

Australian Government

Department of Health Office of the Gene Technology Regulator

Risk Assessment and Risk Management Plan for

DIR 127

Commercial release of canola genetically modified for herbicide tolerance (MON 88302)

Applicant: Monsanto Australia Ltd

November 2014

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Summary of the Risk Assessment and Risk Management Plan

for

Licence Application No. DIR 127

Decision

The Gene Technology Regulator (the Regulator) has decided to issue a licence for this application for the intentional, commercial scale release of a genetically modified organism (GMO) into the environment. 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 licence.

Application number	DIR 127
Applicant	Monsanto Australia Ltd (Monsanto)
Project title	Commercial release of canola genetically modified for herbicide tolerance (MON 88302) ¹
Parent organism	Brassica napus (canola)
Introduced gene and modified trait	5-enolpyruvylshikimate-3-phosphate synthase (<i>cp4 epsps</i>) gene derived from the bacterium <i>Agrobacterium</i> sp. strain CP4 (herbicide tolerance)
Proposed locations	Australia-wide, in all canola growing areas
Primary purpose	Commercial release of the GM herbicide tolerant canola

The application

This commercial release follows field trial work conducted under licence DIR 105.

Risk assessment

The risk assessment concludes that risks to the health and safety of people or the environment from the proposed dealings, either in the short or long term, are negligible. No specific risk treatment measures are required to manage these negligible risks.

The risk assessment process considers how the genetic modification and activities conducted with the GMO might lead to harm to people or the environment. Risks are 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 are considered.

¹ The title of the licence application submitted by Monsanto is "General release of *Brassica napus* genetically modified for herbicide tolerance (MON 88302) in Australia".

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 GM canola has previously been grown under limited and controlled conditions in Australia since 2011 without adverse effects on human health or environment; the widespread presence of the same or similar proteins encoded by the introduced gene in the environment and lack of known toxicity or evidence of harm from them; and the limited capacity of the GM canola to spread and persist in undisturbed natural habitats. In addition, food made from the GM canola has been assessed and approved by Food Standards Australia New Zealand as safe for human consumption.

Risk management

The risk management plan concludes that risks from the proposed dealings, either in the short or long term, to the health and safety of people, or the environment, are negligible. No specific risk treatment measures are proposed.

Risk management is used to protect the health and safety of people and to protect the environment by controlling or mitigating risk. The risk management plan evaluates and treats identified risks and considers general risk management measures. 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 under post-release review (PRR) 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

a.e.	Acid equivalent
ADF	Acid detergent fibre
AGSWG	Australian Glyphosate Sustainability Working Group
APVMA	Australian Pesticides and Veterinary Medicines Authority
CaMV	Cauliflower mosaic virus
CFIA	Canadian Food Inspection Agency
COFEPRIS	Federal Commission for the Protection against Sanitary Risk (Mexico)
cp4 epsps	epsps gene from Agrobacterium sp. strain CP4
CP4 EPSPS	EPSPS protein from Agrobacterium sp. strain CP4
СТР	Chloroplast transit peptide
ctp2	Chloroplast transit peptide coding region from the <i>epsps</i> gene of <i>A</i> . <i>thaliana</i>
dw	Dry weight
DIR	Dealings involving Intentional Release
DNA	Deoxyribonucleic acid
EFSA	European Food Safety Authority
ELISA	Enzyme-linked immunosorbent assay
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
ha	Hectare
μg	Microgram
umole	Micromole
MAFF	Ministry of Agriculture, Forestry and Fisheries (Japan)
MHLW	Ministry of Health, Labour and Welfare (Japan)
MOTIE	Ministry of Trade, Industry and Energy (Korea)
NDF	Neutral detergent fibre
OGTR	Office of the Gene Technology Regulator
PEP	Phosphoenol pyruvate
PRR	Post release review
SNP	Single nucleotide polymorphism
TDF	Total detergent fibre
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 that is being enacted in each State and Territory, 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).

RISK ASSESSMEN	IT CONTEXT			
LEGISLATIVE REQUIREMENTS (including Gene Technology Act and Regulations)				
RISK ANALYSIS FRAMEWORK				
OGTR OPERATIONAL POLICIES AND GUIDELINES				
PROPOSED DEALINGS Proposed activities involving the GMO Proposed limits of the release Proposed control measures GMO Introduced genes (genotype) Novel traits (phenotype) PREVIOUS RELEASES	PARENT ORGANISM Origin and taxonomy Cultivation and use Biological characterisation Ecology RECEIVING ENVIRONMENT Environmental conditions Agronomic practices Presence of related species Presence of similar genes			

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 with, 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. This means that, 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 councils² 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. Seventeen public submissions were received and their consideration is summarised in Appendix C.

7. The Risk Analysis Framework (OGTR 2013a) 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, National Industrial Chemicals Notification and Assessment Scheme and Department of Agriculture. 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. Monsanto Australia Ltd (Monsanto) proposes to release into the environment canola that has been genetically modified for herbicide tolerance. The GM canola proposed for release is designated MON 88302, which is also referred to as TruFlex[™] Roundup Ready[®] canola.

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 would include:

- (a) conducting experiments with the GMO
- (b) making, developing, producing or manufacturing the GMO
- (c) breeding the GMO with other canola cultivars
- (d) propagating the GMO
- (e) using the GMO in the course of manufacture of a thing that is not the GMO
- (f) growing, raising or culturing the GMO

² Monsanto is seeking approval for unrestricted commercial release of MON 88302 canola in all canola growing areas of Australia. This involves a significant proportion of the land in the Australian winter cereal belt of NSW, Victoria, South Australia, and Western Australia. It also includes Southern Queensland and Tasmania. Therefore, the Regulator decided to consult with all of the local councils in Australia, except for those that have

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.

- (g) transporting the GMO
- (h) disposing of the GMO
- (i) importing the GMO

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

Section 4 The parent organism

12. 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 Western Australia, New South Wales, Victoria and South Australia. Canola has been grown in Australia since the 1960s primarily for its seeds, which yield from 35% to over 45% oil. More detailed information on canola can be found in the document, *The Biology of* Brassica napus *L. (canola)* (OGTR 2011b), which was produced to inform the risk assessment process for licence applications involving GM canola plants. This document is available from the <u>Risk Assessment References page</u> of the OGTR website.

4.1 Weediness of non-GM canola

13. Baseline information on the characteristics of weeds in general, and the factors limiting the spread and persistence of non-GM canola plants in particular, is found in the document, *The Biology of* Brassica napus *L. (canola)* (OGTR 2011b).

14. Canola is considered a major weed in agricultural ecosystems in Australia (Groves et al. 2003). Surveys have shown that canola occurs as a volunteer weed in up to 10% of cereal crops in southern Australia (Lemerle et al. 1996) and similar levels have been reported in Canadian cereal crops (Leeson et al. 2005; Thomas et al. 1998). Canola also occurs as a weed in cropping regions in the USA (Weed Science Society of America 1992).

15. Due to its primary colonising nature, canola can take advantage of disturbed land (Salisbury 2002b). Canola plants are often observed growing near transport routes and at field margins (Agrisearch 2001; Crawley & Brown 2004; Nishizawa et al. 2009; von der Lippe & Kowarik 2007b) and occur in disturbed habitats along roadsides, railway lines, field margins and waste lands in all countries where it is grown (Crawley & Brown 2004; Norton 2002). In Australia and Canada, roadside canola populations are thought to be reliant on re-supply of seed from seed spillage during harvest and transport operations rather than forming self-sustaining weed populations (Gulden et al. 2008; Salisbury 2002b). Canola is also a poor competitor and will be displaced unless the habitats are disturbed on a regular basis (Beckie et al. 2001; OECD 1997; Salisbury 2002b).

16. Although canola is not grown commercially in northern Australia, it has been trialled in the Northern Territory as one of the potential biofuel crops (OGTR 2011b). However, large-scale planting of canola in northern Australia appears to be unlikely in the short term. Nonetheless, there is some uncertainty associated with the potential commercial canola production in northern regions of Australia, and whether canola could become weedy, including potential seed dispersal by flooding and crossing with related species in the new areas.

17. Canola is not considered a significant weed, nor invasive of natural undisturbed habitats in Australia (Dignam 2001; Norton 2002), Canada (Beckie et al. 2001; Canadian Food Inspection Agency 1994; Warwick et al. 1999) or the UK (Crawley et al. 2001).

18. In the context of this RARMP, characteristics of canola when present <u>as a volunteer</u> in the relevant agricultural land uses, in intensive use areas such as roadsides and in nature conservation areas are examined.

19. The Australian/New Zealand Standards HB 294:2006 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 New Zealand & CRC for Australian Weed Management 2006). These properties relate to invasiveness, impacts and potential distribution. The weed risk potential of canola has been assessed using methodology based on the National Post-Border Weed Risk Management Protocol (see Appendix 1, OGTR 2011b).

4.1.1 Potential to cause harm

20. 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 all land use areas
- minor effect on degradation of the landscape or ecosystems.

21. Canola seeds are used to produce two major products, canola oil and meal, but only the oil is used in human food. With respect to the potential to negatively affect the health of people, *B. napus* contains two natural toxicants in the seed: erucic acid and glucosinolates. The presence of high levels of erucic acid in traditional rapeseed oil has been associated with detrimental effects in experimental animals. Glucosinolates are located in the seed meal, which is used exclusively as livestock feed. The products of glucosinolate hydrolysis have negative effects on animal production (OECD 2001).

22. The term canola refers to varieties of *B. napus* that meet specific standards on the levels of erucic acid and glucosinolates. Canola must contain less than 2% erucic acid in the oil and less than 30 μ moles/g of glucosinolates in the meal. Australian canola varieties typically contain levels well below the maximum levels specified in the current standards (OGTR 2011b).

4.1.2 Invasiveness

23. With regard to invasiveness, non-GM canola has:

- the ability to reproduce sexually, but not by vegetative means
- low ability to establish amongst existing plants
- low tolerance to average weed management practices
- short time to seeding
- high annual seed production
- low ability to undergo long distance spread by natural means
- high possibility for spread long distance by people from dryland and irrigated cropping areas, as well as from intensive land uses such as road sides, but low possibility to be spread by people from or to nature conservation areas.

4.2 Sexually compatible plants

24. Canola is predominantly self-pollinating but inter-plant outcrossing occurs at an average rate of 30%. Outcrossing frequencies are highest in the first 10 m of the recipient fields, and rates decline with distance (Husken & Dietz-Pfeilstetter 2007). In a commercial situation, where different canola crops may be grown in adjacent fields, outcrossing is likely to occur beyond 10 m of the field borders. Some degree of cross pollination between canola lines is inevitable given sufficient proximity and exposure. However, under Australian conditions, even adjacent commercial canola fields would have much less than 1% gene transfer (Rieger et al. 2002).

25. Canola can also cross with other *B. napus* groups or subspecies (including vegetable forms), *B. oleracea, B. juncea* and *B. rapa* under natural conditions. Naturally occurring hybrids between *B. napus* and *R. raphanistrum, H. incana* and *S. arvensis* have also been reported at very low frequencies (Salisbury 2002a; Warwick et al. 2009). All of these species are naturalized in Australia and weedy forms are known to be present (Groves et al. 2003). *B. juncea, H. incana, R. raphanistrum* and *S. arvensis* are problematic weeds in commercial canola growing regions of Australia. However, hybridisation requires synchronicity of flowering between canola lines and sexually compatible species to enable cross-pollination and gene flow to occur. More detail about outcrossing rates and sexually compatible plants can be found in the *The Biology of* Brassica napus *L. (canola)* (OGTR 2011b).

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

5.1 Introduction to the GMO

26. MON 88302 canola contains the *cp4 epsps* gene which confers herbicide tolerance. The gene is derived from *Agrobacterium* sp. strain CP4 and encodes 5-enol-pyruvylshikimate-3-phosphate synthase (EPSPS), an enzyme of the shikimic acid pathway which is involved in the biosynthesis of plant phenolics.

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

5.2 The introduced gene, its encoded protein and associated effects

5.2.1 The cp4 epsps gene, its protein and end product

28. The *cp4 epsps* gene in MON 88302 canola confers tolerance to glyphosate (N-phosphonomethyl glycine). The gene was isolated from *Agrobacterium* sp. strain CP4 and encodes EPSPS, a 47.6 kDa protein consisting of a single polypeptide of 455 amino acids (Padgette et al. 1996). EPSPS is a key enzyme involved in the shikimate biosynthetic pathway in plants and microorganisms. The shikimate pathway enables biosynthesis of the aromatic amino acids phenylalanine, tyrosine and tryptophan from carbohydrate precursors in a series of seven biosynthetic steps. The penultimate step in the pathway is the condensation of shikimate 3-phosphate and phosphoenol pyruvate (PEP) to form 5-enolpyruvylshikimate 3-phosphate and phosphoenol pyruvate (PEP) to form 5-enolpyruvylshikimate 3-phosphate, a reaction catalysed by EPSPS (reviewed by Herrmann & Weaver 1999). EPSPS performs this function in plants, bacteria, algae and fungi, but is absent from mammals, birds, reptiles and fish, which are not able to synthesize these aromatic amino acids (Bentley 1990; Gasser et al. 1988; Padgette et al. 1993). On the basis of their amino acid sequences and catalytic efficiencies in the presence of glyphosate, EPSPS enzymes have been divided into two classes. Those from plants and *E. coli*, which are largely sensitive to glyphosate, are

designated as class I, while those from some species of bacteria, such as *Agrobacterium* strain CP4 (the *cp4 epsps* gene) and *Achromobacter* strain LBAA, which have tolerance to this herbicide, are designated as class II (Funke et al. 2006).

29. Glyphosate is the active ingredient in a number of broad-spectrum systemic herbicides that have been approved for use in Australia and was first marketed as the proprietary herbicide Roundup[®]. The herbicidal activity of glyphosate is derived from its ability to inhibit the function of EPSPS. Glyphosate competes with PEP for binding to the complex formed between EPSPS and shikimate 3-phosphate. Upon glyphosate binding, the EPSPS:shikimate 3-phosphate complex is very stable and has a slow reversal rate, effectively terminating the shikimate pathway prematurely and preventing biosynthesis of essential aromatic compounds, including the amino acids phenylalanine, tyrosine and tryptophan, and eventually leading to cell death (Dill 2005).

30. The CP4 EPSPS protein encoded by the *cp4 epsps* gene from *Agrobacterium* sp. is naturally insensitive to the effects of glyphosate (Padgette et al. 1993), as are a number of other microbial EPSPS enzymes (Eschenburg et al. 2002; Schulz et al. 1985). Consequently, in GM plant cells containing 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 1999).

31. The *cp4 epsps* gene and a variant of the *gox* gene from *Ochrobactrum anthropi* are the basis of glyphosate tolerance in Roundup Ready[®] canola (also referred to as GT73 or MON-00073-7 canola) which was developed by Monsanto and has been approved for commercial release in Australia (DIR 020/2002) and overseas (see Section 7.3 for additional information regarding overseas approvals). The nucleotide sequences of both genes were modified by Monsanto for plant-preferred codon usage but these nucleotide substitutions did not alter the sequence of the encoded proteins. The *gox* gene was isolated from the soil bacterium *O. anthropi* strain LBAA, and encodes a glyphosate detoxifying enzyme (GOX) that converts glyphosate into aminomethylphosphonic acid and glyoxylate (Pipke & Amrhein 1988). Additional information can be found in the DIR 020/2002 RARMP that was prepared to inform the decision to approve commercial release of GM Roundup Ready[®] canola in Australia.

32. MON 88302 canola differs from the commercially released Roundup Ready[®] canola in that it contains only one copy of the *cp4 epsps* gene, which is under the control of a different promoter to that used in Roundup Ready[®] canola, and does not contain the *gox* gene. MON 88302 canola can tolerate higher rates of glyphosate herbicides and has a wider window (up to first flowering) for herbicide application compared to Roundup Ready[®] canola. Glyphosate can only be applied to Roundup Ready[®] canola plants prior to flower formation (up to the six-leaf stage of growth), with later application leading to loss of yield.

5.2.2 Toxicity and allergenicity of the CP4 EPSPS protein

33. The *cp4 epsps* gene has been used extensively in GM plants as a selectable marker or a source of field resistance to the glyphosate herbicide. Consequently, the toxicity and allergenicity of the CP4 EPSPS protein to people, or the toxicity to other organisms, have been previously reviewed by the Regulator and other overseas regulatory agencies on numerous occasions.

Toxicity/allergenicity to humans

34. The CP4 EPSPS protein is 47.6 kDa, a molecular weight that falls within the typical range documented for allergenic proteins. However, it is unlikely to be an allergen because it

does not display characteristics common to known protein allergens in food (ANZFA 2001; Canadian Food Inspection Agency 1997; Harrison et al. 1996). All plants contain structurally similar EPSPS proteins (Padgette et al 1996). No homology was found between the CP4 EPSPS protein sequence and known toxins or allergens (DIR 020/2002), and GM cotton (Bollgard II[®]/Roundup Ready[®], DIR 012/2002; Roundup Ready[®], DIR 023/2003; Roundup Ready[®] Flex, DIR 059/2005 and DIR 066/2006) and canola (Roundup Ready[®], DIR 020/2002) lines containing the *cp4 epsps* gene have been approved by the Regulator for commercial release in Australia. 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 2009; EFSA 2013).

35. The amino acid sequence of the CP4 EPSPS protein expressed in MON 88302 canola is identical to the amino acid sequence of the CP4 EPSPS protein expressed in other commercially produced GM crops. These GM crops include Roundup Ready® canola, Roundup Ready® soybean, Roundup Ready® 2 Yield soybean and Roundup Ready Flex® cotton. People have consumed these GM crops and their processed products since 1996 without any reports of adverse effects (James 2005). Furthermore, Roundup Ready® soybean expressing the identical introduced CP4 EPSPS protein has been shown not to be allergenic to humans (Batista et al. 2005).

36. The applicant has received approval from FSANZ for the use of food derived from MON 88302 canola (FSANZ 2013). In Australia, food derived from GM canola, cotton, lucerne, maize, soybean and sugarbeet lines that express the *cp4 epsps* gene have also been considered safe for human consumption by FSANZ (ANZFA 2000; FSANZ 2005a; FSANZ 2005b; FSANZ 2006a; FSANZ 2006b; FSANZ 2007). The assessments by FSANZ noted that there was no evidence of toxic and allergenic properties associated with the CP4 EPSPS protein. The CP4 EPSPS protein has also been considered an inert ingredient by regulatory agencies in the United States (EPA 1996; EPA 1997).

Toxicity to animals, including livestock

37. The *cp4 epsps* gene introduced into the GM canola plants was isolated from the common soil bacterium *A. tumefaciens*. Homologues of the gene and the encoded enzyme occur naturally in a wide range of plants (including food crops), algae and fungi (Bentley 1990; Padgette et al. 1993). EPSPS is involved in the biosynthesis of aromatic amino acids, which are naturally produced in plants including those widely consumed by animals. The CP4 EPSPS protein is structurally similar and functionally identical to endogenous plant EPSPS (Padgette et al 1996), and it is not known to be involved in any other metabolic pathways associated with toxin production. On this basis, animals have long been exposed to the *cp4 epsps* gene, the encoded protein and its end products, via consumption of plant material.

38. The CP4 EPSPS protein is readily inactivated under a range of conditions. One study has found that 90% of the CP4 EPSPS protein is degraded in the soil within 9 days (Dubelman et al. 2005). Further, the CP4 EPSPS protein is rapidly inactivated by heat, enzymatic digestion, and acid in simulated mammalian digestive or gastric fluid (ANZFA 2001; Canadian Food Inspection Agency 1997; Harrison et al. 1996).

39. A range of animal feeding studies have been conducted using products derived from Roundup Ready[®] canola. In these studies, animals including rat (Naylor 1994; Nickson & Hammond 2002), trout (Brown et al. 2003), quail (Campbell & Beavers 1994; Campbell et al. 1993), chicken (Stanisiewski et al. 2002; Taylor et al. 2004), lamb (Stanford et al. 2003; Stanford et al. 2002) and pig (Aalhus et al. 2003; Caine et al. 2007) were fed unprocessed seed from Roundup Ready[®] canola or processed meal from Roundup Ready[®] canola seed. Another feeding study on dairy cow using whole seed from Roundup Ready[®] cotton has also

been conducted (Castillo et al. 2004). No treatment-related adverse effects were observed in these studies, supporting the conclusion that the genetic modifications present in Roundup Ready[®] canola have not resulted in additional toxicity or anti-nutritional effects compared to non-GM canola controls. Roundup Ready[®] canola has been grown overseas since 1995 (see the RARMP for DIR 105) and there have been no reports of toxicity associated with the CP4 EPSPS protein. Toxicity experiments with animals (mainly mice and rats), often involving the feeding of exaggerated doses of the protein, have not shown any deleterious effects upon the subjects (Hammond et al. 2004; Harrison et al. 1996; Teshima et al. 2000; Zhu et al. 2004).

Toxicity to honey bees

40. Canola is primarily self-pollinating but cross pollination does occur, which is mainly facilitated by honeybees in Australia. 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 1999a; USDA-APHIS 1999b; USDA-APHIS 2004a; 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). The Canadian Food Inspection Agency (CFIA) concluded that the unconfined release of Roundup Ready[®] canola would not result in altered impacts on interacting organisms, and that their potential impact on biodiversity is equivalent to that of currently commercialised non-GM canola varieties (Canadian Food Inspection Agency 1995).

41. As discussed below (Section 5.5.3), no significant differences were observed between MON 88302 canola and non-GM canola crops for the abundance of beneficial arthropods. This indicates that arthropods, including honey bees, will interact with MON 88302 canola in the same way as with conventional canola varieties.

42. The level of the CP4 EPSPS protein in pollen from MON 88302 canola has been measured at 8 μ g/g fresh weight (fw) (Chapter 1, Section 5.5.2). This is approximately double that found in Roundup Ready Flex[®] cotton pollen (about 4 μ g/g fw, see Chapter 1, Section 2, RARMP for DIR 059/2005) but approximately one twentieth of that in MON 88017 glyphosate-tolerant GM corn pollen (170 μ g/g fw) (Stillwell & Silvanovich 2007), which has been approved for commercial release in Argentina, Canada, Japan and the USA.

Effects on soil microbes

43. In reviewing the literature relating to effects of GM plants on soil microorganisms, a number of authors have commented on the technical difficulties in measuring, assessing and interpreting such effects (O'Callaghan et al, 2005, Bruinsma et al, 2003; Weinert et al, 2010). As the *cp4 epsps* gene is derived from *Agrobacterium sp.* found in the soil, and homologues of the *cp4 epsps* gene are widespread in plants and microorganisms, it is expected that many soil organisms are regularly exposed to the EPSPS proteins or their degradative peptide products. However, the CP4 EPSPS protein does not stably remain in soil for a long time (Dubelman et al. 2005).

44. Studies have confirmed the lack of permanent effects on soil biota by GM glyphosate tolerant crops. For example, no permanent effects on soil biota were observed in a series of experiments designed to estimate the effect of glyphosate tolerant soybean and maize, and their management, on the abundance of detritivorous soil biota and crop litter decomposition

(Powell et al. 2009). While statistically significant effects were observed in a few of the measured groups, in most cases the effects were only observed in the first year of the study and were not consistent across sample dates or across the four study years. The most frequent effect of the glyphosate tolerant herbicide system was a transient shift toward more fungal biomass relative to bacterial. The genetic modification in the soybean and maize had little effect on litter decomposition, although the use of glyphosate did reduce decomposition of surface (but not buried) litter.

45. In a field experiment conducted at six sites in Canada, repeated plantings of glyphosate tolerant wheat and glyphosate tolerant canola grown in rotation had only minor and inconsistent effects on soil microorganisms over a wide range of growing conditions and crop management regimes (Lupwayi et al. 2007). As is the case for many studies that show an effect of herbicide tolerant cropping systems on microbial communities, the effects of the glyphosate tolerance trait and the herbicide applications were not separated in this study. Application of herbicides is known to affect proportions of soil microbes (for example, see Becker et al. 2001; Gyamfi et al. 2002; Kremer & Means 2009; Mijangos et al. 2009).

46. Crop type (GM or non-GM) made no difference to the abundance or structure of microbial communities in a study designed to separate the effects of GM glyphosate tolerant maize from the use of glyphosate on denitrifying bacteria and fungi (Hart et al. 2009). The GM maize in this study expressed the cp4 epsps gene, and the authors note that the use of a protein derived from a common soil bacterium may affect soil microbial communities less than modifications that introduce novel proteins into the soil.

Toxicity to plants

47. In terms of toxicity of the CP4 EPSPS to plants, an OECD report (1999) concluded that the expression of glyphosate-tolerant EPSPS in GM plants is not detrimental to the growth of other plants based on the similar agronomic performance of the GM crops compared to their non-GM parents. This conclusion is further supported by new data discussed in Section 5.5.3.

5.2.3 Toxicity of herbicide metabolites

48. The potential toxicity of the herbicide metabolites is considered by the APVMA in its registration of herbicides. There is no expected difference in the metabolic fate of glyphosate in non-GM canola and in GM canola expressing the cp4 epsps gene. In the case of CP4 EPSPS, as discussed in Section 5.2.1, no new metabolic products are formed.

5.3 The regulatory sequences

49. Promoters are DNA sequences that are required in order to allow RNA polymerase to bind and initiate correct transcription. The expression of cp4 epsps in the GM canola line is under the control of a chimeric constitutive promoter, P-FMV/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 Tsfl gene, which encodes elongation factor EF-1 alpha (Axelos et al. 1989; Richins et al. 1987). Recently it has been suggested that protein P6, encoded by gene VI of the Caulimovirus and Soymovirus families, could result in harm to humans if expressed in GM plants, and perhaps interfere with the anti-pathogen defences of GM plants (Latham & Wilson 2013). The FMV belongs to the Caulimovirus family, and the FMV 35S promoter overlaps sequences of gene VI. However, bioinformatic analysis indicates that it is extremely unlikely that the P6 protein possesses any allergenic or toxic properties (Podevin & du Jardin 2012). The GM canola contains only a short variant of the FMV promoter that overlaps with a short, non-essential domain of the P6 protein coding sequence. Caulimovirus promoters containing partial gene VI sequences have been used in a number of GM crops grown commercially in a number of countries without adverse effects, for example: Roundup Ready[®] canola in Australia, Canada and the USA; Roundup Ready Flex[®] cotton in Australia; Roundup Ready[®] and Roundup Ready 2 Yield[®] soybean in USA.

50. A leader and intron sequence derived from the *Tsf1* gene are also included in the introduced *cp4 epsps* gene construct (L-*Tsf1* and I-*Tsf1*, respectively) (Axelos et al. 1989). The inclusion of these sequences ensures strong and reliable constitutive expression of the *cp4 epsps* coding sequence in the GM canola.

51. In plants, aromatic amino acid synthesis occurs in the chloroplast (Kishore & Shah 1988; Klee et al. 1987). 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). Once cleaved from the mature protein, CTPs are rapidly degraded (Bartlett et al. 1982; 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 thale cress (*A. thaliana*) (Klee et al. 1987), to provide transport of the encoded CP4 EPSPS into the canola chloroplast. The *ctp2* sequence present in MON 88302 canola is the same as that used in Roundup Ready[®] 2 Yield soybean.

52. Also required for gene expression in plants is an mRNA termination region, including a polyadenylation signal. The mRNA terminator for the introduced *cp4 epsps* gene in the GM canola line is the T-*E9* DNA sequence derived from pea (*P. sativum*), containing the 3' nontranslated region of the ribulose-1,5-bisphosphate carboxylase small subunit (RbcS2) *E9* gene (Coruzzi et al. 1984).

5.4 Method of genetic modification

53. MON 88302 was developed using *Agrobacterium tumefaciens* mediated transformation with the disarmed binary vector PV-BNHT2672 containing the *cp4 epsps* gene expression cassette. Information about this transformation method can be found in the risk assessment reference document *Methods of plant genetic modification* available from the <u>Risk</u> <u>Assessment References</u> page on the OGTR website.

54. The parental canola variety used for genetic modification was Ebony. Genetically modified canola cells expressing the introduced *cp4 epsps* gene were selected through their ability to grow in the presence of glyphosate, allowing glyphosate-tolerant plants to be regenerated. These were transferred to soil for growth and allowed to self-pollinate seed for several generations. Homozygous plants containing only one copy of the introduced *cp4 epsps* gene were then selected by the combination of glyphosate treatment, polymerase chain reaction analysis and Southern blot analysis, resulting in the glyphosate-tolerant canola variety MON 88302.

5.5 Characterisation of the GMO

5.5.1 Molecular characterisation

55. The applicant carried out Southern blot hybridisation analysis to determine the copy number of the transgene present in MON 88302 canola. A single copy of the introduced gene at a single integration site was demonstrated (Monsanto Company 2010c), which was also confirmed by segregation of the *cp4 epsps* gene during the development of MON 88302 (information provided by the applicant). DNA sequence analysis confirmed that the organisation and sequence of the genetic elements within the *cp4 epsps* expression cassette in MON 88302 canola was identical to that in the plasmid PV-BNHT2672 (Monsanto Company 2010c).

56. The applicant has also conducted bioinformatics analysis which has shown that the insertion of the *cp4 epsps* expression cassette is not within a known coding sequence in MON 88302 canola. The applicant has used single nucleotide polymorphism (SNP) markers to determine the exact genomic location of the introduced DNA. Based on linkage with 5 SNP markers, the introduced *cps epsps* gene is located on linkage group N4 on the A genome of *Brassica napus*. The closest SNP marker is at 5 centimorgans from the insertion site.

57. PCR and Southern blot analysis were used to confirm that plasmid backbone sequences of PV-BNHT2672 (ie the part of the plasmid not intended to be transferred to the plants) are not present in the GM canola plants. The selectable marker gene *aadA*, which confers resistance to spectinomycin and streptomycin, is present in the backbone of the plasmid PV-BNHT2672, and was used to select for Agrobacteria containing the plasmid prior to the generation of the GM canola plants in the laboratory. This selectable marker gene is not present in MON 88302 canola (Monsanto Company 2010c).

58. The integrity of the single insertion site in MON 88302 genome was also examined by PCR and sequence analysis using genomic DNA extracted from MON 88302 and from the non-GM, parental canola variety Ebony (Monsanto Company 2010c). Sequence alignment showed a deletion of 29 base pairs from the canola genomic DNA, replaced by an insertion of nine base pairs, immediately adjacent to the 3' end of the intended MON 88302 insert. Such changes commonly occur during the process of *Agrobacterium*-mediated transformation, likely resulting from the plant's double-strand break repair mechanism (Salomon & Puchta 1998). In addition, a single nucleotide difference between the genomic sequence flanking the 3' end of the MON 88302 insert and the non-GM Ebony genomic sequence was also detected, which was likely caused by a single SNP segregating in the canola population (Trick et al. 2009).

5.5.2 Levels of CP4 EPSPS protein expression in various tissues

59. The applicant has applied a validated enzyme-linked immunosorbent assay (ELISA) using a mouse monoclonal antibody specific for CP4 EPSPS protein to determine the levels of CP4 EPSPS protein expressed in various tissues of MON 88302 canola from field trials in North America (Monsanto Company 2010a) and Australia (Monsanto Company 2013b).

60. From the 2009 field trials in the USA and Canada, CP4 EPSPS protein levels were determined in nine tissue types including forage (all above ground plant parts, as used for animal feed), leaf at four developmental stages, root at two developmental stages, and seed. The mean CP4 EPSPS protein levels were highest in leaf (up to 230 μ g/g dry weight), followed by forage (170 μ g/g dw), root (up to 82 μ g/g dw) and seed (27 μ g/g dw) (Table 1). The mean CP4 EPSPS protein level in MON 88302 pollen was also determined using tissue collected from plots planted in a greenhouse in the USA, which was lower at 9.0 μ g/g dw (Table 1). Values for mean levels of CP4 EPSPS protein in forage, leaf and seed from the 2012 Australian field trials are very similar (Table 1).

61. It has been shown that glyphosate treatment does not change the expression level of CP4 EPSPS protein in the leaf and seed tissues of Roundup Ready[®] canola (OGTR 2003a). On a fresh weight basis, the ranges of CP4 EPSPS protein expression level in MON 88302 leaf $(10 - 85 \ \mu g/g)$, when considering data from both North American and Australian trials and all leaf types in Table 1) are similar to that of Roundup Ready[®] canola $(12 - 51 \ \mu g/g)$ with samples collected from field trials in Canada and Europe from1992 to 1994 (OGTR 2003a). However, according to information provided by the applicant, MON 88302 canola can tolerate higher glyphosate spray rates and has a wider window of application than Roundup Ready[®] canola. For Roundup Ready canola plants, two applications of glyphosate at a rate of 0.621 kg acid equivalent (a.e.) per hectare (ha) can be applied from emergence up to the six-

leaf stage of growth (prior to flower formation) but later application can lead to yield loss. In contrast, MON 88302 canola can tolerate glyphosate applications from emergence to first flowering at a rate up to 0.91 kg a.e. per ha. This is likely due to the relatively higher CP4 EPSPS protein expression level in MON 88302 tissues, including pollen.

Table 1.	CP4 EPSPS protein levels in MON 88302 tissues collected from field trials in the
USA and (Canada in 2009 and Australia in 2012

Tissue	Development Stage ¹	2009 Trials in USA and Canada		2012 Trials in Australia		
	Utage	CP4 EPSPS Mean (SD) Range (µg/g fw) ²	CP4 EPSPS Mean (SD) Range (µg/g dw) ⁴	CP4 EPSPS Mean (SD) Range (µg/g fw) ³	CP4 EPSPS Mean (SD) Range (µg/g dw) ⁴	
Forage	Rosette (30 BBCH)	18 (4.4) 14 - 28	170 (22) 120 - 210	22 (5.2) 13 - 36	150 (33) 94 - 230	
Leaf-1	3-4 Unfolded leaves (13-14 BBCH)	23 (10) 10 - 45	180 (40) 110 - 250	25 (8.3) 11 - 48	180 (52) 77 - 290	
Leaf-2	7-9 Unfolded leaves (17-19 BBCH)	22 (5.9) 18 - 37	180 (41) 120 - 250	33 (8.7) 18 - 51	190 (56) 83 - 290	
Leaf-3	Rosette (30 BBCH)	31 (6.3) 20 - 41	230 (50) 130 - 300	30 (6.5) 16 - 42	180 (44) 110 - 260	
Leaf-4	Early flowering (60-62 BBCH)	36 (14) 20 - 85	210 (80) 110 - 500	38 (10) 22 - 73	140 (36) 71 - 230	
Root-1	Rosette (30 BBCH)	19 (4.1) 11 - 25	82 (17) 46 - 100	NT	NT	
Root-2	Pod development (71-73 BBCH)	10 (3.3) 7.0 - 17	38 (14) 24 - 62	NT	NT	
Pollen ⁵	Flowering (60-69 BBCH)	8.1(0.64) 7.4 - 8.6	9.0 (0.71) 8.2 - 9.6	NT	NT	
Seed	Harvested (99 BBCH)	25 (5.2) 21 - 43	27 (5.6) 22 - 46	26 (6.5) 8.5 - 44	28 (7.1) 9.2 - 48	

¹The canola development stages are based on the BBCH-scale (Meier 2001); ²Protein levels are expressed as the arithmetic mean, standard deviation (SD) and range (minimum and maximum value) in microgram (μ g) of protein per gram (g) of tissue on a fresh weight (fw) basis, calculated for each tissue across all sites. The numbers of samples (n) are as follows: Forage n = 20, seed n = 16, Leaf-1 n = 16, Leaf-2 n = 9, Leaf-3 n =20, Leaf-4 n = 20, Root-1 n = 19, Root-2 n = 11 and Pollen n =3; ³ Protein levels are expressed the same as above, calculated for each tissue across all sites (n=32); ⁴Protein levels are expressed as the arithmetic mean, SD and range in μ g of protein per g of tissue on a dry weight (dw) basis. The dry weight values were calculated by dividing the μ g/g fw by the dry weight conversion factor obtained from moisture analysis data; ⁵Pollen tissue was collected from three plots planted in a greenhouse; NT, not tested.

5.5.3 Phenotypic and agronomic characterisation

62. MON 88302 canola (Ebony background) has been assessed by the applicant for plant growth and development characteristics in field trials and laboratory studies to identify any unintended phenotypic effects relative to non-GM canola. These include field trials conducted

at eight sites in the United States of America (USA) and nine sites in Canada during 2009, three sites each in the USA and Canada in 2010, and ten sites in Australia in 2012 and 2013.

63. The plant characterisation in field trials and laboratory studies carried out in North America in 2009 focused on the following general categories:

- Germination and dormancy
- Vegetative growth
- Reproductive growth (including pollen characteristics)
- Seed retention on the plant and lodging
- Plant response to abiotic stress and interactions with diseases and arthropods.

64. MON 88302 was compared to the control variety Ebony and various commercial canola varieties (four varieties for each site and a total of 24 varieties across all sites) that provide a range of comparative values for each of the above categories. The experimental design at each site was a randomized complete block with four replicates.

65. Seed dormancy and germination characteristics (percent seed germinated, percent dead seed, percent viable non-dormant seed and percent dormant seed) were assessed (Monsanto Company 2010b). Seed was tested at five temperature regimes of constant 5, 15, 25 and 30°C, as well as at the 15/25°C temperature cycle recommended by the Association of Official Seed Analysts (AOSA). No statistically significant differences (p>0.05) were found between MON 88302 and the control for seed germination and dead seed at any of the temperature regimes. No statistical differences were detected between MON 88302 and the control at 5°C for non-dormant seed. Due to low seed numbers, variances on dormant seed for all temperatures and viable non-dormant seed at the 15° C, 25° C, 30° C and $5/25^{\circ}$ C temperature regimes were not analysed.

Twelve phenotypic characteristics were also assessed in these field trials: early stand 66. count, seedling vigour, plant height, days to first flowering, seed maturity, lodging, visual rating for pod shattering, quantitative pod shattering, seed quality, yield, seed moisture and final stand count (Monsanto Company 2011). In a combined-site analysis, statistically significant differences were only detected for days to first flowering (61.1 days after planting for MON 88302 vs 56.2 days for Ebony) and seed moisture (13.2% vs 11.7%). In individualsite analysis, statistically significant differences between MON 88302 and Ebony were detected for 20 out of 133 comparisons among the 10 remaining phenotypic characteristics. However, these differences were not consistent between sites. For example, MON 88302 canola showed lower early stand count than Ebony at one site (23.6 vs. 29.0 plants/linear metre) but not at other sites; MON 88302 was shorter than Ebony at one site (41.8 vs. 44.0 inches), taller at 4 sites and not different at other sites; MON 88302 had less lodging than Ebony at one site (1.0 vs. 1.5 rating) but had more lodging at another site (3.3 vs. 2.0); MON 88302 had lower seed quality (i.e. more green seed) than Ebony at three sites (6.5 % vs. 1.8 %, 0.5 % vs. 0.0 % and 11.3 % vs. 6.8 %) but not at other sites. This suggests that the small differences detected for other phenotypic characteristics are not biologically significant but rather reflect environmental factors.

67. The two statistically significant differences detected between MON 88302 and the control in the combined-site analysis were 61.1 days to first flowering and 13.2 % seed moisture for MON 88302 compared to 56.2 days and 11.7 % for Ebony. However, the mean values of MON 88302 for days to first flowering and seed moisture were both within the reference range of the commercial reference varieties for each characteristic, which were 45.9 - 67.5 days and 7.5% - 14.8%, respectively.

68. The applicant conducted additional field trials in the USA and Canada in 2010, which included a negative segregant of MON 88302 in addition to Ebony and 20 non-GM canola reference varieties. In these trials, no difference was observed between MON 88302 and its negative segregant for days to first flowering (Monsanto Company 2012). This suggests that the difference between MON 88302 and Ebony observed in the 2009 trials is most likely due to seed selection from a segregating population and not to the genetic modification.

69. The viability and morphology of pollen from MON 88302 canola, Ebony and four commercial reference varieties were examined in a growth chamber $(21^{\circ}C day/18^{\circ}C night, 16 hour photoperiod)$, without glyphosate treatment. No statistically significant differences (p>0.05) were identified between the GM canola and the controls for percent viable pollen or pollen grain diameter, and no visual differences in general pollen morphology were observed.

The response of MON 88302 canola, Ebony and the selected commercial reference 70. varieties to a range of abiotic and biotic stresses was assessed four times during the growing season at all 17 sites in the United States and Canada (Monsanto Company 2011). This included qualitative observations of plant responses to abiotic stress (cold, compaction, drought, flood, frost, hail, heat, nitrogen deficiency and wind), disease damage (Alternaria, aster yellow, bacterial leaf spot, black leg, Cercospera leaf spot, clubroot, downy mildew, Fusarium, Phytophthora, powdery mildew, root rot, Sclerotina, seedling blight, seedling disease complex, white mold and white rust) and arthropod-related damage (alfalfa looper, aphid, bertha armyworm, blister beetle, cabbage seedpod weevil, cabbage worm, cutworm, diamondback moth larvae, flea beetle, grasshopper, lygus bug, red turnip beetle, wireworm) at all 17 sites, as well as quantitative assessment of damage by flea beetle and seedpod weevil at four of the 17 sites. The qualitative assessments did not identify any difference between MON 88302 and the Ebony control for 436 out of 437 comparisons (including 131 abiotic stress response, 141 disease damage, and 165 arthropod damage comparisons). The one observed difference in abiotic stress response was for frost damage at one site in Canada, where MON 88302 was rated severe but the control was moderate, however the MON 88302 rating was within the range of the damage observed among the canola reference varieties (slight to severe). In addition, this difference was not observed during any of the other frost damage observations among the sites.

71. Quantitative data on abundance of beneficial arthropods [chironomid midge, lacewings (Chrysopidae), ladybird beetles (Coccinellidae), micro- and macro-parasitic hymenoptera, miniature pirate bug (*Orius* spp.), spiders (Aranaea) and sphecid wasps (Sphecidae)] were collected from 15 observations across 4 sites (Monsanto Company 2011). No statistical differences were detected between MON 88302 and the non-GM control fields.

72. A set of phenotypic and agronomic data was also collected for MON 88302 trialled in Australia in 2012 and 2013 under the DIR 105 licence (Monsanto Company 2013a). The 2012 trials were carried out at eight sites in New South Wales, Victoria and Western Australia. MON 88302 canola, Ebony and four commercial reference varieties were evaluated at each site with a randomised complete block design with four replicates. Using the combined-site data, the following phenotypic characteristics were statistically assessed: early stand count, days to 50% flowering, seed maturity, plant height, yield, oil content, final stand count and seed quality. No significant differences were recorded for early stand count, plant height, yield, oil content and seed quality between MON 88302 (non-glyphosate treated) and Ebony. However, significant differences were revealed in three phenotypic characteristics: MON 88302 developed slower than Ebony in terms of days to 50% flower (120.3 vs 115.2 days) and days to reach seed maturity (169.1 vs 166.1 days) but had a higher final stand count (53.3 vs 44.7 plants/m²). The observation that MON 88302 canola flowers later than Ebony is

consistent with the result from the previous North America trials (see above). The difference in final stand count is explained by variation in seed size between seed lots. Although seeds were sown at all eight sites at the same rate of 2.33 kg/ha, the MON 88302 canola seed lot used had a 1000 seed weight of 2.5 g, while the Ebony seed lot had a 1000 seed weight of 2.86 g (information provided by the applicant).

73. In the 2013 trials at two sites in Western Australia, two different canola lines CQ6598 and N19727 containing the MON 88302 event (named CQ6598-RR2 and N19727-RR2, respectively) were tested for days to 50% flower and crop vigour (Monsanto Company 2013a). In individual-site analysis, no significant difference in crop vigour was observed between CQ6598-RR2 or N19727-RR2 and their non-GM controls. For flowering time, no significant difference was detected between CQ6598-RR2 and its non-GM parent CQ6598. However, N19727-RR2 reached 50% flowering faster than the non-GM N19727 control at both sites (97.8 vs 99 days and 106.8 vs 109.5 days, respectively), contrary to the observed later flowering of MON 88302 canola (in an Ebony background) compared to non-GM Ebony in both the North American trials and in the 2012 Australian trials, as described above. This supports the contention that the earlier observed delay in flowering was not due to the genetic modification itself but to differences in the genetic background arising through the breeding and selection process.

74. The applicant has performed compositional analysis for seed from MON 88302, Ebony and seven commercial reference varieties grown at two sites in USA and three sites in Canada during the 2009 growing season. This includes proximates (ash, carbohydrate, crude fat and protein), fibre (ADF, NDF and TDF), amino acids, fatty acids, minerals, vitamin E and antinutrients (glucosinolates, phytic acid, sinapic acid and tannins). The compositional data collected by the applicant has been assessed by FSANZ (FSANZ 2013), CFIA (CFIA 2013) and EFSA (EFSA 2014), and their conclusion was that seed from MON88302 canola (glyphosate-treated or untreated) is compositionally equivalent to seed from conventional canola varieties.

Section 6 The receiving environment

75. The receiving environment forms part of the context in which the risks associated with dealings involving the GMOs are assessed. This includes the size, duration and regions of the dealings, any relevant biotic/abiotic properties of the regions where the release would occur; intended agronomic practices, including those that may be altered in relation to normal practices; other relevant GMOs already approved for commercial release; and any particularly vulnerable or susceptible entities that may be specifically affected by the proposed release (OGTR 2013a).

76. The applicant has proposed to release the MON 88302 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 wherever it is suitable to cultivate canola. 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.

77. Canola has been commercially cultivated in Australia since 1996 (OGTR 2011b). Areas in Australia where canola can be grown are mainly limited by water availability, the suitability of the soil, diseases, temperature and the length of the growing season. The canola growing areas are mainly in the Australian winter cereal belt of NSW, Victoria, South Australia, and Western Australia. It also includes Southern Queensland and Tasmania. Although canola is not grown commercially in northern Australia, it has been trialled in the Northern Territory as a potential biofuel crop (OGTR 2011b).

6.1 Relevant agricultural practices

78. It is anticipated that the agronomic practices for the cultivation of the GM canola will not differ from industry best practices used in Australia. The GM canola plants would therefore receive applications of water, fertilisers, herbicides, insecticides and other agronomic management practices similar to other commercially grown canola plants, including other approved herbicide tolerant GM canola; however, rates and timing of glyphosate application may differ compared to other canola crops (as detailed below). Herbicides would be applied according to label directions. Standard cultivation practices for canola are discussed in more detail in *The Biology of* Brassica napus *L. (canola)* (OGTR 2011b).

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

The agronomic management of MON 88302 canola containing the cp4 epsps gene 80. (herbicide tolerance trait) would differ from the management of non-GM canola in that glyphosate herbicide could be applied over the top of the canola crop to control weeds. Similar to the agronomic management of GM Roundup Ready[®] canola, the applicant has developed a MON 88302 Canola Technology Stewardship Strategy. Implementation of this strategy is intended to manage the risk of weeds developing herbicide resistance. Growers of MON 88302 canola would be required to follow the relevant Crop Management Plan and the label instructions for Roundup Ready[®] Herbicide with PLANTSHIELD[®] by Monsanto. These include management strategies that aim to control canola volunteers, minimise gene flow, and prevent the development of herbicide resistant weeds. It should be noted that the Regulator has not proposed any measures 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. The APVMA assesses all herbicides used in Australia and sets their conditions of use, including resistance management.

81. The Australian Glyphosate Sustainability Working Group (AGSWG) is a collaborative initiative of Australian academics and industry members that is dedicated to facilitating the sustainable and effective use of glyphosate in Australian agriculture (http://www.glyphosateresistance.org.au). Monsanto is a member of the group. In overview, the group has concluded that the main factors that contribute to the evolution of glyphosate resistance are intensive use of the herbicide and the failure to use other alternate measures of weed control. In relation to Australian winter cropping areas, the group has indicated that glyphosate resistant annual ryegrass or rigid ryegrass (*Lolium rigidum*) has become a problem (AGSWG 2012). To reduce the problem of such resistance it recommends the use of strategies such as tillage, alternate herbicide s, "double knock" (glyphosate followed by tillage or another herbicide) and other non-herbicide practices to prevent formation of viable weed seed. Further, the group has produced a document entitled *Integrated Weed Management in Australian Cropping Systems* for use by farmers and other interest groups.

82. CropLife Australia, an organisation that represents agricultural chemical and plant biotechnology interests in Australia, publishes a *Herbicide Resistance Management Strategies*

guide (CropLife Australia 2012). At a general level, this document emphasises the need to resist the temptation to rely upon a single strategy to prevent the development of herbicide resistances. Specifically in relation to glyphosate (a Group M herbicide), the document records that weeds resistant to this herbicide are associated with its intensive use, the lack of rotation of other strategies, and the failure to till/cultivate after its application.

6.2 Relevant biotic factors

6.2.1 Presence of related plants in the receiving environment

83. Both GM and non-GM herbicide tolerant varieties of canola are grown commercially in Australia. In addition, non-GM varieties of Indian mustard (*Brassica juncea*), also called Juncea canola, are grown commercially in Australia.

84. There are two conventionally bred herbicide tolerant canola varieties currently being grown throughout Australia – triazine tolerant (TT) and imidazolinone tolerant (IT or Clearfield[®]). Since the introduction of non-GM TT canola varieties in 1993, their use has become widespread despite a significant yield penalty associated with the mutation that confers herbicide tolerance. The first non-GM Clearfield canola variety was registered for use in 1995, and together TT and Clearfield varieties comprise approximately 75 % of the Australian canola crop by 2007 (Norton & Roush 2007). Non-GM Clearfield Juncea canola varieties became available for commercial production in 2013 (DPI NSW 2013).

85. GM Roundup Ready[®] canola was approved for unrestricted commercial release by the Regulator in 2003 (DIR 020/2002). However, it was not grown commercially until 2008 (New South Wales and Victoria) and 2010 (Western Australia), due to restrictions imposed by State and Territory governments for marketing and trade reasons (ABCA 2012; OGTR 2014). Roundup Ready[®] varieties represented around 8% of canola grown in Australia in the 2010 growing season, most of which (50 – 60%) was grown in WA (DAFWA 2010) and it increased to almost 10% in 2012 (ABCA 2012). GM glufosinate ammonium tolerant InVigor[®] canola and 'stacked' Roundup Ready[®] × InVigor[®] canola (ie canola with these two GM traits combined) were also approved for commercial release by the Regulator in 2003 (DIR 021/2002) and 2011 (DIR 108), respectively. However, these canola varieties have not yet entered commercial production in Australia.

86. Therefore, there are currently three herbicide tolerance traits present in Australian commercial canola production systems (TT, Clearfield[®] and Roundup Ready[®]), and a fourth (InVigor[®]), that although available, has to date not been used. These commercial canolas and the GM canola proposed for release by Monsanto could potentially combine to produce multiple-herbicide tolerant progeny

87. As discussed in Section 4.2, *B. napus* is known to cross with other species within the *Brassicaceae* tribe. Of the many *Brassica* species in Australia, canola may potentially hybridise under natural conditions with sexually compatible related species that include: other *B. napus* groups or subspecies (including vegetables such as swede, rutabaga, kale), *B. juncea*, *B. rapa* (canola, turnip rape or white turnip; includes vegetables such as turnip, Chinese cabbage and pak choi) and *B. oleracea* (wild cabbage; includes vegetables such as cauliflower, brussel sprouts and cabbage) (Salisbury 2002a). Naturally occurring hybrids between *B. napus* and species from other genera in the *Brassicaceae* tribe have been reported at very low frequencies for *Raphanus raphanistrum* (wild radish), *Hirschfeldia incana* (Buchan weed) and *Sinapis arvensis* (charlock) (Salisbury 2002a).

6.2.2 Presence of other biotic factors

88. 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. Other diseases of canola include *Sclerotinia* stem rot, *Rhizoctonia* seedling wilt and *Alternaria* black spot, all of which are caused by fungal pathogens (Howlett et al. 1999).

89. 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 WA 2006).

90. Weeds are also a significant problem for commercial canola producers, and can reduce yield by competition and seed quality due to contamination. The most significant 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 raphinastrum*), Indian hedgemustard (*Sisymbrium orientale*), Shepherd's purse (*Capsella bursa-pastoris*), wild turnip (*Brassica tournefortii*), turnip weed (*R. rugosum*), charlock (*Sinapis arvensis*), musk weed (*Myagrum perfoliatum*) and Buchan weed (*Hirschfeldia incana*) (Sutherland 1999), some of which are sexually compatible with canola, as described in Section 6.2.1.

91. Additional information regarding the biotic factors relating to the growth and distribution of commercial canola in Australia are discussed in the reference document, *The Biology of* Brassica napus *L. (canola)* (OGTR 2011b).

6.3 Relevant abiotic factors

92. The abiotic factors relevant to the growth and distribution of canola currently used in commercial production in Australia are discussed in *The Biology of* Brassica napus *L*. *(canola)* document (OGTR 2011b). In brief, the geographical distribution of commercial canola cultivation in Australia is limited by a number of abiotic factors, the most important being water availability.

93. Canola is generally grown as a winter crop in dominant winter rainfall environments that receive more than 400 mm rainfall per year. Sufficient soil moisture is required for germination of seed, and drought stress after anthesis can significantly reduce yield due to abortion of seed and reduced pod numbers. However, canola is also sensitive to waterlogged soils, so sites prone to water-logging tend to be avoided by commercial producers (Walton et al. 1999). Canola can also be grown during summer, but only at sites that receive sufficient rainfall or are under irrigation. For this reason, summer cultivation is generally restricted to high-value seed production.

94. Soil nutrient availability is also an important abiotic factor affecting canola cultivation. Most Australian soils tend to be low in nutrients and canola can only be profitably grown if fertilisers are intensively applied (Hocking et al. 1999). Other abiotic factors that can reduce seed yields include high soil acidity, frost and high temperatures.

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

95. 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 (Padgette 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 a number of varieties of GM canola and cotton that are grown commercially in Australia.

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

Section 7 Previous releases

7.1 Australian approvals of the GM canola line

97. MON 88302 has been approved by the Regulator for limited and controlled release under licence DIR 105 and has been field trialled in NSW, Victoria and WA since 2011. The Regulator has not received any report of adverse effects as a result of this release.

7.2 Approvals by other Australian agencies

98. 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 (see Section 2, this chapter).

99. FSANZ is responsible for human food safety assessment and food labelling, including GM food. FSANZ has approved the use of food derived from MON 88302 canola. This approval is listed in the Schedule to Standard 1.5.2 of the Australia New Zealand Food Standards Code at Items 1.4. 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 (FSANZ 2013).

100. The APVMA has regulatory responsibility for agricultural chemicals, including herbicides and insecticidal products, in Australia. Roundup Ready[®] Herbicide with PLANTSHIELD[®] by Monsanto has been registered by APVMA. This herbicide is currently in use in Australia for Roundup Ready[®] canola crops. Its use in MON 88302 canola is expected to differ only slightly from its use in Roundup Ready[®] canola. Specific use patterns for MON 88302 have not yet been approved by APVMA.

7.3 International approvals

101. MON 88302 canola has been approved for commercial release in a number of other countries; and products from MON 88302 are also approved for human food use and/or animal feed (Table 2).

Country	Authority	Type of Approval	Approval Date
Canada	CFIA	Feed and Environment	June 2012
Canada	Health Canada	Food	June 2012
European Union	EFSA	Food and feed	June 2014
Japan	MHLW	Food	October 2013
Japan	MAFF	Feed	October 2013
Republic of Korea	MOTIE	Food and feed	February 2014
Mexico	COFEPRIS	Food	February 2013
United States	FDA	Food	April 2013
United States	USDA	Environment	September 2013

Table 2. International approvals of MON 88302 canola

Chapter 2 Risk assessment

Section 1 Introduction

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



Figure 2 The risk assessment process

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

104. Postulated risk scenarios are screened to identify substantive risks that warrant detailed characterisation. A substantive risk is only identified for further assessment when a risk scenario is considered to have some reasonable chance of causing harm. Pathways that do not lead to harm, or could not plausibly occur, do not advance in the risk assessment process.

105. 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 2013a). 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). In

addition, risk scenarios postulated in previous RARMPs prepared for licence applications of the same and similar GMOs are also considered.

106. 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

107. Postulated risk scenarios are comprised of three components (Figure 3):

- 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.



Figure 3. Risk scenario

108. In addition, the following factors are taken into account when postulating relevant risk scenarios:

- the proposed dealings, which may be to conduct experiments, develop, produce, breed, propagate, grow, import, transport or dispose of the GMOs, use the GMOs in the course of manufacture of a thing that is not the GMO, and the possession, supply and use of the GMOs in the course of any of these dealings
- 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

109. 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.

110. As discussed in Chapter 1, the GM canola has been modified by the introduction of one glyphosate herbicide tolerance gene. This introduced gene is considered further as a potential source of risk.

111. The genetic modification also has the potential to cause unintended effects in several ways including altered expression of endogenous canola genes by random insertion of introduced DNA in the genome, increased metabolic burden due to expression of the introduced protein, novel traits arising out of interactions with non-target proteins and secondary effects arising from altered substrate or product levels in biochemical pathways. Unintended effects might result in adverse outcomes such as toxicity or allergenicity.

However, the range of possible unintended effects produced by genetic modification is not likely to be greater than that from accepted conventional breeding techniques (Bradford et al. 2005; Committee on Identifying and Assessing Unintended Effects of Genetically Engineered Foods on Human Health 2004; The GM Science Review Panel 2003). New varieties produced by such techniques have rarely had traits that are undesirable for human health, safety or the environment (Hajjar & Hodgkin 2007; Steiner et al. 2013; Weber et al. 2012)³. Therefore, unintended effects resulting from the process of genetic modification will not be considered further.

2.2 Causal pathway

112. 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 effects of the introduced gene(s) and gene product(s) on the properties of the organism
- 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 (invasiveness) of the GM plant, including
 - establishment
 - reproduction
 - dispersal by natural means and by people
- 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 (HGT)
- unauthorised activities.

113. Although all of these factors are taken into account, some have been considered in previous RARMPs or are not expected to give rise to substantive risks.

2.2.1 Tolerance to abiotic factors

114. 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 (see *The Biology of* Brassica napus *L.(canola)* (OGTR 2011b). The introduced gene is unlikely to make the GM canola plants more tolerant to abiotic stresses that are naturally encountered in the environment, and is therefore unlikely to alter the potential distribution of the GM canola plants. As discussed in Chapter 1, Section 5.5.3, there was no significant difference between MON 88302 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.

³ More detail on potential for unintended effects as a result of the process of genetic modification can be found in the document *Methods of plant genetic modification* available from the <u>Risk Assessment References</u> page on the OGTR website.

2.2.2 Gene transfer to sexually compatible relatives

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

116. Baseline information on vertical gene transfer associated with non-GM canola plants can be found in *The Biology of* Brassica napus *L. (canola)* (OGTR 2011b). In summary, canola is predominantly self-pollinating with average inter-plant outcrossing rates of 30%. Under field conditions, canola has the ability to cross pollinate through physical contact between neighbouring plants and/or insect pollination, while wind-borne pollen plays a minor role in long-distance pollination. In Australia, honeybees play a major role in pollen transfer over long distances. The highest rate of outcrossing between fields occurs within the first 10 m of the recipient field, and rates decline rapidly with distance.

117. As discussed in Chapter 1, Sections 4.2 and 6.2.1, under natural conditions, canola can cross with cultivated *Brassica* species (*B. napus*, *B. juncea*, *B. rapa* and *B. oleracea*) and, at very low frequencies, with three weed species important in Australia (*R. raphanistrum*, *H. incana* and *S. arvensis*).

118. The risks associated with transfer of the introduced genes from Roundup Ready[®] canola to *B. rapa, H. incana, R. raphanistrum* and *S. arvensis* were previously assessed as very low, while the risks associated with gene flow to *B. napus* vegetables and forage rape, *B. oleracea* or *B. juncea* were assessed as negligible (OGTR 2003a). The risk associated with gene transfer from the stacked InVigor[®] x Roundup Ready[®] canola to all of these related species was subsequently assessed as negligible (OGTR 2011a). As there is no significant differences in pollen characteristics between MON 88302 canola and non-GM canola (Chapter 1, Section 5.5.3), the potential for gene flow to compatible species is not expected to be altered. Therefore, as previously assessed for the above GM herbicide-tolerant canola varieties, the associated risk will be negligible. Therefore, only gene transfer to other canola, including other commercially approved herbicide tolerant GM and non-GM canola plants, will be considered further.

2.2.3 Gene transfer by HGT

119. The potential for horizontal gene transfer (HGT) and any possible adverse outcomes has been reviewed in the scientific literature (Keese 2008) as well as assessed in many previous RARMPs. HGT was most recently considered in detail in the RARMP for DIR 108 (OGTR 2011a). This and other RARMPs are available from the <u>GMO Record</u> on the OGTR website or by contacting the OGTR. 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, HGT will not be assessed further.

2.2.4 Herbicide resistance management

120. There is some potential for development of herbicide-resistant weeds if the GM canola and its corresponding herbicide are used inappropriately. The repetitious use of a single

herbicide, or herbicide group⁴, 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).

121. Herbicide resistance comes under the regulatory oversight of the APVMA. The APVMA has primary regulatory responsibility for agricultural chemicals in Australia and sets their conditions of use. The APVMA 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. The development of resistance to glyphosate herbicide would have implications for the choice of herbicide(s) available for weed control operations in agriculture and elsewhere.

122. Glyphosate has historically been considered a low risk herbicide for the development of herbicide resistance because its mode of action imposes genetic and biochemical constraints associated with potential mechanisms of resistance (Bradshaw et al. 1997; Jasieniuk 1995) and the frequency of mutations that impart glyphosate tolerance in plants is lower than that for other herbicides (Weersink et al. 2005).

123. However, the intensive use of glyphosate across large areas has resulted in several reports of glyphosate-resistant weed species (Green et al. 2008; Neve et al. 2004; Powles et al. 1998; Powles & Preston 2006; Pratley et al. 1999; Yu et al. 2006). Among others, these weeds include: annual ryegrass in Australia; hairy fleabane (*Conyza bonariensis*) in South Africa and North America; goosegrass (*Eluesine indica*) in Malaysia; Italian ryegrass (*Lolium multiflorum*) in Chile; Buckhorn plantain (*Plantago lanceolata*) in South Africa; and yellow nutsedge (*Cyperus esculentus*), tropical spiderwort (*Commelina benghalensis*), morning glory (*Ipomoea* spp.) and wild buckwheat (*Acalypha*) in North America (Green et al. 2008; Heap 2011; Powles & Preston 2006).

124. MON 88302 canola is a second-generation glyphosate-tolerant canola. In comparison to the first-generation Roundup Ready[®] canola, it cannot only tolerate higher rates of glyphosate application, but also allows a wider window for glyphosate application. If the end users (farmers) choose to apply glyphosate more frequently on their GM canola crops for weed control, this may result in increased selective pressure for development of herbicide-resistant weeds.

125. Herbicide resistance is primarily a risk to agricultural production, rather than a risk to the health of people or the environment. As discussed in Chapter 1, Section 6.1, a Canola Technology Stewardship Strategy, including a Crop Management Plan, has been developed by Monsanto for MON 88302 canola. The Crop Management Plan together with the relevant herbicide product label to be approved by the APVMA will address issues of development of herbicide resistant weeds. Therefore, this issue will not be discussed further.

2.2.5 Unauthorised activities

126. The potential for unauthorised activities to lead to an adverse outcome 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.

⁴ 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.

2.3 Potential harm

127. 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 yield of desirable vegetation
- 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).

128. These harms are based on those used to assess risk from weeds (Standards Australia 2006). Judgements of what is considered harm depend on the management objectives of the land where the GM plant is expected to spread to and persist. 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

129. Five risk scenarios were postulated and screened to identify substantive risk. These scenarios are summarised in Table 3 and more detail of these scenarios is provided later in this Section. 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, including pollen.

130. 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.

Risk scenario	Risk source	Causal pathway	Potential harm	Substantive risk?	Reason
1	Introduced gene for herbicide tolerance	Expression of the herbicide tolerance gene in the GM canola Exposure of people undertaking the dealings to the GM plants or products thereof, or exposure of the public by consumption of GM canola products, contact with GM canola products, or inhalation of GM canola pollen	Increased toxicity or allergenicity for people	No	 The CP4 EPSPS protein encoded by the <i>cp4</i> <i>epsps</i> gene is not known to be toxic or allergenic to people. Seed from MON 88302 is compositionally equivalent to that from non-GM canola. Products derived from MON 88302 have been approved by FSANZ for use in human food. Roundup Ready® canola containing the same <i>cp4</i> <i>epsps</i> gene has been widely grown in Australia since 2008.

Table 3 Summary of risk scenarios from dealings with MON 88302 canola

Risk scenario	Risk source	Causal pathway	Potential harm	Substantive risk?	Reason
					 There are no reports of adverse findings for commercial GM crops with an introduced cp4 epsps gene.
2	Introduced gene for herbicide tolerance	Expression of the herbicide tolerance gene in the GM canola Exposure of other organisms to GM plant material through contact or ingestion	Increased toxicity for other organisms	No	 No known toxicity of CP4 EPSPS protein to any animals or microorganisms. The <i>cp4 epsps</i> gene and related genes, and the encoded proteins, are widespread in the environment. Apart from expression of CP4 EPSPS, MON 88302 canola is comparable to non-GM canola.
3	Introduced gene for herbicide tolerance	Establishment of volunteer GM canola plants in agricultural areas Expression of the herbicide tolerance gene in GM plants Reduced effectiveness of weed management measures to control the volunteer GM canola plants Persistence of volunteer GM canola plants in agricultural areas	Reduced establishment or yield of desirable agricultural crops	No	Standard agronomic practice for canola cultivation includes integrated weed management practices that will effectively control volunteer populations.
4	Introduced gene for herbicide tolerance	Dispersal of GM canola seed to non-agricultural areas Establishment of GM plants in nature reserves or disturbed habitats Expression of the herbicide tolerance gene in GM plants Increased potential of GM plants to spread and persist	Reduced establishment of desirable native vegetation	No	 The genetic modification is not expected to alter the response of GM canola to biotic and abiotic stresses that naturally limit the geographical distribution of the species. The genetic modification will only give an advantage to the GM canola plants in managed environments, where glyphosate herbicide is applied. Canola plants with tolerance to glyphosate can still be controlled by other herbicides or mechanical means.
5	Introduced gene for herbicide tolerance	Transfer of herbicide tolerance gene to other canola, including other herbicide-tolerant non- GM and commercially approved GM canola plants.	Reduced establishment of desirable agricultural crops	No	 Transfer of the introduced gene to other herbicide tolerant GM canola by pollen flow is expected to be limited.

Risk .	Risk source	Causal pathway	Potential harm	Substantive	Reason
scenario				risk?	
		by pollen flow Establishment of volunteer GM canola plants in agricultural areas Reduced effectiveness of weed management measures to control volunteers Persistence of volunteer canola plants in agricultural areas			 Multiple-herbicide tolerant individuals are as susceptible to alternative herbicides as single- herbicide tolerant canola plants or their non-GM counterparts. Standard measures for controlling canola volunteers will limit volunteer numbers, further limiting their potential to reduce establishment of desirable crops

2.4.1 Risk scenario 1

Risk source	Causal pathway	Potential harm
Introduced herbicide	Expression of herbicide tolerance gene in GM plants	Increased toxicity or allergenicity for
tolerance gene	Exposure of people undertaking the dealings to the GM plants or products thereof, or exposure of the public by consumption of GM canola products, contact with GM canola products, or inhalation of GM canola pollen	people

Risk source

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

Causal pathway

132. 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).

133. 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).

134. Increased toxicity or allergenicity of GM plants could be due to direct expression of the introduced gene in the GMOs. The herbicide tolerance gene *cp4 epsps* is expressed in all parts of MON 88302 canola plants at all developmental stages including leaf, stem, root, pollen and seed (Chapter 1, Section 5.5.2). People undertaking dealings with the GM canola may be exposed through contact; the general public may be exposed to the GM canola products through consumption or contact, including inhalation of pollen.

Potential harm

135. Expression of the introduced *cp4 epsps* gene for herbicide tolerance could potentially result in the production of novel toxic or allergenic compounds in the GM canola plants, or alter the expression of endogenous canola proteins. People exposed to the protein expressed from the introduced gene or the associated metabolites may show increased toxic reactions or allergenic reactions.

136. The *cp4 epsps* gene introduced into the GM canola line encodes the CP4 EPSPS protein that is well characterised. Based on all available information, the protein is not known to be toxic or allergenic, nor is it involved in biochemical pathways that produce toxic or allergenic

products (Chapter 1, Section 5.2.2). In addition, the metabolic products of the enzymatic action of the EPSPS protein upon glyphosate are not known to be toxic (Chapter 1, Section 5.2.3). Roundup Ready[®] canola containing the same *cp4 epsps* gene has been approved by the Regulator for commercial release and its food use has been approved by FSANZ. It has been grown in Australia since 2008 in NSW and Victoria, and 2010 in WA. There have been no reported adverse effects on human health from Roundup Ready[®] canola or other commercial GM crops with an introduced *cp4 epsps* gene.

137. The introduced gene is controlled by regulatory sequences derived from other organisms, including plant pathogens. As discussed Chapter 1, Section 5.3, the *cp4 epsps* gene in MON 88302 canola is driven by a chimeric promoter containing a partial sequence from the FMV 35S promoter. It has been suggested that a truncated protein P6 may be expressed from this promoter, which could lead to harm to humans if expressed in GM plants. This risk has been discussed and assessed in detail in the RARMP for DIR 118, concluding that it is not a risk that could be greater than negligible (OGTR 2013b). It should also be noted that the use of variants of this promoter in a number of commercially grown GM crops in Australia and other countries, including the Roundup Ready Flex[®] cotton and Roundup Ready 2 Yield[®] soybean containing this genetic modification, has not been linked to any harms to human health. P6 proteins are already widespread in the environment, including in human food plants, through the presence of the viruses which encode it.

138. Analysis of the compositional data for seed from MON 88302 canola also indicates that there are no meaningful differences in the levels of compounds, including natural toxicants, when compared to non-GM canola from the same background and to other commercial canola varieties (FSANZ 2013).

139. FSANZ has approved the use of food derived from MON 88302 canola for human consumption in Australia (Chapter 1, Section 7.2). Food use of MON 88302 canola has also been approved in other countries including Canada, Japan, Korea, Mexico and the United States (Chapter 1, Section 7.3).

Conclusion

140. Risk scenario 1 is considered to be a negligible risk due to the lack of toxicity or allergenicity of the CP4 EPSPS protein to humans, a history of safe use of GM crops containing the introduced gene and compositional equivalence of seed from MON88302 canola and conventional canola varieties. Therefore, this risk is not considered to be a substantive risk that warrants further detailed assessment.

2.4.2 Risk Scenario 2

Risk source	Causal pathway	Potential harm
Introduced	Expression of herbicide tolerance gene in the GM canola	Increased toxicity
herbicide	. ↓	for other
tolerance gene	Exposure of other organisms to GM plant material through contact or ingestion	organisms

Risk source

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

Causal pathway

142. As mentioned in Risk Scenario 1, the introduced *cp4 epsps* gene is expressed in all parts of the MON 88302 canola plants. Therefore, other organisms including animals and microorganisms may be exposed to the GM canola or its product through contact or ingestion. Livestock fed on canola seed meal and forage will be exposed to the introduced gene product.
Insects including non-pest insect species that consume the GM crop, butterflies and desirable insects such as predators of the pest organisms, parasitoids, or pollinators such as bees may be exposed to the introduced gene products. Microorganisms such as soil microbes may also be exposed to the introduced gene product through contact with the root exudates or plant material left on the ground after harvest.

143. Canola volunteers are commonly found along roadsides neighbouring cultivation sites and some transport routes, which may provide a pathway for exposure. However, there appears to be limited ability for canola to establish persistent populations at these locations (Chapter 1, Section 4.1), so extended exposure to the GM canola will occur mostly in the agricultural context.

Potential harm

144. There is potential for adverse impacts on the health of these organisms if the CP4 EPSPS protein is toxic to these organisms.

145. As discussed in Chapter 1, Section 5.2.2, animal feeding studies on a range of animals including rat, trout, chicken, quail, lamb, pig and cow using seed or seed meal from GM canola or cotton containing the CP4 EPSPS protein revealed no adverse effects on animal growth and other characteristics such as weight gain, carcass composition, meat tenderness and fat content. Grazing by livestock on the GM canola that express the CP4 EPSPS protein is also not expected to result in harm to the animals, because MON 88302 canola is comparable to non-GM canola in other respects (see Chapter 1, Section 5.5.3).

146. Homologous EPSPS proteins that perform the identical biochemical reaction to the CP4 EPSPS protein occur in all plants and many other microorganisms. As noted in Chapter 1, Section 5.2.2, no published study indicates that the CP4 EPSPS protein has any toxic property to arthropods, including endangered species or other species that are beneficial to agriculture. Furthermore, the low CP4 EPSPS protein level in the pollen of MON 88302 canola makes it extremely unlikely to be toxic to bees.

147. The *cp4 epsps* gene was isolated from the common soil bacterium *Agrobacterium* sp., which is widespread and prevalent in the environment. Therefore, many soil organisms are already exposed to the CP4 EPSPS protein. As discussed in Chapter 1, Section 5.2.2, there are no permanent effects on soil biota by GM crops expressing the CP4 EPSPS protein have been reported.

Conclusion

148. Risk Scenario 2 is considered to be a negligible risk due to the lack of toxicity of the CP4 EPSPS protein to animals and microorganisms, and the widespread occurrence of this gene, related genes and their encoded proteins in the environment. Therefore, this risk is not considered to be a substantive risk that warrants further detailed assessment.

Risk source	Causal pathway	Potential harm
Introduced	Establishment of volunteer GM canola plants in agricultural areas	Reduced
herbicide	•	establishment or
tolerance gene	Expression of the herbicide tolerance gene in GM plants	yield of desirable
	•	agricultural crops
	Reduced effectiveness of weed management measures to control the	
	volunteer GM canola plants	
	Persistence of volunteer GM canola plants in agricultural areas	

2.4.3 Risk Scenario 3

Risk source

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

Causal pathway

150. If volunteer GM canola plants expressing the CP4 EPSPS protein were to establish in agricultural areas, expression of the herbicide tolerance gene could reduce effectiveness of weed management measures for control of volunteer GM canola.

151. The GM canola proposed for release will contain the glyphosate tolerance trait. Expression of this trait will confer a selective advantage over non-GM counterparts in environments in which glyphosate is applied, such as agricultural settings and along roadsides.

152. Volunteer plants are likely to occur in the field following a canola crop, but also be dispersed into neighbouring areas. As canola does not reproduce vegetatively under natural conditions, the most likely method of dispersal is via seed. Non-GM canola is primarily dispersed by human activities (harvest, transport) (Agrisearch 2001; Crawley & Brown 2004; von der Lippe & Kowarik 2007b) and this would be the case with MON 88302 canola. Pod shattering can disperse seeds over short distances. It is also possible that GM canola plant material from windrows, including seed, could be blown beyond the GM canola field boundaries. Dispersal distance would depend on the wind strength, the amount of trash on the ground and the moisture content of the material. Canola seed can be also be dispersed by grazing animals (Stanton et al. 2003) or wild birds (Twigg et al. 2008; Woodgate et al. 2011).

153. There are no differences between MON 88302 canola and non-GM canola with respect to the intrinsic characteristics contributing to spread and persistence, such as seed production, shattering or dormancy, and competitiveness (see Chapter 1, Section 5.5.3). MON 88302 canola only has a survival advantage in the presence of glyphosate. Glyphosate is commonly used in broad-acre cropping for pre-emergent weed control prior to planting. Glyphosate would not be effective in controlling canola volunteers in situations where MON 88302 canola had been grown previously. The presence of MON 88302 canola volunteers in agricultural areas has implications for the choice of herbicide(s) in situations where glyphosate is the principal weed control strategy (Chapter 1, Section 6.1).

154. 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. Herbicides from different mode of action groups or products with multiple mode of action groups could be used to control MON 88302 volunteers. Specifically, herbicides from Groups B, C, F, G, H, I, L, N, O and Q are registered for use on canola in various crop and non-crop situations by the APVMA. In addition, several herbicides with multiple mode of action groups (eg Groups B + I, C + F, C + H, C + I, F + I, H + I, Q + L and K + B) are registered for use on canola volunteers. Further details of registered herbicide products are available on the APVMA website (www.apvma.gov.au).

155. MON 88302 canola is as susceptible as non-GM canola to all herbicides other than glyphosate. The GM canola volunteers can therefore be controlled by using integrated weed management practices, which would 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.

156. The MON 88302 Canola Technology Stewardship Strategy developed by Monsanto includes a Crop Management Plan for growers to follow, this incorporating management strategies for control of canola volunteers.

Potential harm

157. Volunteer canola (non-GM and GM) represents a weed of agricultural production systems (Beckie et al. 2001; Legere et al. 2001; Martens 2001; Simard & Legere 2001; Simard et al. 2002). 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 (Chapter 1, Section 4.1.1). 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.

158. The use of alternative herbicides for the control of MON 88302 canola volunteers may raise concerns that these herbicides could be more toxic or more persistent than glyphosate, which may result in harm to human health or the environment. However, the APVMA registers herbicides on the basis that, when used as specified on the approved label, they will not compromise the health of users or the environment. The APVMA also has a program for reporting any adverse effects associated with agricultural chemical use and a program to review already registered agricultural chemicals.

Conclusion

159. Risk scenario 3 is considered to be a negligible risk, as integrated weed management practices will control GM canola volunteers in cropping areas. Therefore, this risk is not considered to be a substantive risk that warrants further detailed assessment.

2.4.4	Risk	Scen	ario	4

Risk source	Causal pathway	Potential harm
Introduced gene for herbicide tolerance	Dispersal of GM canola seed to non-agricultural areas Establishment of GM plants in nature reserves or disturbed habitats Expression of the herbicide tolerance gene in GM plants Increased potential of GM plants to spread and persist	Reduced establishment of desirable native vegetation

Risk source

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

Causal pathway

161. If GM canola seeds were dispersed into non-agricultural areas such as nature reserves or disturbed habitats (for example roadsides) and GM plants became established, expression of the introduced gene for herbicide tolerance could increase the potential of GM plants to spread and persist.

162. Dispersal of viable seed to nature reserves could occur in a variety of ways including endozoochory (dispersal through ingestion by animals), the activity of animals such as rodents and herbivores, through extremes of weather such as flooding or high winds, or via spillage during transport.

163. Human activity is considered the most significant method of long-distance seed dispersal. Studies in the UK, North America, Japan, Germany and Australia have shown that both GM

and non-GM canola plants are often found growing near roads and railways, suggesting that seed is lost during transportation (Agrisearch 2001; Nishizawa et al. 2009; Schafer et al. 2011; von der Lippe & Kowarik 2007a). If GM canola plants were to establish along transportation routes, this could be an avenue by which GM plants could spread into native areas. As discussed in the RARMPs prepared for DIR 020/2002 and DIR 108, surveys of GM canola growing areas found GM canola volunteers along roadsides but generally they were only found close to the edges of roads. In Australia roadside canola populations are thought to be reliant on re-supply of seed from seed spillage during harvest and transport operations rather than forming self-sustaining weed populations (Gulden et al. 2008; Salisbury 2002b).

164. If MON 88302 canola were commercialised, its distribution in unmanaged areas adjacent to fields and along many transportation corridors would be expected to be comparable to that of non-GM canola volunteers. In areas where glyphosate is used, such as along some roadways, the GM canola plants would have an advantage but as discussed earlier in Risk Scenario 3, these plants can be controlled by the use of other herbicide or mechanical means such as slashing. The geographic range of non-GM canola in Australia is limited by a number of biotic and abiotic factors, including disease pressure, water and nutrient availability (OGTR 2011b). As discussed in Chapter 1, Section 5.5.3, the agronomic characteristics of MON 88302 canola were comparable to its parental variety Ebony, apart from a small delay in flowering time. The genetic modification is not expected to alter the tolerance of plants to biotic or abiotic stresses that normally restrict geographic range and persistence of canola in natural habitats. Therefore, the introduced gene is unlikely to increase the potential weediness of MON 88302 canola or provide the plants with an ecological advantage over non-GM canola, except in managed systems where glyphosate is used.

Potential harm

165. If the GM MON 88302 canola expressing the introduced gene for herbicide tolerance were able to establish and persist in non-cropped disturbed habitats and undisturbed natural habitats, this may give rise to lower abundance of desirable species, reduced species richness, or undesirable changes in species composition.

166. When the weed risk potential of MON 88302 canola is assessed based on the National Post-Border Weed Risk Management Protocol, it is considered to have no higher ratings than non-GM canola in terms of invasiveness or negative impacts on any of the land uses where canola primarily occurs, namely, dryland and irrigated agricultural areas, and highly disturbed areas such as roadsides (see Chapter 1, Section 4.1). The phenotypic characteristics of the MON 88302 canola indicate that it is comparable to non-GM canola. The slight delay in flowering observed does not present a weediness concern (see Chapter 1, Section 5.5.3). The trait of glyphosate tolerance could affect the plant's tolerance to average weed management practices in any areas where glyphosate is used. However, as discussed in Risk Scenario 3, MON 88302 canola remains susceptible to alternative herbicides, as well as standard agronomic and mechanical management practices. Additionally, canola is a poor competitor and will be displaced unless the habitats are disturbed on a regular basis (Beckie et al. 2001; OECD 1997; Salisbury 2002b).

167. As discussed in Chapter 1, Section 4.1, canola is not considered a significant weed, nor invasive of natural undisturbed habitats in Australia (Dignam 2001; Norton 2002), and is not reported to establish in nature conservation land use areas (Groves et al. 2003; Salisbury 2000). The geographic range of non-GM canola in Australia is limited by a number of biotic and abiotic factors, including disease pressure, water and nutrient availability (OGTR 2011b).

Conclusion

168. Risk scenario 4 is considered to be a negligible risk, as the introduced gene does not increase the potential weediness of the GM canola or provide these plants with an ecological advantage over non-GM canola, except in the presence of glyphosate, and is able to be controlled by a variety of other means. Therefore, this risk is not considered to be a substantive risk that warrants further detailed assessment.

2.4.5 Risk Scenario 5

Risk source	Causal pathway	Potential harm
Introduced gene for herbicide tolerance	Transfer of herbicide tolerance gene to other canola, including other herbicide-tolerant non-GM and commercially approved GM canola plants, by pollen flow Establishment of volunteer GM canola plants in agricultural areas Peduced effectiveness of weed management measures to control	Reduced establishment of desirable agricultural crops
	volunteers	
	Persistence of volunteer canola plants in agricultural areas	

Risk source

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

Causal pathway

170. 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.

171. In the broad-acre field situation, cross pollination between the GM canola proposed for release and other canola would most likely occur when canola crops are grown in adjacent paddocks and flower synchronously. Cross pollination may also occur where volunteer plants emerge after the GM canola crops are harvested and develop to flowering stage, or where feral canola populations, resulting from seed being dispersed off-farm, establish along roadsides adjacent to cropping land where other canola crops are planted.

172. As discussed in Chapter 1, Section 5.5.3, MON 88302 canola displayed a small delay in flowering time compared to its parental variety Ebony in some field trials. Such a change may alter the chance of gene transfer from MON 88302 canola to other canola crops in an agricultural setting, either increasing or decreasing it in particular situations. However, this delay in flowering is apparently unrelated to the genetic modification, as it was not observed when comparing MON 88302 canola to its negative segregant, and the difference was reversed in another genetic background. Furthermore, flowering time was within the reference range of commercial canola varieties (see Chapter 1 Section 5.5.3).

173. Gene transfer to non-GM, non-herbicide tolerant canola varieties would result in plants highly similar to the GMO proposed for release. Therefore, any adverse outcomes expected for those progeny would be comparable to MON 88302 canola.

174. As noted in Chapter 1, Section 6.2.1, there are currently three herbicide-tolerant canola varieties widely grown in Australia – the conventionally bred TT and Clearfield[®] canolas and GM Roundup Ready[®] 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; Knispel et al. 2008; Schafer et al. 2011). There is also

another type of GM canola, $InVigor^{\mbox{\sc R}}$, which confers tolerance to herbicides containing glufosinate ammonium. Although $InVigor^{\mbox{\sc R}}$ canola has not been commercially grown in Australia, the stacking of genes for tolerance to up to four different herbicide groups has been a possibility since the approval of $InVigor^{\mbox{\sc R}}$ canola and Roundup Ready^{$\mbox{\sc R}}$ canola in 2003, and $InVigor^{\mbox{\sc R}} \times Roundup Ready^{\mbox{\sc R}}$ canola in 2011.</sup>

175. 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; Dietz-Pfeilstetter & Zwerger 2009; Senior et al. 2002). In laboratory studies, multiple-herbicide tolerant canola plants were no more competitive than single-herbicide tolerant canola plants were to occur, they are unlikely to be more invasive or persistent than non-herbicide tolerant or single-herbicide tolerant canola plants and could be controlled by other herbicides or other (non-chemical) agricultural practices. Glufosinate ammonium is in mode of action Group N, while triazine and imidazoline herbicides are in Group C and Group B, respectively. As discussed in Risk Scenario 3, there are a range of other herbicide products available with alternative or multiple modes of action. Stacking has been assessed in the RARMPs for DIR 020/2002 (OGTR 2003a), 021/2002 (OGTR 2003b) and DIR 108 (OGTR 2011a), and was not found to represent a risk greater than negligible.

176. If MON 88302 canola is commercially released, development of canola plants with glyphosate tolerance together with the other three herbicide tolerance traits may become more likely. However, as MON 88302 canola contains the same cp4 epsps gene as that in the Roundup Ready[®] canola for glyphosate tolerance, no new trait will be added in agricultural areas to create new combinations of herbicide tolerance in canola volunteers.

Potential harm

177. 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.

178. Weed management is a farm stewardship issue that is not confined to herbicide tolerant canola. Cropping areas are subject to standard weed management practices that would minimise the impact of volunteers on the establishment of desirable crop plants. 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.

Conclusion

179. Risk scenario 5 is considered to be a negligible risk, as the presence of the stacked herbicide-tolerant hybrid is expected to be transient and the plants can be controlled using integrated weed management practices, thus limiting their potential to reduce the yield of other crops. Therefore, this risk is not considered to be a substantive risk that warrants further detailed assessment.

Section 3 Uncertainty

180. Uncertainty is an intrinsic part of risk analysis⁵. There can be uncertainty about identifying the risk source, the causal linkage to harm, the type and degree of harm, the chance of harm occurring or the level of risk. In relation to risk management, there can be uncertainty about the effectiveness, efficiency and practicality of controls.

181. Risk analysis can be considered as part of a first tier uncertainty analysis, namely a structured, transparent process to analyse and address uncertainty when identifying, characterising and evaluating risk. However, there is always some residual uncertainty that remains. If the residual uncertainty is important and critical to decision making, then this residual uncertainty may be subjected to further analysis (= second tier uncertainty analysis), such as building 'worst case' scenarios, or by using meta-analysis where results from several studies are combined.

182. 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
 - perception processing and interpreting risk is shaped by our mental processes and social/cultural circumstances, which vary between individuals and over time.

183. For commercial/general releases, where there may not be limits and controls to restrict the spread and persistence of the GMOs and their genetic material in the environment, uncertainty may be addressed through post release review (Chapter 3, Section 4).

184. MON 88302 canola has been approved by the Regulator for limited and controlled release (field trials) under licence DIR 105. The RARMP for DIR 105 identified additional information that may be required for a large scale or commercial release of MON 88302 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. Information provided by the applicant addressing these areas of uncertainty is presented in Chapter 1, Section 5.5 and discussed in relevant sections of that Chapter.

185. For the current application for commercial release of MON 88302 canola, there is uncertainty with respect to flowering time of the GM canola and its potential impact on gene flow (see Chapter 1, Section 5.5.3). As discussed in Risk Scenario 5, the differences in flowering time are likely not a result of the genetic modification itself but rather due to changes in the genetic background arising through breeding and selection. Additionally, flowering time was within the reference range of commercial canola varieties. Even if there were increased levels of gene transfer, it is not expected to lead to any harms (see Risk Scenario 5). Therefore, the associated uncertainty is very low.

⁵ A more detailed discussion is contained in the Regulator's *Risk Analysis Framework* available from the <u>OGTR</u> website or via Free call 1800 181 030.

186. Uncertainty can also arise from a lack of experience with the GMO itself. In regards to MON 88302 canola, the level of uncertainty is considered to be low given that this GMO has been approved for commercial production in the United States and Canada. In addition, the Roundup Ready[®] canola, which contains the same *cp4 epsps* gene, has been commercially grown in Australia and overseas (eg 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.

Section 4 Risk evaluation

187. 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.

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

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

189. 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 3.

190. The *Risk Analysis Framework* (OGTR 2013a), 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. Therefore, 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

Section 1 Background

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

192. 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.

193. 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 provide access to premises to OGTR inspectors and section 65 requires the licence holder to report any information about risks or unintended effects of the dealing to the Regulator on becoming aware of them. Matters related to the ongoing suitability of the licence holder are also required to be reported to the Regulator.

194. 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 identified risks

195. 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 of MON88302 canola. 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 controls are required to treat these negligible risks.

Section 3 General risk management

196. 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
- identification of the persons or classes of persons covered by the licence
- reporting structures
- a requirement that the applicant allows access to specified sites for purpose of monitoring or auditing.

3.1 Applicant suitability

197. 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.

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

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

200. 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

201. Monsanto is required to provide a method to the Regulator for the reliable detection of the presence of the GMOs and 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

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

3.4 Reporting requirements

203. 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.

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

205. 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

206. The Act stipulates, as a condition of every licence, that a person who is authorised by the licence to deal with a GMO, and who is required to comply with a condition of the licence, must allow inspectors and other persons authorised by the Regulator to enter premises where a dealing is being undertaken for the purpose of monitoring or auditing the dealing.

207. 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

208. Regulation 10 requires the Regulator to consider the short and the long term when assessing risks. The Regulator does not fix durations, but 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.

209. 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).

210. 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

211. 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 GMO(s).

4.2 Requirement to monitor specific indicators of harm

212. 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.

213. 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.

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

215. 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 127. However, specific indicators of harm may also be identified during later stages, eg following the consideration of comments received on the consultation version of the RARMP, or if a licence were issued, through either of the other components of PRR.

216. 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

217. 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 caseby-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 needed managing, this could lead to changes to the risk management plan and licence conditions.

Section 5 Conclusions of the RARMP

218. 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.

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

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Appendix A Summary of advice from prescribed experts, agencies and authorities on matters relevant to the preparation of the consultation RARMP⁶

The Regulator received a number of 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 clarification about whether the assessment will consider growing of the GM canola in canola growing areas or all of Australia.	As the applicant proposes no restrictions on where the GM canola can be planted, the potential receiving environment is considered to be all of Australia. This is made clear in the Summary of the RARMP and in Chapter 1, Section 6.
Potential for development of herbicide resistant weeds and related environmental impacts should be considered.	Herbicide resistance issues come under the regulatory oversight of the APVMA. Relevant discussion is included in Chapter 1, Section 2.2.4.
Council has no objection to the proposed trial of GM crops and is generally supportive of GM cropping. However, this is not strictly an issue that the local government has a role in.	-
Notes that their jurisdiction has no set policy on genetically modified foods or specific expertise in this area and that there are no farming areas where canola might be grown in its precinct.	-
Would like the RARMP to conclusively show that use of the GM canola will not pose a risk to human health and safety and to the environment.	The RARMP prepared for this application considers information provided by the applicant as well as other relevant scientific information, both from Australia and elsewhere. The risk assessment compares risk from the GM canola to risks from non-GM canola, and concludes that risks to human health and the environment as a result of gene technology are negligible.
Wants consumers to be able to identify products that have been made from GM canola, so that the public has an informed choice when purchasing such products.	FSANZ has regulatory responsibility for food safety assessment and labelling, including of GM food. FSANZ has approved the use of food derived from MON 88302 canola for human consumption. Labelling oil derived from the GM canola would not be required if no DNA or protein is detectable in the oil and if the composition of the oil is unaffected by the genetic modification. This is expected to be the case for this GM canola.
Does not wish to provide any formal comment due to the release area being outside of the LGA and not having any technical expertise on this matter.	-

⁶ Prescribed agencies include GTTAC, State and Territory Governments, relevant local governments, Australian Government agencies and the Minister for the Environment.

Summary of issues raised	Comment
 Council has a policy in relation to GM crops which advocates for the district to be GMO free. Council therefore does not support the unrestricted commercial release of the GM canola. Prior to the commercial release of GM canola, believes the following concerns need to be addressed: the commercial impact on overseas markets for our product; an assurance that effective segregation will be available; a caveat requiring GM companies to make good any economic loss incurred by farmers and businesses from unintended consequences of the release. If trial of GM plants are to occur, the company carrying out the trial should: notify Council of sites of those trials; advise all neighbouring farmers with properties within 3 km of those sites; advise apiarists with bee within 3 kms of those sites. 	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. Therefore only general conditions are included in the draft licence, to ensure that there is ongoing oversight of the release. 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 are matters for States and Territories, and industry, and some States and Territories have imposed restrictions on the growing of GM crops for marketing reasons. These States and Territories may allow trials of GM crops subject to conditions unrelated to human health and safety and the environment.
Council does not have specialist scientific expertise available to comment but the municipality has been declared to be a GM free district.	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. These matters are decided by individual States and Territories.
There are many significant environmental assets within the Shire and weeds pose a major threat to their integrity. Council would be concerned if GM canola with resistance to glyphosate was planted adjacent to, or within easily vectored distance of the areas of significant biodiversity. Many of these are captured in our roadsides and invasion of canola crops without practical control measures available could be disastrous.	The potential for harm due to expression of the introduced gene for glyphosate tolerance in the GM canola plants or in other related plants, including weedy species, as a result of gene transfer was assessed in Chapter 2 of the RARMP and was not identified as a substantive risk. The GM canola is not expected to be any more invasive or persistent than non-GM canola. Herbicides other than glyphosate or by non-chemical means can be used to control plants resistant to glyphosate.
Council is committed to having a clean and green image that is demonstrated by the significant number of organic farmers in the region. When carrying out any weed control works involving chemical spraying, Council always notify these farms to ensure that no impact is put on the farmer's organic accreditation.	The APVMA has regulatory responsibility for the supply of agricultural chemicals, including herbicides, in Australia. Issues relating to the safety and use of herbicides are assessed and managed by the APVMA.
Wants more details on the locations the GM canola will be planted so the local issues such as biodiversity and organic farms could be raised.	As this is a commercial release application, the GM canola is proposed to be grown anywhere that canola crops are grown.
The State has a ban on genetic modified organisms. Therefore have no relevant comments.	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. These matters are decided by individual States and Territories.
No comment.	-

Summary of issues raised	Comment
The Shire has a conservation strategic focus due to the area having social, economic and environmental value. Council therefore adopts a precautionary approach to the introduction of GM crops by advocating to the State Government to oppose the introduction of GM crops into the Shire and advocating for the mandatory labelling of all GMO products. This approach should stay until all gene technology products are labelled, GM-free zones are established, independent research shows the GMOs are harmless to health and the environment, and a strong and enforceable liability and insurance regime is in place for GMO products. Council officers have concerns that approval of unrestricted licence to release GM canola in all commercial canola growing areas in Australia would fail to take into account locally significant risks to health, safety and the environment. Encourages consideration of working within local areas to determine the appropriateness or otherwise of GM crops.	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 prepared for this application considers information provided by the applicant, other relevant scientific information, both from Australia and elsewhere, and issues raised in submissions. It concludes that risks to human health and the environment are negligible. Consultation with LGAs is required by the Act, and issues raised relating to human health and safety and the environment that may be specific to local areas are taken into account when preparing the RARMP. Marketing and commercial liability issues are outside the matters to which the Regulator may have regard when deciding whether or not to issue a licence. Some areas may be designated GM, GM-free or both under State or Territory law for the purpose of preserving the identity of GM or non-GM crops (or both) for marketing purposes. FSANZ is responsible for human food safety assessment and food labelling, including of GM food. Products derived from MON 88302 canola has been approved by FSANZ for use in
Council strongly opposes gene technology and has endorsed this policy since council's inception in 1997.	-
Council expresses reservation and objects to any introduction of GM TruFlex canola into the Shire.	-
Notes assertion in the summary of application DIR 127 that there have been no credible reports of adverse effects on human health and safety or the environment resulting from previous release of GM canola.	-
A sector of the community in the Shire holds concern that with an unrestricted commercial release of GM canola, some farmers' weed management strategies may change to incorporate an increased use of glyphosate herbicides. There is some community apprehension that increased use of herbicides will eventually impact negatively on human health and safety.	Regulation of agricultural chemicals, including herbicides, is principally the responsibility of the APVMA. The APVMA considers a range of issues in assessing agricultural chemicals for registration, including efficacy, resistance management and human health and environmental impacts. The APVMA will not register a chemical product unless satisfied that its approved use would not be likely to have an effect that is harmful to people or the environment.
Should GM canola seed escape from farms into the surrounding natural environment, the ability of natural environment land managers to control the spread of these invasive plants will be limited unless a wider range of herbicides is applied; something which is undesirable in the management of our natural environment.	As noted above, the regulation of agricultural chemicals is principally the responsibility of the APVMA. The potential for the GM canola itself to cause harm due to spread and persistence in the natural environment was assessed in the context of a commercial scale release in Risk Scenario 4 and was not identified as a substantive risk. Canola is not invasive of undisturbed natural habitats and the genetic modification will not change this. Volunteer GM canola can be controlled by a range of alternative herbicides approved by the APVMA, and by non-chemical management methods.

Summary of issues raised	Comment
Organic farming takes place within the Shire. Council is promoting its 'clean green' brand and high quality image. However, both globally and locally, there is a deeply held view that there is no compatibility between organic and GM farming operations. Therefore, local community is concerned that growing GM canola might result in damage to the region's reputation and its high standing in the agricultural sector, and eventually affect local organic producers' income. There is a wide community interest in the Supreme Court of WA case involving the growing of GM canola on one farm and its alleged effects on a neighbouring organic farming operation. The result of this court case will help the broad community to address the issues around the unrestricted commercial release of GM canola and provide Council with an opportunity to better represent the views of the Shire. Urges the Regulator to still accept public responses well after the release of the findings of this court case.	 When deciding whether or not to issue a licence, matters that relate to marketing and trade, including coexistence of GM and non-GM crops, are outside the legislative responsibility of the Regulator. These are matters for State and Territory governments, who may designate GM free zones for marketing purposes. As the WA Supreme Court case in question relates to segregation and marketing issues, not health and safety issues, its outcome is unlikely to impact on the Regulator's decision. There will be a further opportunity for Council and public input after release of the RARMP.
Council does not have access to specialist scientific advice and can only provide comment on the basis of the community views and Council resolutions. Council passed a resolution to be a GM free cropping zone, in alignment with nearby municipalities, noting that Council has no jurisdiction in this matter.	Some areas may be designated under State or Territory law for the purpose of preserving the identity of GM or non-GM crops (or both) for marketing purposes. However, marketing issues are outside the matters to which the Regulator may have regard when deciding whether or not to issue a licence.
 The major concerns highlighted by Council officers and the community (in relation to GM food and GM crops) include: Potential for allergic reactions to substances unknown to be contained within genetically modified food or the creation of new allergens; The unknown long term implications of genetically altering genes; Antibiotic resistance; The potential invasion of GM Canola as an environmental weed within Council's Bushland and Foreshore Reserves and the impact on biodiversity; The impact on Council's nursery stock if GM Canola seed were to be contained within externally sourced potting mix; Potential impact on the region's golfing, market gardens, viticulture and flower growing industry. 	The potential for allergic reactions in people, or toxicity in people, as a result of exposure to GM plant materials was assessed in Risk Scenario 1 and was not identified as a substantive risk. FSANZ is responsible for human food safety assessment, including of GM food. The use in food of products derived from MON 88302 canola has been approved by FSANZ. The potential for both short and long term effects, and the impact of uncertainty, were considered as part of the risk assessment, and no substantive risks were identified. Nevertheless, if a licence were issued, the Regulator would include a requirement for ongoing oversight of the release to provide feedback on the findings of the RARMP and ensure the outcomes remain valid for future findings or changes in circumstances. MON 88302 canola does not contain any introduced genes that confer antibiotic resistance. The potential for adverse effect due to spread and persistence of the GM canola in agricultural and natural environments was assessed in the context of a commercial scale release in Risk Scenarios 3 and 4, and was not identified as a substantive risk. The impact of this GM canola is not expected to be greater than that of non-GM canola. The GM canola plants can be controlled with herbicides other than glyphosate or by non-chemical means.
 Council has made the following commitments: Monitor trends, research and understand the local impacts of GMOs on food production, in response to local community concerns about safety of GMO food; Convene an internal reference group; Research and write background paper on this issue. 	-

Summary of issues raised	Comment
Council considers matters related to risks to human health and safety and the environment from Application DIR 127 are very low within the LGA as it is primarily a grazing area.	Noted.
Council has a neutral stance regarding GM food in general.	-
 Requests Regulator to seriously consider the following two principles when preparing a RARMP: GM crops are only approved if they are proven to be safe 'beyond reasonable doubt' using evidence from independent, long-term, published and peer reviewed studies – measuring indicators relevant to human health; All GM food is clearly labelled, including highly processed products such as oils, starches and sugars from GM crops and meat, milk, cheese and eggs from animals fed GM feed. 	The RARMP prepared for this application considers information provided by the applicant, other relevant scientific information, both from Australia and elsewhere, and issues raised in submissions. It concludes that risks to human health and the environment are negligible. Issues relating to food labelling are outside the scope of the Regulator's assessments. FSANZ is responsible for human food safety assessment and food labelling, including of GM food.
Given the biology and ecology of canola, and the safety records of GM canola from field trials and commercial release, the environmental risks posed by this commercial release are likely to be low and manageable.	Noted.
 However, the following uncertainties should be discussed in the RARMP for this application: If this application is granted, the GM canola may not only be grown in current canola growing areas, but also in some new areas, such as northern Australia. Although canola is not grown commercially in northern Australia, it has been trialled in the Northern Territory as one of the potential biofuel crops there. Its weediness, including potential seed dispersal by flooding and crossing with related species, in the new areas should be taken into account; There is a delay in the flowering time of the GM canola. This may influence the activity of insect pollinators, such as honeybees, on crops. Honeybees are generally inactive in cold weather and late flowering correlating with temperature increase may affect these pollinators and the pollen distribution of the GM canola. 	These issues and the associated uncertainties have been discussed in Chapter 1, Sections 4.1 and 5.3.3, and Chapter 2, Sections 2.4.5 and 3. The application has been assessed on the basis that the release may occur Australia- wide. The delay in flowering observed in some trials does not appear to be due to the genetic modification itself but to differences in the genetic background arising through the breeding and selection process.

Appendix B Summary of advice from prescribed experts, agencies and authorities on the consultation RARMP⁷

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

Summary of issues raised	Comment
Council adopted a GM Crops Policy in September 2012, which states that council does not support the growing of GM crops within its district. This policy is based on the notion that there is an absence of conclusive evidence that GM crops are safe for people or the environment. Council is concerned that the Regulator has chosen to consider risks associated with product release rather than assuring product safety. Council acknowledges the commercial pressures in the context of the proposed release. Council urges approval to be withheld until safety can be proven rather than deeming the risks acceptable.	The Act requires the Regulator to protect human health and safety and the environment by identifying and managing risks posed by or as a result of gene technology. Therefore, the Regulator does risk assessments in accordance with the Act. FSANZ conducts safety assessments of GM foods and has approved the use in foods derived from this GM canola in Australia. Food and feed use of this GM canola have also been approved in other countries, such as the USA, Canada, EU Japan, Mexico and Korea. Commercial production of the GM canola has also been approved in the USA and Canada.
Satisfied that the RARMP covers the concerns provided in our previous submission during the first round of consultation. The assessment indicates that there is no serious public health and safety or environmental risks. Also confirmed that the food labelling issue is dealt by other agencies.	Noted.
Council has recently reaffirmed its policy view opposing any trial of GM canola within the council area.	Noted.
Council confirms its reasonable expectation that responsible State and Federal Agencies will provide or require suitable monitoring to ensure that there are no deleterious effects to people or the environment from the commercial release of the GM canola if approved, and that these agencies shall also provide any necessary resources to respond appropriately in the event that any adverse impact is identified in the future.	General licence conditions are proposed to ensure that there is ongoing oversight of the release. These include a requirement to submit an annual report containing information about the volumes of the GMOs grown in each State. Any adverse impacts or new information relating to risks to human health and safety or the environment caused by the GMOs must also be promptly reported to the Regulator. The licence also includes conditions relating to post release review (see Chapter 3, Section 4) that require the licence holder, upon request by the Regulator, to collect and provide further information on the progress of the dealing.
Notes that the GM canola has been assessed and approved as safe for food.	Noted.

⁷ Prescribed agencies include GTTAC, State and Territory Governments, relevant local governments, Australian Government agencies and the Minister for the Environment.

Summary of issues raised	Comment
Considered the RARMP and has no comment.	Noted.
Satisfied with the conclusions of the RARMP.	Noted.
Council does not have access to specialist scientific advice and can only provide comment on the basis of the community views and Council resolutions. Council passed a resolution to be a GM free cropping zone, in alignment with nearby municipalities, noting that Council has no jurisdiction in this matter. Wants more details on the locations the GM canola will be planted so the local issues such as biodiversity and organic farms can be considered.	This is a commercial release application and therefore the GM canola is proposed to be grown anywhere in Australia that canola crops are grown. This means that the planting areas will be determined by individual farmers and will differ each year. Marketing and trade issues, including matters relating to segregation and coexistence of different farming systems, are the responsibility of the States and industry, not the Regulator. 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.
Unsure whether stakeholders such as farmers and consumers were consulted in the process of evaluating the application.	A wide range of experts, prescribed agencies and authorities, including the Gene Technology Technical Advisory Committee, other Australian Government regulators, the Minister for the Environment, State/Territory governments, local councils, and the general public were asked for their advice on the consultation RARMP. The public consultation process undertaken in relation to the RARMP exceeded the requirements of the Act and included media advertisements in national and regional newspapers, postings on the OGTR website and direct mail or email to interested parties who have registered on the OGTR mailing list.
Supports the OGTR assessment that the proposed dealing poses negligible risk of harm to human health and the environment.	Noted.
Because the new GM canola can tolerate higher rates of glyphosate and has a wider window for herbicide application than Roundup Ready canola, the two features may increase the rate of development of glyphosate resistant weeds. Acknowledged that this concern is outside of the OGTR's scope and it should be discussed with the APVMA.	
Supportive of the application as the consultation RARMP indicates that the proposed commercial release would pose negligible risks to human health or the environment. It is understood that a range of licence conditions would ensure there is ongoing oversight of the release. It is also noted that FSANZ has approved the food use of this GM canola.	Noted.
Council is in a highly urban area and does not see that the proposed release of herbicide resistant canola would have an impact on our area in the short term. Given that there are examples in other states where GM canola has become a roadside weed, we still urge caution for the widespread release of GM canola as it could pose a threat to our agricultural industry and natural bushland areas in the long term.	Discussion of roadside canola is presented in both the RARMP and the 2011 Biology of Canola document produced by the OGTR. Canola is not considered to be a significant weed in Australia, nor invasive of natural undisturbed environments. In Australia, the occurrence of roadside canola is thought to be dependent upon spillage during harvest and transport, and not to constitute self- sustaining populations. Herbicides other than glyphosate, or non- chemical means, can be used to control plants resistant to glyphosate.

Summary of issues raised	Comment
Agrees with the overall conclusions of the RARMP. Agrees that all plausible risk scenarios relating to human health and safety and the environment have been identified and that characterisation of the risk scenarios is adequate. Notes that herbicide resistance management issues are addressed through herbicide registration requirements of the APVMA.	Noted.

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

The Regulator received seventeen 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.

Abbreviations:

Issues raised: AH: Animal health; AP: Agricultural Performance; C: Coexistence; Co: Consultation; E: Environment; Ec: Economics; F: Food safety; FL: Food labelling; H: Human health; HR: Herbicide resistance; HT: Herbicide tolerance; HU: Herbicide use; M: Marketing; Mis: Miscellaneous;
S: Segregation; Sc: Scope of legislation; Res: Independent research; U: Uncertainty; UE: Unintended effects; W: Weediness

Other abbreviations: Act: The *Gene Technology Act 2000*; **APVMA**: Australian Pesticides and Veterinary Medicines Authority; **FSANZ**: Food Standards Australia New Zealand; **GM**: Genetically modified; **GMO**: Genetically modified organism; **RARMP**: Risk Assessment and Risk Management Plan. **Regulator**: The Gene Technology Regulator

Submission number	Issue	Summary of issues raised	Comment
1	C, S	GM canola should not be released until there is legislation and regulations that enable organic farming without the risk of contamination of GM plants.	Marketing and trade issues, including matters relating to segregation and coexistence of different farming systems, are the responsibility of the States, Territories and industry, not the Regulator. 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.
	H, E, HU	GMO crops are not safe and the use of Roundup Ready [®] herbicide is not good for the soil and only benefits the companies that supply it.	The RARMP concluded that the proposed release of the GM canola poses negligible risks to the health and safety of people and the environment. Issues relating to the safety and use of herbicides are assessed and managed by the APVMA. The commercial motives of biotechnology companies are outside the scope of responsibility of the Regulator.
2	M, C, S	Concerns with how pollen from a GM crop will be prevented from contaminating an organic crop (thus jeopardising the organic status of the latter), and how refineries will not mix GM and organic oils. Notes that under the Food Standard Code, the GM oil will be identified.	See comments for Submission 1 regarding segregation and coexistence of different farming systems. FSANZ is responsible for human food safety assessment and food labelling, including GM food. However, labelling of the oil from GM canola is not required, as the oil is highly refined and does not contain any novel ingredients, DNA or protein.

Submission number	Issue	Summary of issues raised	Comment
	H	Concerns that there is much information about GM products being unhealthy and causing cancer, and questioned if they have been tested on rodents prior to release into the market.	The RARMP for this release considered information provided by the applicant as well as currently available scientific information from Australian and international sources. Chapter 1 of the RARMP discusses potential toxicity including the studies conducted on the introduced protein and animal feedings studies. The RARMP concluded that risks to human health and the environment are negligible. FSANZ conducts safety assessments of GM foods and has approved food derived from the GM canola for human consumption.
3	H, E	Disagrees that there is 'no significant risk' when there is a large body of evidence that shows exactly that.	The RARMP prepared for this application concludes that the proposed commercial release of this GM canola poses negligible risks to the health and safety of people and the environment. This is based on information provided by the applicant, other relevant scientific information, both from Australia and elsewhere (as discussed in Chapter 1 and 2 of the RARMP), and issues raised in submissions.
	Mis	Doesn't want the Regulator to cave in to the 'megalomaniacs' from private companies who have interest only in profits.	The commercial motives of biotechnology companies are outside the scope of responsibility of the Regulator.
4	ΗU	Concerns that Monsanto is poisoning Australia's environment. The use of herbicides is linked to a range of birth defects.	Issues relating to herbicide use are outside the scope of the Regulator's assessments. The APVMA has regulatory responsibility for the registration of agricultural chemicals, including herbicides, in Australia. A range of issues, including effects on human health, resistance management and environmental impacts are considered by the APVMA in assessing agricultural chemicals for registration. The APVMA will not register a chemical product unless satisfied that its approved use is unlikely to be harmful to people or the environment.
5	H, E, U	Long term effects of the GM canola on the environment and human health are not documented or not adequately investigated.	The RARMP concluded that the commercial release of this GM canola poses negligible risks to the health and safety of people and the environment, both in the short term and long term. Its preparation included the use of information provided by the applicant, published scientific literature, and advice received from a range of Australian government authorities, agencies, experts and the public. Ongoing oversight of the release will occur and the licence holder is required by the licence to report any unintended effects or risks.
	HR, HU	Weed problems associated with resistance to 'Roundup' are evident in the USA and Canada. Chemical tolerant strains result in increased chemical use, which is undesirable for the environment and human health.	See comments for Submission 4 regarding issues relating to agricultural chemicals.

Submission number	Issue	Summary of issues raised	Comment
	Н	The problem of individuals or groups trying to avoid GM canola will cause mental stress to many. Others will give up the attempt, and this sense of loss of power and control in their lives and loss of a natural world power are detrimental to human well-being.	The RARMP concluded that the commercial release of this GM canola poses negligible risks to the health and safety of people. Herbicide tolerant GM canola has been commercially grown in Australia and overseas for many years without any report of adverse effects on human health. Consumer choice relates to segregation and labelling issues which is outside the scope of what the Regulator can consider.
6	-	Strongly against the proliferation of Round- up Ready canola in Australia. There is reason to introduce it into Australia as there is little to gain and a lot to lose.	Noted. The Regulator is required to assess the risks of GMOs and cannot consider the benefits of gene technology.
	Μ	Concerns about Monsanto establishing a monopoly in the release of food derived from canola. Monsanto is aggressive in the litigation process for its patented products.	Issues such as marketing, trade, and the commercial motives of biotechnology companies, are outside the scope of responsibility of the Regulator.
	W	GM canola seed can be spread by wind and the canola will be a super weed that will cause major problems in surrounding organic and conventional farms. Machinery could be contaminated if used by multiple growers.	The weediness potential of the GM canola in agricultural areas was assessed in Risk Scenario 3, Chapter 2 of the RARMP. The GM canola is considered to pose a negligible risk of weediness due to the use of integrated weed management practices.
	W	GM seed could fall during transportation and plants grow along roadways and hence spread easily.	Roadside canola is discussed in both the RARMP (Chapters 1 and 2) and the document "The Biology of <i>Brassica napus</i> (canola)", available from the OGTR web site. Canola is not considered to be a significant weed in Australia, nor invasive of natural undisturbed environments. In Australia, the occurrence of roadside canola is thought to be due to spillage during harvest and transport, and not to constitute self-sustaining populations. Herbicides other than glyphosate, or non-chemical means, can be used to control plants resistant to glyphosate.
	H, AH	Peer review study in Australia has revealed that GM products have devastating effects on stomach lining and intestinal tracts of pigs. GM feed should not be allowed for cattle. Before bringing GM canola into Australia, rigorous study of the long-term effects should be undertaken.	The RARMP concluded that the commercial release of this GM canola poses negligible risks (in the short and long term) to the health and safety of people and other animals, including livestock. Studies of the results of feeding GM Roundup Ready® tolerant canola to animals are discussed in the RARMP (Chapters 1 and 2). An analysis of the pig feeding study has been published by FSANZ (http://www.foodstandards.gov.au/consumer/gmfo od/Pages/Response-to-Dr-Carman%27s-study.aspx). The licence requires any unintended effects or risks to be reported to the Regulator.
	FL	The importation of processed foods that contain GM should be labelled as such.	Labelling of food, including GM foods, is the responsibility of FSANZ.
Submission number	Issue	Summary of issues raised	Comment
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7	Co, W, HU	Considers the consultations undertaken by the Regulator to be pointless and a waste of time if there is no intention to stand up to the giant biotech corporations which are poisoning the world with cross- contaminating unnatural organisms and more toxic herbicides.	The Regulator takes into consideration all submissions received during consultation that raise issues related to the health and safety of people and the environment. The potential for the GMOs to adversely impact on the environment is rigorously assessed in the RARMPs and the Regulator must not issue a licence if the risks cannot adequately be managed. Issues relating to the safety and use of herbicides are assessed and managed by the APVMA.
	Ec, AP	GM canola has been a disaster in Canada and the US by completely overwhelming traditional varieties in North America, producing lesser yields, and resulting in more expenses for the farmers.	Economic and agricultural performance issues, including the comparison of the yields of different varieties, are not the responsibility of the Regulator.
	W	GM canola has escaped into the countryside and onto roadsides, necessitating the use of nasty chemicals to eradicate it.	See comments for Submission 6 regarding roadside canola.
	H	Serious negative effects on animals fed with GM foods are being ignored, and so there could be long term effects on humans. There are too many risks and unknowns to allow this heinous experiment to occur in Australia.	The RARMP concluded that the commercial release of this GM canola poses negligible risks to the health and safety of people (and other animals) and the environment. Studies of the results of feeding GM Roundup Ready [®] canola tolerant canola to animals are discussed in Chapters 1 and 2 of the RARMP. FSANZ has published on their website, their response to studies cited as evidence of adverse effects from GM foods (http://www.foodstandards.gov.au/consumer/gmfoo d/adverse/Pages/default.aspx).
	Mis	Has no faith in OGTR as a regulator and feels the OGTR is a rubber stamp for giant biotech companies.	The Regulator is required to assess GMO applications in accordance with the Act, the object of which is to protect the health and safety of people and the environment. The RARMP informs the Regulator when making a decision whether or not to issue a licence. Each RARMP includes a thorough and 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 involving prescribed experts, Australian Government authorities and agencies, experts, State and Territory Governments, relevant Australian local councils, the Minister for the Environment and the public.

Submission number	lssue	Summary of issues raised	Comment
8	H, AH, HU	Claims that there are well documented and peer reviewed publications which indicate clearly that animals are harmed by ingestion of the canola and glyphosate. Includes two papers (each with a large numbers of references) and hopes that the OGTR has seen and evaluated all of these observations on human populations, rather than accepting only the claims of commercial interests. The two papers are: 1. Samsel A and Seneff S (2013). Interdiscip Toxicol 6(4):159-184 2. Samsel A and Seneff S (2013). Entropy (15): 1416-1463.	The two papers describe a possible role of glyphosate in the inhibition of cytochrome P450 enzymes, this in-turn being linked to toxicity and celiac disease. See comments for Submission 4 regarding issues relating to agricultural chemicals. FSANZ conducts safety assessments of GM foods and has approved for human consumption food derived from the GM canola. The APVMA is responsible for the assessment of agricultural chemicals.
	Μ	Claims the Australian grain export markets are threatened by the Chinese military ban on consumption of GM canola produce. Australia's clean green food markets should not be lost.	Issues of marketing and trade implications are outside the scope of the Regulator's assessment required by the Act. These issues are the responsibility of the States and industry.
	ΗU	Suggests that glyphosate, as a chelating agent, can lock up minerals and trace elements essential for the health of soil biota, plants and animals, leading to diseases in humans and animals.	See comments for Submission 4 regarding issues relating to agricultural chemicals.
	W	Canola is a major weed in California and will probably become a major weed in Western Australia, displacing roadside wildflowers.	In Australia, although canola can be a problem weed in cultivated areas, it is not considered a significant weed in non-cropped disturbed regions and natural environments. See comments for Submission 6 regarding the weediness of canola.
	Ш	Concerns that the GM canola will have adverse effects upon our environment, including birds, insects and bees.	Chapter 2 of the RARMP concluded that commercial release of the GM canola poses negligible risks to the health and safety of the environment, including animals.
9	ΗT	The possibility exists that the GM canola could breed with other herbicide tolerant canola and produce multiple herbicide tolerant progeny, as stated in the RARMP	Multiple herbicide tolerant plants, resulting from the hybridisation of Roundup Ready®, Clearfield®, and/or triazine tolerant plants are susceptible to other herbicides. In the absence of spraying with a herbicide for which these plants are tolerant, there is no reason to expect any hybrids to be more invasive or persistent than plants that have a single herbicide tolerance.

Submission number	lssue	Summary of issues raised	Comment
	UE	Believes that the RARMP is dismissive of unintended effects resulting from genetic modification.	Unintended effects can be induced from the transformation process. However, such effects also result from conventional breeding, which also involves the moving and insertion of genetic sequences. The accumulated experience of conventional breeding and genetic modification is that plants with unintended characteristics that are detrimental to human/animal health or the environmental are rarely generated. Evidence available for this GM canola does not indicate unintended effects that would be harmful. The licence requires any unintended effects to be reported to the Regulator.
	Res	Concerns that information such as the copy number of the transgene and the site of insertion is supplied by the applicant, not ascertained by research conducted by an independent body. Other assessments relevant to health are left to other government agencies such as FSANZ.	Copy number and the site of insertion of any transgene provide information about the makeup of the GMO, which is then used as part of the risk assessment. Each RARMP includes a thorough and critical assessment of data supplied by the applicant, together with a review of other relevant national and international scientific literature. FSANZ and APVMA are required by their respective legislation to assess specific aspects of this GM canola.
	H, HU, Res	Does not believe that the supposed absence of ill effects from currently commercially cultivated GM canola is relevant to the risk assessment of this GM variety, and further field trials are necessary. The assessment ignores the numerous scholarly articles about the effects of pesticides on microorganisms in water and soil - and MON 88302 canola farming requires a cocktail of chemicals. Wants to know what the short and long term effects are on soil fertility, groundwater, beneficial insects, and gene changes or unusual variable in crops or weeds.	The GM canola has been tested in field trials in Australia under the licence DIR 105 since 2011. Data obtained from the field trials has been used in the risk assessment. Roundup Ready® canola has been cultivated in Australia (DIR 020/2002) and elsewhere in the world without report of detrimental effects to human health or the environment. The GM canola of this application involves the same introduced gene (and hence protein), but different regulatory sequences. Hence, information from Roundup Ready canola is relevant to this assessment. In regards to herbicide use in farming systems, please refer to comments for Submission 4 about regulation of agricultural chemicals in Australia. Potential short and long term effects related to the GM canola were assessed in the RARMP using the extensive range of studies available, and the risks were considered negligible.
	Н	The risk assessment does not use a control study of people having either a non-GM or GM diet. Studies have suggested that GM foods can result in gastrointestinal disorders and allergies.	FSANZ conducts safety assessments of GM foods and has approved food derived from this GM canola for human consumption. The role of feeding studies is discussed in the FSANZ website (http://www.foodstandards.gov.au/consumer/gmfo od/Pages/roleofanimalfeedings3717.aspx).
10	HU	Objects to the use of concentrated glyphosate on canola and it going into food.	See comments for Submission 4 regarding issues relating to agricultural chemicals.

Submission number	Issue	Summary of issues raised	Comment
	H	Laboratory studies in France have proven that genetically engineered food attacks the human liver which then becomes enlarged and diseased. There is also a possibility that the foetus becomes deformed.	Chapters 1 and 2 of the RARMP discussed the potential for toxicity from the GM canola. The RARMP concluded that risks to human health and the environment are negligible. See response to Submission 7 regarding FSANZ's webpage of studies reporting adverse effects.
	FL	It is imperative that all foods that have GM be clearly labelled.	Labelling of food, including GM foods, is the responsibility of FSANZ. See response to Submission 2.
	M, C, S	Concerns that organic foods will become contaminated with GM produce and destroy export markets.	See comments for Submission 1 regarding segregation and coexistence of different farming systems.
11	Sc	States that it is not reasonable for comments about a GM crop specifically designed to tolerate and accumulate a herbicide to not involve any reference to the use of agricultural chemicals and food safety. Questions the scope of the evaluations conducted by the Regulator and recommends that this issue be referred to the Ethics Committee.	Australia's regulatory system for gene technology involves a number of agencies/authorities and where possible, duplication is avoided. OGTR, FSANZ and APVMA are required by their respective legislation to assess specific aspects of this GM canola.
	H, HU	Concerns that the GM canola will be able to accumulate higher concentrations of glyphosate, which will have adverse effects on the web of life. Reference to Dr Don Huber, Emeritus Professor at Purdue University, who has stated that glyphosate will change soil ecology, microbial ecology and intestinal microbiology. This herbicide has been described as a chelator, endocrine disruptor and antibiotic. Cites international cases that focus on the alleged adverse health effects of widespread use of glyphosate. States that tabled petitions have been tabled in both WA Houses of Parliament calling on a Royal Commission into the use of pesticides. There has been a failure of the APVMA and some state health departments to take the necessary action to prevent the risk of harm of the release of GM crops that involve the use of pesticides and herbicides.	Chapters 1 and 2 assessed the potential for toxicity of the GM canola, including the potential for metabolites. See comments for Submission 4 regarding issues relating to agricultural chemicals.
	M, S, C	Believes that the Act cannot and does not "protect the health and safety of people and the environment" by simply "managing those risks through regulating certain dealing with GMOs". The recent and ongoing Marsh versus Baxter legal case as well as other known cases of GMO trespass onto both private and public land are evidence of this failure.	The Act clearly states the responsibility of the Regulator to protect the health and safety of people and the environment. As the Marsh vs Baxter legal case relates to segregation and marketing issues, not health and safety issues, it is outside the scope of the Regulator's assessment required by the Act.

Submission number	Issue	Summary of issues raised	Comment
12	HU, H, E	Glyphosate has been associated with a range of detrimental effects to humans and the environment, as has consumption of GM plant material that has been modified for the expression of genes for tolerance to this herbicide. Human toxicology testing of glyphosate needs to take place before a 'negligible risk' can be concluded. There is negligence in the spraying of chemicals in our communities and there is currently a call for a Royal Commission into the use of pesticides and harm to public health.	Chapters 1 and 2 assessed the potential for toxicity of the GM canola, including the potential for metabolites. The RARMP concluded that the commercial release of this GM canola poses negligible risks to the health and safety of people and the environment. See comments for Submission 4 regarding issues relating to agricultural chemicals.
	HU	Residue levels of glyphosate have increased in foods in recent years, this being based on economics and not concern for health and safety.	FSANZ conducts safety assessments of GM foods, in its assessments taking into consideration any negative effects that could be associated with the food (such as the presence of herbicide residues) Both the APVMA and FSANZ are involved in setting maximum residue limits (MRLs) for agricultural and veterinary chemicals in food.
13	-	Asks the OGTR to reject the application as it would be a breach of the OGTR's duty of care that this GM canola poses negligible risk.	Noted
	FL	GM canola is being grown in WA, and the public is not aware where it is being grown and whether it is finding its way into the food chain. Current food labelling laws are inadequate. Few if any GM items on the supermarket shelf carry a GM label.	Labelling of food, including GM foods, is the responsibility of FSANZ. See response to Submission 2.
	H, HU	Claims that there have been no public health studies on the effects of GM canola that have already been released. However, feeding studies of GM maize with glyphosate tolerance and Roundup on rats have suggested that they have significant health concerns (Seralini et al).	The RARMP assessed information provided by the applicant, published scientific literature, and advice received from a range of Australian government authorities, agencies, experts and the public. The RARMP concluded that the commercial release of this GM canola poses negligible risks to the health and safety of people and the environment. See response in Submission 7 regarding FSANZ and feeding studies. See comments for Submission 4 regarding general issues relating to agricultural chemicals.
	W, S	GM canola spreads across the landscape and is persistent in the environment. As such, contamination events occur and negligible risk (to land, water, air, pollinators and non-GM products) cannot be concluded. GM canola weeds still occur in Tasmania even though it has been ten years since GM trials were stopped in that state. GM contamination events have occurred around the world, and therefore negligible risk cannot be concluded.	See comments for Submission 6 regarding the weediness of canola. The RARMP acknowledges that there will be some spread of seed and plants into the environment from this commercial release, but concludes that risks to people and the environment, from these transient populations of GM canola are negligible.

Submission number	Issue	Summary of issues raised	Comment
14	Mis	There is no such thing as a canola plant. Canola is a genetically engineered plant developed from the rapeseed plant.	Canola refers to varieties of <i>Brassica napus</i> that have been selected (via conventional breeding techniques) to have low levels of erucic acid and glucosinolates. The term rapeseed is usually taken to refer to those varieties of <i>B. napus</i> that have high levels of these compounds. Canola was not generated by GM technology.
	H	Both rapeseed and canola oil have health concerns. These include the production of erucic acid, oleic acid, and trans fatty acids, the depletion of vitamin E and lung cancers. The disease of 'scrapie' in cattle can be linked to rapeseed oil. There have been no long term studies done on GM canola oil, but there are reports on the internet that it has caused many kidney, liver, and neurological health issues.	Chapter 1 of the RARMP discusses the potential toxicity of non-GM canola, and more detail can be found in the document, The Biology of <i>Brassica napus</i> L. (canola) prepared by OGTR to assist with the assessment of GM canola. FSANZ conducts safety assessments of food, including GM foods, and has approved for human consumption food derived from the GM canola.
	E, HU	There is growing scientific evidence that GM crops are harmful to biodiversity and the environment. The herbicide Roundup Ready® has been shown to have serious impacts upon biodiversity, and be highly toxic to certain wildlife species, such as tadpoles and beneficial nitrogen-fixing bacteria. A UK study showed low number of weed species in GM canola fields leading to a reduction in butterfly numbers and a reduction in weed seeds available for birds.	See comments for Submission 4 regarding issues relating to agricultural chemicals. Unlike some areas in Europe, Australia's agricultural areas are not an important source of weeds that are required to support biodiversity.
15	H, E	Concerns that the OGTR is not willing to assess existing evidence of harm.	The RARMP concluded that the commercial release of this GM canola poses negligible risks to the health and safety of people and the environment. Its preparation included the use of information provided by the applicant, published scientific literature, and advice received from a range of Australian government authorities, agencies, experts and the public. Risk scenarios took into consideration potential harms to people and the environment.
	HU	The GM canola will lead to increased dispersal of glyphosate into the environment, increased concentrations of glyphosate residue in harvested crops, animal feed and plant derived products.	See comments for Submission 4 regarding issues relating to agricultural chemicals.
	Co	The scope of the OGTR risk assessment precludes the involvement of other government agencies, such as FSANZ, APVMA, and TGA <i>etc</i> .	Australia's gene technology regulatory system operates as part of an integrated legislative framework that avoids duplication and enhances coordinated decision making. Other Australian government agencies, such as FSANZ, APVMA, TGA, are also involved in regulating GMOs or GM products. These agencies are consulted when preparing risk assessments for all GM organisms proposed for environmental release, as required by the Act.

Submission number	Issue	Summary of issues raised	Comment
	F	The public is subject to the failings of FSANZ to assess the potential of GM food to cause harm to animal and human health.	In conducting its safety assessments of foods (GM and non-GM), FSANZ takes into consideration all available evidence before approving a product for human consumption.
	W,C, S	GM canola spreads across the landscape and is persistent in the environment (something that is evident from the Marsh versus Baxter legal case). GM canola weeds still occur in Tasmania even though it has been ten years since GM trials were stopped in that state. Refers to other incidence of GM contamination	See comments for Submissions 6 and 13 regarding the weediness of canola. The Marsh vs Baxter legal case and incidences with commercially approved GM crops relates to segregation and marketing issues, not health and safety issues, and as such is outside the scope of the Regulator's assessment required by the Act.
	HU	The use of glyphosate is associated with health concerns in humans and animals, and changes in farming practices may result in a build-up of toxic residues. GM plants also increase the uses of pesticides.	See comments for Submission 4 regarding issues relating to agricultural chemicals.
	UE	The GM transformation process can induce mutagenic effects that can result in unintended changes in composition, including new toxins or allergens.	See comments for Submission 9 regarding unintended effects from genetic modifications.
	Н	Animal feeding studies are often too short to show the signs of toxicity, and both industry and regulators frequently dismiss findings of toxicity in such studies.	See comments for Submissions 5 and 7 regarding long term effects of the GM canola on human health and animal feeding studies.
16	Т	There has not been adequate multigenerational safety clinical trials in animals and humans by the applicant or independent laboratories to demonstrate there are no risks to humans and/or animals.	See comments for Submissions 5 and 7 regarding long term effects of the GM canola on human health and animal feeding studies.
	S	The OGTR does not require buffer or exclusion zones and thus the environment is not protected from escape of GM plants. As such, neighbouring organic or conventional farms are at risk of contamination. Contamination could also occur from machinery and equipment used to harvest or transport the GM material.	The RARMP concluded that risks to human health and safety, and to the environment, from this commercial release of GM canola are negligible, and thus there was no necessity for buffer or exclusion zones, or other restrictions to minimise dispersal. Marketing and trade issues, including matters relating to segregation and coexistence of different farming systems, are the responsibility of the States, Territories and industry, not the Regulator.
	W	The ongoing oversight of the release is inadequate to prevent contamination of the environment with canola seed.	The RARMP acknowledges that there will be some spread of seed and plants into the environment from this commercial release, but concludes that risks to people and the environment, from these transient populations of GM canola are negligible.
	HU	There is inadequate attention paid to the level of residues of glyphosate in the crop and whether this is safe for consumption. New scientific studies are starting to link glyphosate with a range of illnesses and further research should be done before approving any increase in GM crops that require glyphosate.	See comments for Submission 4 regarding issues relating to agricultural chemicals.

Submission number	lssue	Summary of issues raised	Comment
17	Mis	The strategic plans of genetic modification reflect chemical industries that are determined to globalise their products and obtain market dominance.	The commercial motives of biotechnology companies are outside the scope of responsibility of the Regulator.
	W, E	Concern with weed problems and animal plagues in Australia and pathogens coming in via free trade.	The RARMP concluded that the risk posed by the GM canola as a weed was negligible. The inserted gene is unlikely to increase the ability of the plants to spread and persist, and the plants will still be susceptible to other herbicides. Issues of non-GM weeds, animal plagues and the importation into Australia of non-GM pathogens are the responsibility of federal government departments such as the Department of Agriculture and corresponding state departments.
	M, C, S	A 'green' farmer is now opposing in court his neighbour and former friend for sowing GM seeds and contaminating his crop.	The Marsh vs Baxter legal case relates to segregation and marketing issues, not health and safety issues, and as such is outside the scope of the Regulator's assessment required by the Act. Matters relating to segregation and coexistence of different farming systems are the responsibility of the States, Territories and industry. 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.
	HU	Does not want more glyphosate approved in our landscape.	See comments for Submission 4 regarding issues relating to agricultural chemicals.
	FL	Food labelling laws are far from satisfactory in Australia.	Labelling of food, including GM foods, is the responsibility of FSANZ.