for human consumption, and because there is ample evidence of probable harm, the AAEM asks physicians to educate their patients, the medical community, and the public to avoid GM foods when possible and provide educational materials concerning GM foods and health risks."</p> <p>Seralini et al conducted the world's first whole-of-life study of a Roundup Ready "food", published in 2012 and subsequently republished. The study in rats compared the effects of GM alone, Roundup alone, GM and Roundup together, and a control group, also considering male-female differences. The parameters of this study should form the minimum benchmark for regulators. Harmful effects were observed at concentrations of Roundup significantly less than that already approved by regulators and therefore significantly less than proposed in DIR138.</p>	<p>The RARMP concludes that the commercial release of this GM canola poses negligible risks to the health and safety of people. The RARMP was prepared using a combination of critical assessment of data provided by the applicant, review of published scientific literature, information on relevant previous approvals and any adverse effects of these releases, and advice received from a range of Australian government authorities, agencies, experts and the public. It was supported by a previous assessment by FSANZ who found that food derived from the GM canola is safe for human consumption.</p> <p>It is noted that the two parental GM canola lines in this licence application have been grown commercially in North America since 1995 and 1996, respectively, without any evidence of adverse health effects.</p> <p>The World Health Organization states regarding the safety of GM foods:</p> <p>"Different GM organisms include different genes inserted in different ways. This means that individual GM foods and their safety should be assessed on a case-by-case basis and that it is not possible to make general statements on the safety of all GM foods.</p> <p>"GM foods currently available on the international market have passed safety assessments and are not likely to present risks for human health. In addition, no effects on human health have been shown as a result of the consumption of such foods by the general population in the countries where they have been approved."</p> <p>Prof. Seralini's study has been assessed by FSANZ, the OGTR, the European Food Safety Authority, and many other national and international scientific bodies as having serious design, analysis and reporting flaws. Therefore, OGTR does not accept its conclusions. A response to the Seralini paper can be found on the <a href="#">FSANZ website</a>.</p>
	<p>Concerned that the industry does not submit accurate applications to regulators.</p>	<p>Note that giving false or misleading information in connection with an application made to the Regulator is an offence under the Act and is punishable by imprisonment or substantial fines.</p>
	<p>The proposed heavier and prolonged use of glyphosate in Roundup is enough reason to reject DIR 138. But further, there has been no testing of the combinatorial effects of glyphosate and glufosinate on human health. There has been no testing of the synergistic effects of glyphosate and glufosinate in the environment.</p>	<p>Issues relating to herbicide use are outside the scope of the Regulator's assessments. The APVMA has regulatory responsibility for agricultural chemicals, including herbicides, in Australia. The APVMA considers risks to human health and the environment in assessing agricultural chemicals for registration. Further information on the safety of glyphosate is available on the <a href="#">APVMA website</a>. The APVMA are responsible for assessing an application for use of glyphosate and glufosinate on the GM canola.</p>

Sub. No.	Summary of issues raised	Comment
	<p>It is evident from the Marsh v Baxter case in the WA Supreme Court Feb 10-28, 2014, that GM canola spreads across the landscape and is persistent in the environment. Subsequent actions by the GM industry applying for increased levels of GM and glyphosate in both conventional and organic food is an admission that the spread cannot be controlled. Ongoing regular audits of GM canola trial sites in Tasmania have cleared only 4 of 57 sites of GM canola weeds although it is now more than 10 years since the GM trials were stopped and a moratorium on GM crops legislated (Marsh v Baxter, witness statement by Andrew Bishop).</p> <p>GM contamination events around the world over the past two decades, such as in the US, Canada, South America, India and Philippines, are evidence that there are many unresolved issues of liability and unacceptable risk to land, water, air, pollinators and brand integrity of GM-free products once GMOs are released to the environment. Regulators cannot deny that these GM contamination events occur and therefore negligible risk cannot be concluded.</p>	<p>GM canola volunteers would be expected to grow following the cultivation of GM canola, in the same way as non-GM canola volunteers grow following cultivation of non-GM canola. Risk scenarios 2 and 3 in Chapter 2 of the RARMP consider the potential for adverse effects due to spread and persistence of GM canola. The harms resulting from spread and persistence of GM canola are not considered greater than the harms from spread and persistence of non-GM canola. The RARMP concludes that the commercial release of this GM canola poses negligible risks to the health and safety of people or the environment.</p> <p>Marketing and trade issues, including segregation and coexistence regimes, are outside the matters to which the Regulator may have regard when deciding whether or not to issue a licence. These matters are decided by individual States and Territories.</p>
	<p>Until these problems are duly recognised by industry and resolved by law makers, regulators and policy makers, calls for a freeze on all new approvals of GM crops. Further, in the light of new evidence, calls for a re-analysis of the effects of GM crops previously approved. No new GM applications should be approved until post-market reviews are done. OGTR must reject application DIR 138.</p>	<p>This RARMP incorporated post-market review of the two parental GM canola lines, as Section 6.2 of Chapter 1 of the RARMP reviewed new or updated information regarding the parental GM canola lines since issue of their RARMPs. If a risk issue had been identified, this would have triggered re-assessment of the existing licences.</p>
10	<p>Asks OGTR to reject application DIR138 for the commercial release of InVigor® x TruFlex™ Roundup Ready® canola which is claimed to be similar to DIR108 and is a hybrid conventionally bred from GM canola parents DIR021/2002 InVigor® and DIR127 TruFlex™.</p> <p>Concerns were raised on the previous applications, many of which were questionably dismissed as outside scope or negligible safety risk to health and environment. However, assumption-based risk assessments based on industry-only data which focuses on commercial interest ahead of public interest does not prove these GM crops as safe. Asks OGTR to re-analyse concerns for each application individually, as the risks would only be compounded by the combination.</p>	<p>The RARMP concludes that the commercial release of this GM canola poses negligible risks to the health and safety of people or the environment. The RARMP was prepared using a combination of critical assessment of data provided by the applicant, review of published scientific literature, information on relevant previous approvals and any adverse effects of these releases, and advice received from a range of Australian government authorities, agencies, experts and the public. The RARMPs for the previous applications DIRs 021/2002, DIR 108 and DIR 127 were studied while preparing this RARMP, including consideration of relevant risk issues raised in public submissions.</p>
	<p>Concerned that claims made by industry may not be accurate.</p>	<p>Note that giving false or misleading information in connection with an application made to the Regulator is an offence under the Act and is punishable by imprisonment or substantial fines.</p>

Sub. No.	Summary of issues raised	Comment
	<p>Concerned that the combination of the two chemicals glyphosate and glufosinate is potentially more poisonous.</p>	<p>Issues relating to herbicide use are outside the scope of the Regulator's assessments. The APVMA has regulatory responsibility for agricultural chemicals, including herbicides, in Australia. The APVMA considers risks to human health and the environment in assessing agricultural chemicals for registration. The APVMA are responsible for assessing an application for use of glyphosate and glufosinate on the GM canola.</p>
	<p>Absence of evidence of harm is not proof of safety if the testing is not done to look for side-effects and quantify the risk. Without proper pre-market trials with long-term multigenerational animal testing of GM crops looking for human health endpoints, without clinical trials, and without any post-market review of the previously approved GM crops, the OGTR should conclude that the risk of commercial release of GM canola DIR138 to health and environment is unacceptable.</p> <p>In the re-review, please consider new evidence of the risk of harm which is increasing with the passage of time as chronic and teratogenic effects become visible. Too often we hear that "Doctors have been baffled by the recent explosion in food allergies in Australian children." According to Dr Susan Prescott, we have an epidemic of childhood allergy and asthma.</p> <p>We have increasing cancer, diabetes, autism, irritable bowel, leaky gut, depression, behavioural problems. In the U.S. where Roundup Ready crops are prevalent and there is no labelling of food derived from GM organisms, we see progressive parents, paediatricians and medical practitioners prescribing a GMO-free diet and seeing significant improvement in patient health.</p>	<p>The potential for the GM canola or its products to be toxic or allergenic to people is considered in Risk Scenario 1 in Chapter 2 of the RARMP. The assessment is supported by a previous assessment by FSANZ which found that food derived from the GM canola is safe for human consumption. The RARMP concludes that the commercial release of this GM canola poses negligible risks to the health and safety of people.</p> <p>No evidence was provided in the submission, or found in scientific or medical literature, to suggest any link between the medical conditions listed and GM canola. This RARMP incorporated post-market review of the two parental GM canola lines, as Section 6.2 of Chapter 1 of the RARMP reviewed new or updated information regarding the parental GM canola lines since issue of their RARMPs. If a risk issue had been identified, this would have triggered re-assessment of the existing licences.</p>
	<p>A GMO-free diet is at risk from GM contamination as evidenced by the Marsh v Baxter case. This damage could have been prevented by proper laws and regulations to protect GMO-free farmers prior to commercial release of GM canola.</p>	<p>Marketing and trade issues, including segregation and coexistence regimes, are outside the matters to which the Regulator may have regard when deciding whether or not to issue a licence. These matters are decided by individual States and Territories.</p>
11	<p>The RARMP states, in reference to parental GM canola lines, that "there have been no credible reports of adverse effects on human health or the environment from any of these releases". What constitutes a definition of credible? There must have been some adverse reports for this statement to have been made. So, what were they? What independent assessment was made re "no credible reports"? If a person were susceptible to the GM canola pollen, what would be the distinguishing symptoms to look for? How could one prove that those symptoms arose from contact with the canola GMO, in order to supply a "credible report"? What is the distinguishing test for presence of the GM protein/s?</p>	<p>A credible report would be information reporting an incident of exposure to GMOs, and a specific adverse effect on human health or the environment that could plausibly be linked to the exposure. Any such report would trigger a detailed investigation and appropriate protective actions from OGTR.</p>
	<p>The RARMP states, in reference to food safety assessment of parental GM canola lines, that "FSANZ has determined that food derived from these GM lines of canola is as safe for human consumption as food derived from conventional (non-GM) canola varieties." The reasoning appears to be that since the GM parent canolas</p>	<p>FSANZ considers that no separate approval is necessary for foods derived from a stacked GM line that is the result of traditional breeding between approved GM parent lines. The reasons for this regulatory approach are explained on the <a href="#">FSANZ website</a>.</p>



Sub. No.	Summary of issues raised	Comment
	<p>were approved for use as food, therefore the GM canola offspring will be "as safe". Safety is exactly what has to be demonstrated via evidence obtained from controlled, human trials.</p> <p>The RARMP states, in reference to the introduced proteins, that "based on all available information these proteins are not known to be toxic or allergenic." But these proteins are mixed together in the genome to produce a novel product which therefore has to be proved to be safe.</p>	
	<p>The RARMP states that "herbicide metabolites would be present if the GM canola had been treated with glyphosate or glufosinate". Glyphosate / glufosinate would be incorporated within the GM canola seed, they being considered safe for animal feed despite the adverse animal health effects listed in the RARMP that "metabolites of glucosinolate ... can be toxic to the liver and kidneys". Herbicides are OK in feed?</p>	<p>Issues relating to herbicide use are outside the scope of the Regulator's assessments. The APVMA has regulatory responsibility for agricultural chemicals, including herbicides and their metabolites, in Australia. The APVMA considers risks to human health, animals and the environment in assessing agricultural chemicals for registration. The APVMA will assess an application for use of glyphosate and glufosinate on the GM canola.</p> <p>Note that glucosinolate is not a herbicide, despite the similarity in name. Glucosinolate is an anti-nutrient that occurs naturally, and at equivalent levels, in both GM and non-GM canola.</p>
	<p>The RARMP states that "the rate of outcrossing between canola plants averages around 30%. Outcrossing frequencies between adjacent fields of canola are highest in the first 10 m of the recipient fields...outcrossing rates between neighbouring commercial canola field were less than 0.1% averaged over whole fields". Risk Scenario 4 concludes that "hybrids between the GMOs and other canola would be generated at low levels". However, most of the outcrossing damage occurs where the GM/non-GM canola crops are in close proximity (ie within first 10 m). The 0.1% rate is misleading, irrelevant if it is to generate policy re outcrossing. It is the 30% outcrossing rate, where the different crops are contiguous, which is relevant. The proponents of the GMO canola have derived policy from the "less than 0.1%" outcrossing rate, to imply the outcrossing situation is minor, therefore needs minimal attention. Offers suggestions for co-operation between GM and non-GM canola growers to reduce incidences of outcrossing.</p>	<p>The RARMP has been rewritten to present information regarding outcrossing more clearly, and prevent any misunderstanding. While outcrossing between canola plants averages 30%, most of this outcrossing occurs between adjacent plants in the same field. The outcrossing rate in the first 10 m of adjacent fields averages 1.8%.</p> <p>The average outcrossing rate over a whole commercial canola field is considered the most relevant data for risk assessment, because in general a canola field is harvested as a single crop, not in separate 10 m strips.</p> <p>Risk Scenario 4 in Chapter 2 of the RARMP considers the potential for adverse effects due to outcrossing between the GM canola and other canola plants, and did not identify a substantive risk.</p>
	<p>Recommends that the commercial release of the GM canola be withheld until controlled, human trials are undertaken to provide necessary and sufficient evidence of safety of the double-stacked GMO as food/feed. Note that some participants in a recent medical trial of a new drug in France became seriously ill. The drug was previously assessed on several species of animal. The proponents would not be expecting their drug to have adverse human-health outcomes, as would not the proponents of the GM canola. Yet, there were serious effects, in the former case. Hence, human trials necessary, in the latter case.</p>	<p>FSANZ has regulatory responsibility for food safety assessments in Australia. Human trials are not part of the information required by FSANZ for the safety assessment of a GM food.</p> <p>The OGTR assesses the safety of GM feed. Human trials are not considered necessary to assess the safety of GM canola as animal feed.</p>