Australian Government
Department of Health
Office of the Gene Technology Regulator

November 2018

Risk Assessment and Risk Management Plan
for

DIR 164

Limited and controlled release of canola genetically modified for herbicide tolerance

Applicant – Monsanto Australia Proprietary Limited

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Summary of the Risk Assessment and Risk Management Plan
for
Licence Application No. DIR 164

Decision

The Gene Technology Regulator (the Regulator) has decided to issue a licence for this application for the intentional 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 the 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 concluded that the field trial poses negligible risks to human health and safety and the environment and that any risks posed by the dealings can be managed by imposing conditions on the release.

The application

Application number	DIR 164
Applicant	Monsanto Australia Pty Ltd (Monsanto)
Project title	Limited and controlled release of canola genetically modified for herbicide tolerance
Parent organism	Canola (*Brassica napus* L.)
Introduced genes and modified traits	• *dmo* gene from the bacterium *Stenotrophomonas maltophilia* (dicamba herbicide tolerance) • *cp4 epsps* gene from *Agrobacterium* sp. strain CP4 (glyphosate herbicide tolerance)
Proposed location	Up to 15 sites per year for the first two years and 20 sites for the third and fourth years, to be selected from 140 possible local government areas in New South Wales (NSW), Queensland (QLD), South Australia (SA), Victoria (VIC) and Western Australia (WA)
Proposed release size	Maximum area of 30 hectares (ha) in 2020 and 2021 (maximum area of 2 ha per site), 50 ha in 2022 (maximum area of 5 ha per site) and 100 ha in 2023 (maximum area of 20 ha per site)
Proposed release dates	January 2020 – January 2024
Primary purpose	To assess agronomic performance of the GM canola in all canola growing areas of Australia

Risk assessment

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

The risk assessment process considers how the genetic modification and proposed activities conducted with the GMOs 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 current scientific/technical knowledge, information in the application (including proposed limits and controls) and relevant previous approvals. Both the short and long term impacts are considered.

Pathways to potential harm that were considered included exposure of people or animals to the GM plant material, potential for persistence or dispersal of the GMOs, and transfer of the introduced genetic material to other non-GM canola, commercially approved GM canola plants or related species. Potential harms associated with these pathways included toxicity or allergenicity to people, toxicity to desirable animals, and environmental harms due to increased weediness.

The principal reasons for the conclusion of negligible risks are that the GM plant material will not be used for human food or animal feed, and the proposed limits and controls effectively control the GMOs and their genetic material and minimise exposure.

Risk management plan

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

As the level of risk is considered negligible, specific risk treatment is not required. However, since this is a limited and controlled release, the licence includes limits on the size, location and duration of the release, as well as controls to prohibit the use of GM plant material in human food or animal feed, to minimise dispersal of the GMOs or GM pollen from the trial site, to transport the GMOs in accordance with the Regulator's guidelines, to destroy GMOs not required for testing or further planting, and to conduct post-harvest monitoring at each trial site to ensure the GMOs are destroyed.

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Abbreviations

APVMA	Australian Pesticides and Veterinary Medicines Authority
CCI	Confidential Commercial Information under section 185 of the *Gene Technology Act 2000*
CFIA	Canadian Food Inspection Agency
DIR	Dealings involving Intentional Release
dmo	Dicamba monooxygenase gene from *Stenotrophomonas maltophilia*
DMO	Dicamba monooxygenase
EFSA	European Food Safety Authority
FSANZ	Food Standards Australia New Zealand
EPSPS	5-enolpyruvylshikimate-3-phosphate synthase
GM(O)	Genetically modified (organism)
ha	Hectare
HGT	Horizontal gene transfer
km	Kilometre(s)
LGA	Local government area
m	Metre(s)
NSW	New South Wales
OGTR	Office of the Gene Technology Regulator
PC2	Physical containment level 2
QLD	Queensland
RARMP	Risk Assessment and Risk Management Plan
Regulations	Gene Technology Regulations 2001
Regulator	Gene Technology Regulator
the Act	The *Gene Technology Act 2000*
USDA-APHIS	United States Department of Agriculture - Animal and Plant Health Inspection Service
VIC	Victoria

Chapter 1 Risk assessment context

Section 1 Background

1. An application has been made under the *Gene Technology Act 2000* (the Act) for Dealings involving the Intentional Release (DIR) of genetically modified organisms (GMOs) into the Australian environment.

2. The Act in conjunction with the Gene Technology Regulations 2001 (the Regulations), an inter-governmental agreement and corresponding legislation in States and Territories, comprise Australia's national regulatory system for gene technology. Its objective is to protect the health and safety of people, and to protect the environment, by identifying risks posed by or as a result of gene technology, and by managing those risks through regulating certain dealings with GMOs.

3. This chapter describes the parameters within which risks to the health and safety of people or the environment posed by the proposed release are assessed. The risk assessment context is established within the regulatory framework and considers application-specific parameters (Figure 1).

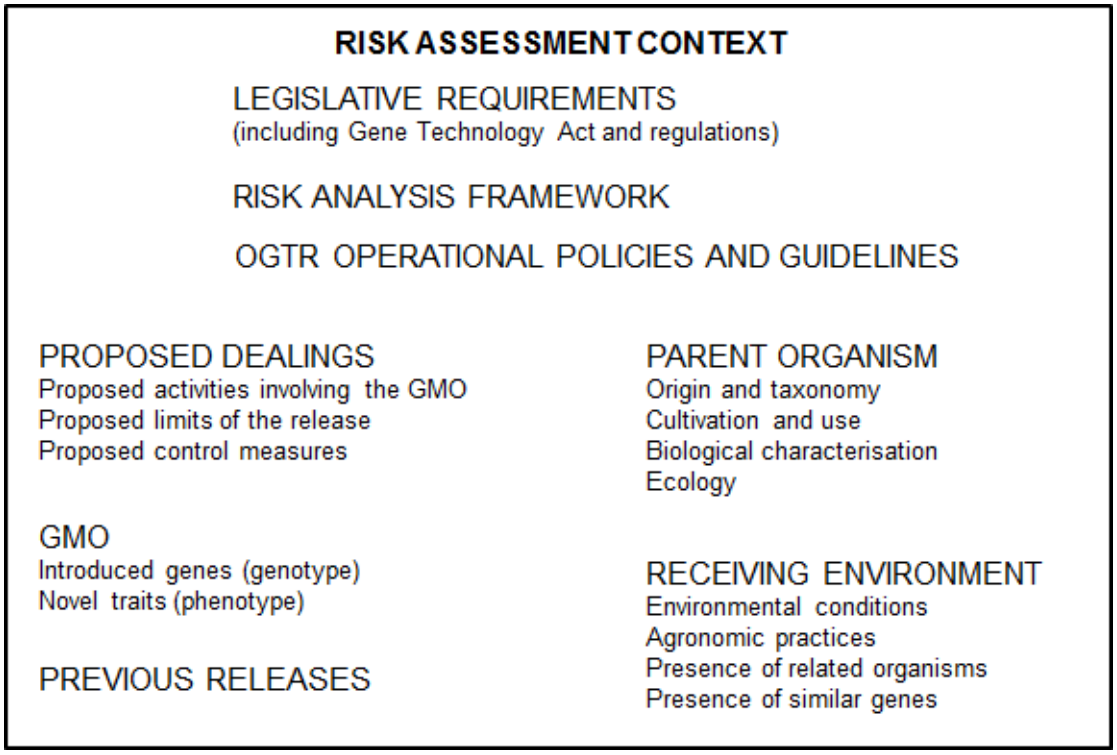

Figure 1 Summary of parameters used to establish the risk assessment context

Section 2 Regulatory framework

4. Sections 50, 50A and 51 of the Act outline the matters which the Gene Technology Regulator (the Regulator) must take into account, and who must be consulted, when 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. In accordance with section 50A of the Act, this application is considered to be a limited and controlled release application, as the Regulator was satisfied that: its principal purpose is to enable the applicant to conduct experiments and the applicant has proposed appropriate limits on the size, location and duration of the release, as well as controls to restrict the spread and persistence of the

GMOs and their genetic material in the environment. Therefore, the Regulator was not required to consult with prescribed experts, agencies and authorities before preparation of the RARMP.

6. Section 52 of the Act requires the Regulator to seek comment on the RARMP from the States and Territories, the Gene Technology Technical Advisory Committee, Commonwealth authorities or agencies prescribed in the Regulations, the Minister for the Environment, relevant local council(s), and the public. The advice from the prescribed experts, agencies and authorities and how it was taken into account is summarised in Appendix A. Nine public submissions were received and they are summarised and addressed in Appendix B.

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), the Australian Pesticides and Veterinary Medicines Authority, the Therapeutic Goods Administration and the Department of Agriculture and Water Resources. These dealings may also be subject to the operation of State legislation declaring areas to be GM, GM free, or both, for marketing purposes.

Section 3 The proposed dealings

9. Monsanto Australia Pty Ltd (Monsanto) proposes to release genetically modified (GM) canola into the environment under limited and controlled conditions. The purpose of the release is to assess agronomic performance of the GM canola in all canola growing areas of Australia.

10. The dealings involved in the proposed intentional release are:

- conducting experiments with the GMOs
- breeding the GMOs
- propagating the GMOs
- growing the GMOs
- importing the GMOs
- transporting the GMOs
- disposing of the GMOs

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

3.1 The proposed limits of the dealings (duration, size, location and people)

11. The applicant proposes to conduct the trials in canola growing areas of Australia from January 2020 to January 2024. The proposal is to plant up to 15 sites with a maximum combined area of 30 ha per year in 2020 and 2021, and up to 20 sites with a maximum area of 50 ha and 100 ha in 2022 and 2023, respectively. The maximum planting sizes of individual trial sites are proposed to be 2 ha in 2020 and 2021, 5 ha in 2022 and 20 ha in 2023. The sites would be selected from 140 local government areas (LGAs) in NSW, QLD, SA, VIC and WA (Table 1). The selection of sites would depend on a number of factors, including: the availability of water and land during a growing season; adequate site distribution across Australian canola growing areas; the ability to ensure isolation and containment; and the ability to segregate from commercial canola crops. Details of site locations would be provided to the Regulator prior to each planting season.

Table 1 Proposed local government areas in which GM canola may be released

New South Wales	Victoria	South Australia	Queensland	Western Australia
Berrigan	Ararat	Grant	Goondiwindi	Albany
Bland	Ballarat	Kingston	Lockyer Valley	Beverley
Blaney	Benalla	Mt Gambier	Toowoomba	Boddington
Boorowa	Buloke	Naracoorte	Somerset	Boyup Brook
Cabonne	Bendigo	Robe	Southern Downs	Bridgetown-Greenbushes
Conargo	Central Goldfields	Tatiara	Western Downs	Brookton
Coolamon	Glenelg	Wattle Range		Broomehill
Coonamble	Golden Plains			Carnamah
Cootamundra	Greater Geelong			Coorow
Corowa	Greater Shepparton			Corrigin
Cowra	Hepburn			Cranbrook
Deniliquin	Hindmarsh			Cuballing
Dubbo	Horsham			Cunderdin
Forbes	Indigo			Dalwallinu
Gilgandra	Loddon			Denmark
Greater Hume	Macedon Ranges			Donnybrook-Balingup
Griffith	Mitchell			Dowerin
Gunnedah	Moorabool			Dumbleyung
Gundagai	Mount Alexander			Esperance
Gwydir	Moyne			Gnowangerup
Harden	Northern Grampians			Goomalling
Jerilderie	Pyrenees			Greenough
Junee	Southern Grampians			Jerramungup
Leeton	Wangaratta			Katanning
Liverpool Plains	West Wimmera			Kent
Lockhart	Wodonga			Kojonup
Mid-Western	Wyndham			Majnimup
Moree Plains	Yarriambiack			Mingenew
Murry				Moora
Muswellbrook				Morowa
Narrabri				Mullewa
Narrandera				Narrogin
Narromine				Nannup
Orange				Northam
Parkes				Perenjori
Tamworth				Pingelly
Temora				Plantagenet
Upper Hunter				Quairading
Urana				Ravensthorpe
Wagga Wagga				Tambellup
Wakool				Tammin
Walgett				Three Springs
Warrumbungle				Toodyay
Weddin				Victoria Plains

New South Wales	Victoria	South Australia	Queensland	Western Australia
Wellington				Wagin
Young				Wandering
				West Arthur
				Wickepin
				Williams
				Wongan-Ballidu
				Woodanilling
				Wyalkatchem
				York

12. Only trained and authorised staff would be permitted to deal with the GM canola.

13. GM plant materials or products would not be used in human food or animal feed.

3.2 The proposed controls to restrict the spread and persistence of the GMOs in the environment

14. The applicant has proposed a number of control measures to restrict the spread and persistence of the GMOs and their introduced genetic material, each of which were considered in the evaluation of this application. These include:

- locating the proposed trial sites at least 50 m away from the nearest natural waterway
- restricting gene flow by controlling related species around the trial sites and adopting one of the following combination of controls (Figure 2):
    a. surrounding the Planting Area with a 50 m Monitoring Zone and maintaining an Isolation Zone of at least 1 km to other canola crops; or
    b. surrounding the Planting Area with a 15 m Pollen trap of non-GM canola and a 50 m Monitoring Zone and maintaining a 400 m Isolation Zone to other canola crops
- ensuring that the 50 m Monitoring Zone is kept free of related species
- restricting access to the trial sites to authorised persons, or visitors accompanied by an authorised person
- treating all non-GM plants used in the trial as if they were the GM canola proposed for release
- cleaning equipment prior to use for other purpose
- cleaning the trial sites and other adjacent areas on which viable material may be present (such as clean down areas) following harvest
- transporting and storing GM plant material in accordance with the current Regulator's *Guidelines for the Transport, Storage and Disposal of GMOs*
- destroying all plant material from the trial not required for further evaluation or future trials
- post-harvest monitoring of the trial site at least once every 35 days for at least 24 months and until the site is free of volunteer plants for 12 months, and destroying any volunteer canola plants before flowering
- not allowing the GM plant materials or products to be used for human food or animal feed.

15. Figure 2 shows the proposed site layout, including some of the controls. These controls, and the limits outlined above, have been taken into account in establishing the risk assessment context (this Chapter), and their suitability for containing the proposed release is reviewed in Chapter 3, Section 3.1).

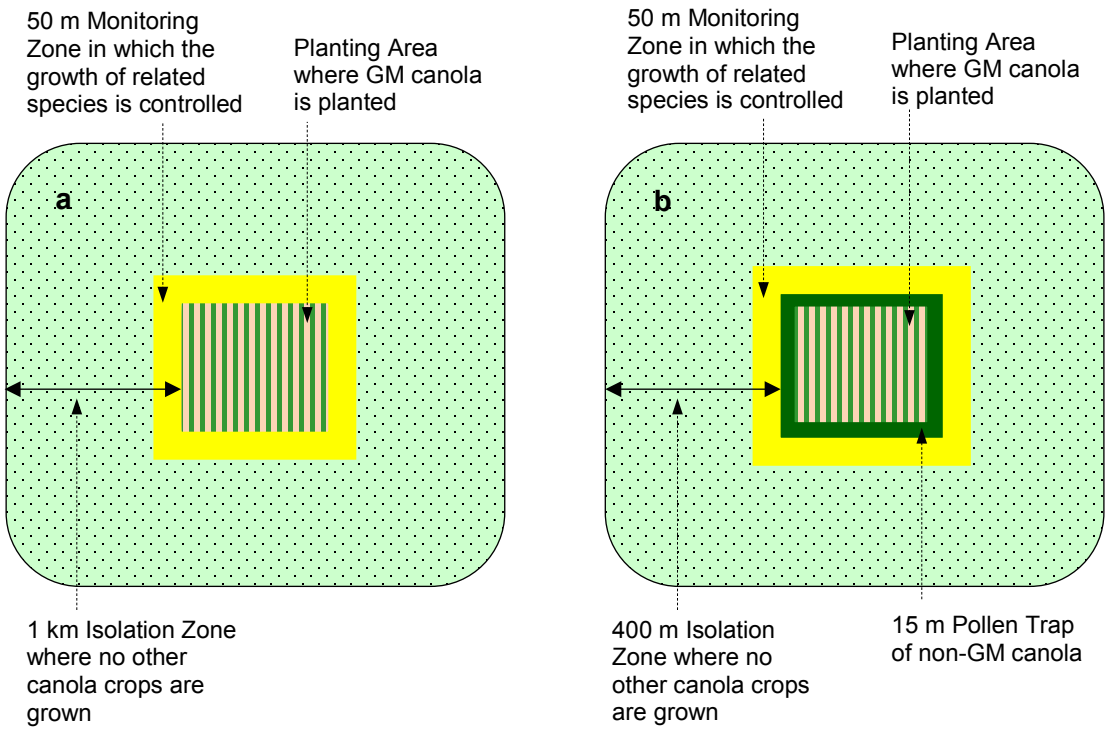

Figure 2 Proposed trial layout, including some of the controls (not to scale)

Section 4 The parent organism

16. 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, NSW, VIC and South Australia. It is Australia's third largest broad acre crop (ABARES, 2018). Canola is primarily grown for its seed oil, which is used as cooking oil and for other food and industrial applications. The seed meal which remains after oil extraction is used as animal feed (OECD, 2011). Information on the use of the parent organism in agriculture is summarised in Section 6 (the receiving environment).

17. The Standards Australia *National Post-Border Weed Risk Management Protocol* rates the weed risk potential of plants according to properties that correlate with weediness for each relevant land use (Standards Australia et al., 2006). These properties relate to the plants' potential to cause harm (impact), to its invasiveness (spread and persistence) and to its potential distribution (scale). For canola, its actual rather than potential distribution is addressed. The weed risk potential of volunteer canola has been assessed using methodology based on the *National Post-Border Weed Risk Management Protocol* (see Appendix 1, OGTR, 2017).

18. More detailed information regarding the parent organism can be found in the document *The Biology of Brassica napus L. (canola) and Brassica juncea (L.) Czern. & Coss. (Indian mustard)* (OGTR, 2017), which was produced to inform the risk analysis process for licence applications involving GM canola plants and is available from the OGTR Biology Documents page. The proposed dealings with the GM canola are evaluated against non-GM canola and commercially approved GM canola as baselines.

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

5.1 Introduction to the GMOs

19. The applicant proposes to release two types of canola genetically modified for herbicide tolerance. The first type is one line of dicamba-tolerant canola. The unique identifying code for this

canola line has been declared Confidential Commercial Information (CCI); under section 185 of the Act, the confidential information is made available to the prescribed experts and agencies that are consulted on the RARMP for this application. For the remainder of the document, this line will be referred to as DT canola line. The second type is GM canola produced by conventional crossing between the DT canola line and MON88302 canola, a GM canola (also known as TruFlex™ Roundup Ready® canola) that was previously approved for commercial release under DIR 127. The resulting dual herbicide tolerant GM canola will have tolerance to dicamba and glyphosate herbicides and will be referred to as DT×MON88302 canola line.

20. In addition to genes responsible for herbicide tolerance, the GM canola lines also contain short regulatory elements used to control gene expression. These sequences are derived from plants, soil bacteria and plant viruses. Details of some introduced regulatory elements have been declared CCI.

21. The DT canola line and the parental MON88302 canola were produced using *Agrobacterium*–mediated transformation. This method has been widely used in Australia and overseas for introducing genes into plants. More information can be found in the document *Methods of Plant Genetic Modification* on the OGTR website (OGTR, 2018b).

5.2 The genetic modifications in the GMOs proposed for release

5.2.1 DT canola line

22. The DT canola line contains a *dmo* gene derived from the strain DI-6 of the gram negative bacterium *Stenotrophomonas maltophilia* (formerly known as *Pseudomonas maltophilia*) (Herman et al., 2005). The *dmo* gene encodes a dicamba mono-oxygenase (DMO) and confers tolerance to dicamba herbicide (2- methoxy-3,6-dichlorobenzoic acid). Dicamba is a Group I herbicide, similar in structure and mode of action to phenoxy herbicides such as 2,4-D, that mimics plant auxin hormones and causes abnormal plant growth by affecting cell division (Cox, 1994; CropLife Australia, 2015). DMO can rapidly demethylate 2- methoxy-3,6-dichlorobenzoic acid to non-herbicidal 3,6-dichlorosalicylic acid (DCSA) and formaldehyde. The *dmo* gene in the DT canola line is the same as that used in the GM cotton MON88701 approved for commercial release in Australia under licence DIR 145.

5.2.2 DT×MON88302 canola line

23. The DT×MON88302 canola line will be produced by conventional crossing between the DT canola line and MON88302 canola. This stacked line will contain both the introduced *dmo* gene for dicamba tolerance and the *cp4 epsps* gene from *Agrobacterium* sp. strain CP4 for glyphosate tolerance. Details of the *cp4 epsps* gene have been extensively discussed in the RARMP for DIR 127 (OGTR, 2014).

5.2.3 Regulatory elements

24. Promoters are DNA sequences that are required in order to allow RNA polymerase to bind and initiate correct transcription. Also required for gene expression in plants are mRNA terminators, including a poly-adenylation signal. Other regulatory sequences may also be present, such as enhancers that influence the expression pattern of a given gene, leader sequences (5' untranslated regions) and transit peptide coding sequences that may contribute to protein translation and localisation of a given gene.

25. The introduced regulatory elements in the DT canola line include promoters, terminators, leader sequences and transit peptide coding sequences derived from plants and plant viruses. Details of these regulatory elements have been declared CCI. The confidential information is made available to the prescribed experts and agencies that are consulted on the RARMP for this application. Details of the regulatory sequences used in the parental MON88302 canola can be found in the RARMP for DIR 127 (OGTR, 2014).

5.3 Toxicity/allergenicity of the proteins encoded by the introduced genes

5.3.1 DMO protein

26. The *dmo* gene and encoded DMO protein have previously been assessed in the RARMP for GM cotton field trial application DIR 120 (OGTR, 2013b) and the RARMP for GM cotton commercial release application DIR 145 (OGTR, 2016b). The assessments for DIR 120 and DIR 145 concluded that the introduced DMO protein in GM cotton lacked toxicity to humans or animals, or allergenicity in humans based on the following considerations:

- The *dmo* gene was derived from the aerobic, environmentally ubiquitous gram negative bacterium *S. maltophilia*, to which people and animals are exposed naturally through their diet and the environment;
- the DMO protein does not have relevant amino acid sequences similar to known allergens, toxins or other proteins that may have adverse effects on mammals; and
- the DMO protein is rapidly digested in simulated gastric and intestinal fluids, and did not show any observable adverse effects in mouse acute oral toxicity analyses.

27. FSANZ has assessed GM soybean (MON87708), GM cotton (MON88701) and GM corn (MON87419) containing the *dmo* gene and concluded that food derived from these crop varieties were as safe for human consumption as food derived from their conventional (non-GM) counterparts (FSANZ, 2012, 2013a, 2016). Further, the DMO protein in these three GM crop varieties has also been assessed by USDA-APHIS (USDA-APHIS, 2014, 2016) and the DMO protein in MON87708 soybean was assessed by EFSA (EFSA, 2013), and no potential public health and safety concerns were identified.

28. DMOs expressed in MON87708 soybean, MON88701 cotton and MON87419 corn exhibit 91.6% to 97.1% amino acid sequence identity to wild type DMO from *S. maltophilia* due to different transformation vectors used, which contain different chloroplast targeting peptide sequences. However, safety studies on these protein variants support the conclusion that the various forms of DMO proteins introduced into DT soybean, cotton and maize are safe for food and feed consumption, and the small amino acid sequence differences outside the active site of DMO do not raise any additional safety concerns (Wang et al., 2016). Although no such information is available on the DMO expressed in the DT canola line, it is expected to be very similar to these DT crops.

29. Canola seeds naturally contain erucic acid and glucosinolates, which are toxins. DMO, which is an oxygenase, is not expected to be involved in the synthesis of these natural plant toxins or alter their metabolic pathways to increase the levels of toxicity or allergenicity of their metabolites.

5.3.2 CP4 EPSPS protein

30. The *cp4 epsps* gene has been used extensively in GM plants as a selectable marker or a source of field tolerance to the glyphosate herbicide. Consequently, the toxicity and allergenicity of the CP4 EPSPS protein to people, or toxicity to other organisms, have been previously reviewed by the Regulator and other overseas regulatory agencies on numerous occasions. In particular, the gene and its encoded protein were assessed in the RARMP for the commercial release of MON88302 under DIR 127 (OGTR, 2014). On the basis of the evidence reviewed there, it was considered that CP4 EPSPS lacks toxicity to humans or animals, or allergenicity to humans. A more recent review (ILSI, 2016) and a search of the current literature revealed no new information to indicate otherwise.

5.3.3 Herbicide metabolites

31. The potential toxicity of herbicide metabolites is considered by the APVMA as part of its process for registration of herbicides.

32. As discussed in Section 5.2.1, the metabolites produced in the DT canola line in the presence of dicamba would be DCSA and formaldehyde. The potential for these metabolites to cause harm was assessed in the RARMP for DIR 120 (OGTR, 2013b), a GM cotton containing the DMO protein, and no safety concerns were identified.

33. There is no expected difference in the metabolic fate of glyphosate in non-GM canola and in GM canola expressing the *cp4 epsps* gene (FAO, 2011). As discussed in the RARMP for DIR 127 (OGTR, 2014), no new metabolic products are formed in GM canola containing the CP4 EPSPS protein in the presence of glyphosate herbicide.

5.4 Characterisation of the GMOs

34. For the DT canola line, the plasmid vector[1] used for transformation contains two separate T-DNAs with one T-DNA harbouring the DMO expression cassette and the other T-DNA harbouring a selectable marker[2] expression cassette. The transformed cells were initially selected using the selectable marker. Conventional breeding and segregation selection, along with a combination of analytical techniques (such as quantitative polymerase chain reaction) were used to eliminate any plants containing the selectable marker gene T-DNA. The applicant has confirmed that the DT canola line proposed for release contains only a single T-DNA with the *dmo* gene.

35. The introduced genes are not expected to confer phenotypic changes other than tolerance to targeted herbicide(s). The applicant stated that observations of GM canola plants grown in PC2 glasshouses did not indicate an unexpected phenotype. Further phenotypic and agronomic data would be collected during the proposed field trials.

36. Detailed information regarding the characterisation of the parental MON88302 canola can be found in the RARMP for DIR 127 (OGTR, 2014).

Section 6 The receiving environment

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

38. Information relevant to the growth and distribution of canola in Australia is discussed in the document *The Biology of Brassica napus L. (canola) and Brassica juncea (L.) Czern. & Coss. (Indian mustard)* (OGTR, 2017).

6.1 Relevant abiotic factors

39. The proposed release would be carried out across a range of geographic and climatic conditions across Australia. The geographical distribution of commercial canola cultivation in Australia is limited by a number of abiotic factors, the most important being water availability. Germination of seed will only occur if there is sufficient soil moisture, and drought stress after anthesis can significantly reduce yield. Canola is also relatively sensitive to waterlogging which restricts root development (Walton et al., 1999; GRDC, 2009, 2017). Other abiotic stresses that can reduce canola yields include frost, particularly during early pod development, and heat stress (GRDC, 2009).

6.2 Relevant biotic factors

40. A number of diseases have the potential to significantly reduce the yield of canola. The fungal pathogen *Leptosphaeria maculans* causes blackleg, the most common and damaging disease affecting canola in Australia. Other serious diseases that affect canola production in Australia include stem rot caused by the fungus *Sclerotinia sclerotiorum* and damping-off caused mainly by the fungus *Rhizoctonia solani* (Howlett et al., 1999; GRDC, 2009). These diseases are further discussed in the document *The Biology of Brassica napus L. (canola) and Brassica juncea (L.) Czern. & Coss. (Indian mustard)* (OGTR, 2017).

[1, 2] The identity and details of the vector and the identity of the selectable marker gene have been declared CCI.

41. 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 from flowering to podding (Miles and McDonald, 1999; GRDC, 2009).

42. Canola is highly susceptible to weed competition during the early stages of growth. The most problematic weeds include grassy weeds, such as annual ryegrass, vulpia and wild oats, volunteer cereals, and weeds from the *Brassicaceae* family. These were recently discussed in more detail in the RARMP for DIR 155 (OGTR, 2018a).

6.3 Relevant agricultural practices

43. Agronomic and crop management practices for the cultivation of the GM canola by the applicant would be the same as for commercial canola crops and would not differ from industry best practice used in Australia, except that the applicant proposes controls to minimise the dispersal and persistence of the GM canola (see Section 3). Standard cultivation and crop management practices for canola are discussed in more detail in the documents *The Biology of Brassica napus L. (canola) and Brassica juncea (L.) Czern. & Coss. (Indian mustard)* (OGTR, 2017) and *Canola best practice management guide for south-eastern Australia* (GRDC, 2009).

44. During the trial, GM canola seed may be planted and harvested in a variety of ways. Seed would be hand-planted or planted with a small plot seeder for small areas, or planted with commercial equipment for larger areas. Harvesting of seed will occur either by hand (for small plantings) or with commercial equipment. Due to multiple herbicide tolerance, some GM plants will be treated differently with respect to herbicide applications for weed management within the crop.

6.4 Presence of related plants in the receiving environment

45. *Brassica napus* is predominantly self-pollinated. However, cross-pollination can occur through physical contact with neighbouring plants, and be mediated by wind and insects. Outcrossing rates vary but average around 30% (Hüsken and Dietz-Pfeilstetter, 2007). The majority of small-scale release trials of GM canola revealed a dramatic decline in outcrossing rates when the distance from the GM source increased (Funk et al., 2006). Outcrossing frequencies between adjacent fields are highest in the first 10 m of the recipient fields (Hüsken and Dietz-Pfeilstetter, 2007; OGTR, 2017) with observations of most of the pollen dispersed within a 4.5 m area around the GM pollen source (Cai et al., 2008). However, low dispersal rates of GM canola pollen (less than 0.015%) were detected up to 2 km from the source (Cai et al., 2008). Under Australian conditions, a large scale study found that outcrossing rates between neighbouring commercial canola fields were less than 0.1% averaged over whole fields, and gene flow between plants at 30 metre separation was reported to be 0.03% (Rieger et al., 2002).

46. Canola is widely grown as an oil seed crop in Australia, and the proposed trial sites are located in commercial canola growing regions. Commercial canola in these areas includes non-GM canola and GM canola authorised for commercial release. Most of the Australian canola crops are herbicide tolerant, having one of three different herbicide tolerance traits. In 2015, the Australia canola crop comprised approximately 60% non-GM triazine tolerant (TT), 15% non-GM imidazolinone tolerant (Clearfield®), 20% GM Roundup Ready® and 5% non-herbicide tolerant canola varieties (OGTR, 2017). The Clearfield® trait is also present in Juncea canola (*Brassica juncea* or Indian mustard) (DPI NSW, 2013). Recently, another GM canola (Optimum™ GLY canola) with a glyphosate tolerance gene different from that in Roundup Ready® canola, and a GM canola (DHA canola) with modified omega-3 oil content have also been approved for commercial production in Australia. Details of all GM canola varieties approved by the Regulator for commercial release in Australia are available from the OGTR website.

47. *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 species that include: other *B. napus* groups or subspecies (including vegetables such as swedes, rutabaga and kale), *B. juncea*, *B. rapa* (wild turnip; includes vegetables such as turnip, chinese cabbage and pak choi) and *B. oleracea* (wild cabbage; includes vegetables such as cauliflower, Brussels sprouts and cabbage) (Salisbury, 2002). However, hybrids between *B. napus* and *B. oleracea* have been shown to be difficult to obtain (Ford et al. 2006).

48. Under open pollination conditions, naturally occurring hybrids between *B. napus* and the related weedy species *Raphanus raphanistrum* (wild radish), *Hirschfeldia incana* (Buchan weed) and *Sinapis arvensis* (charlock) have been reported at very low frequencies (Darmency et al., 1998; Darmency and Fleury, 2000; Salisbury, 2002), and are generally sterile or predominantly sterile (Salisbury, 2002).

6.5 Presence of similar genetic elements and proteins in the environment

49. The introduced *dmo* gene is derived from the environmentally ubiquitous bacterium *S. maltophilia*. *S. maltophilia* is an aerobic, gram negative bacterium commonly present in aquatic environments and soil. It is also found in close association with plants (Ryan et al., 2009). The *cp4 epsps* gene is derived from the common soil bacterium *Agrobacterium* sp. strain CP4, which can also be found on plants and fresh plant produce. Therefore, these genes and their encoded proteins are widespread in the Australian environment.

50. As discussed in Section 5.2.3, the introduced regulatory elements in the DT canola line are derived from plant viruses and common plants. The introduced regulatory elements in the parental MON88302 canola are individually derived from Figwort mosaic virus, thale cress *(Arabidopsis thaliana)* and pea (*Pisum sativum*) (OGTR, 2014).

51. All the source organisms for the introduced genetic elements are widespread and prevalent in the Australian environment and thus humans and other organisms would commonly encounter their genes, encoded proteins and regulatory sequences.

Section 7 Relevant Australian and international approvals

7.1 Australian approvals

Approvals by the Regulator

52. There has been no previous release of the DT canola line in Australia. As such, no GM canola lines generated from the cross between this GM canola line and other GM canola have been approved for release.

53. Commercial release of the parental MON88302 canola included in this application was approved by the Regulator in November 2014 under licence DIR 127. However, to date MON88302 canola has not been grown on a commercial scale in Australia.

Approvals by other government agencies

54. The Regulator is responsible for assessing and managing 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.

55. FSANZ is responsible for human food safety assessment and food labelling, including GM food. FSANZ has assessed and approved the safety of food derived from the parental MON88302 canola. FSANZ has determined that food derived from MON88302 canola is as safe for human consumption as food derived from conventional (non-GM) canola (FSANZ, 2013b). The applicant does not intend to use materials from the GM canola generated in the proposed release in human food.

56. The APVMA has regulatory responsibility for agricultural chemicals, including herbicides, in Australia. The applicant intends to apply herbicides, including herbicides currently unregistered in

Australia, to the GM canola during the field trial. This will require the applicant to obtain a permit from APVMA before carrying out the trial.

57. GM canola seed will be imported into Australia from North, South and Central America at various times throughout the period of the field trial. The applicant will need to obtain import permits for these importations from the Department of Agriculture and Water Resources.

7.2 International approvals

58. The applicant obtained approval from CFIA in 2018 to conduct research trials of the DT canola line in Canada. The applicant has also submitted an application in 2018 to USDA-APHIS for confined field trials of the DT canola line in the United States of America.

Chapter 2 Risk assessment

Section 1 Introduction

59. 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 3).

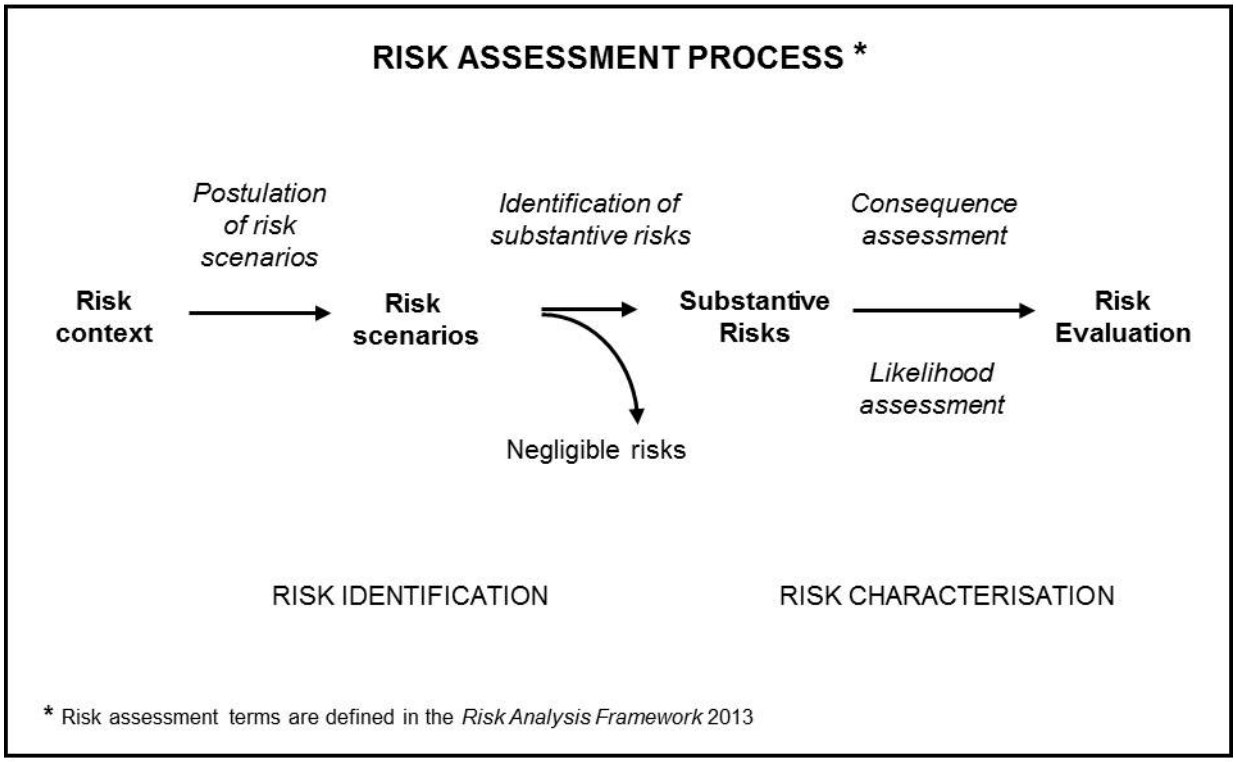

Figure 3 The risk assessment process

60. 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 or long term.

61. Postulated risk scenarios are screened to identify those that are considered to have some reasonable chance of causing harm. Pathways that do not lead to harm, or could not plausibly occur, do not advance in the risk assessment process.

62. 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 used to postulate risk scenarios (Keese et al., 2014). Risk scenarios postulated in previous RARMPs prepared for licence applications of the same or similar GMOs are also considered.

63. Substantive risks (i.e. those identified for further assessment) are characterised in terms of the potential seriousness of harm (Consequence assessment) and the likelihood of harm (Likelihood assessment). The level of risk is then estimated from a combination of the Consequence and Likelihood assessments. The level of risk, together with analysis of interactions between potential risks, is used to evaluate these risks to determine if risk treatment measures are required.

Section 2 Risk identification

64. Postulated risk scenarios are comprised of three components (Figure 4):

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).

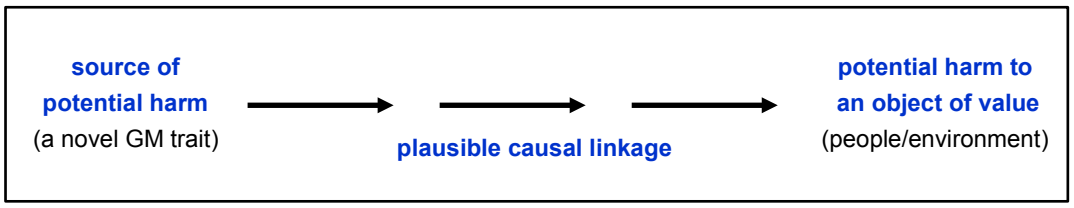

Figure 4 Components of a risk scenario.

65. 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 and
- the characteristics of the parent organism(s).

2.1 Risk source

66. The sources 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.

2.1.1 The introduced genetic elements

67. The DT canola line has been modified by the introduction of one gene for tolerance to the herbicide dicamba. The introduced *dmo* gene and its encoded protein will be considered further as potential source of risk.

68. The DT × MON88302 line will combine the *cp4 epsps* gene with the *dmo* gene. The *cp4 epsps* gene has been assessed individually in the RARMP for DIR 127 (Chapter 1, Section 5.3.2) and in combination with another herbicide tolerance gene (*bar,* giving tolerance to glufosinate herbicides) in the RARMP for DIR 138 (OGTR, 2016a), a commercial release of glyphosate tolerant GM canola in Australia. The gene was assessed as posing negligible risk to human or animal health or to the environment by the Regulator. A search of the literature (Chapter 1, Section 5.3.3) has not revealed any new information which impacts on this conclusion. Therefore, *cp4 epsps* alone will not be considered further as potential source of risk.

69. The introduced *dmo* gene is controlled by regulatory sequences. These regulatory sequences are derived from common plants and plant viruses (Chapter 1, Section 5.2.3). Regulatory sequences are naturally present in plants, and the introduced elements are expected to operate in similar ways to endogenous elements. Although plant viruses are plant pathogens, regulatory sequences are not expressed as proteins and dietary DNA has no toxicity (Society of Toxicology, 2003). Regulatory sequences have no pathogenic, toxic or carcinogenic properties, and cannot of themselves cause disease. Hence, risks from the use of the introduced regulatory elements themselves will not be considered further for this application.

2.1.2 Unintended effects

70. The genetic modification has the potential to cause unintended effects in several ways including altered expression of endogenous genes by random insertion of introduced DNA in the genome, increased metabolic burden due to expression of the introduced protein, novel traits arising out of interactions with non-target proteins and secondary effects arising from altered substrate or product levels in biochemical pathways. However, these types of effects also occur spontaneously and in plants generated by conventional breeding. Accepted conventional breeding techniques such as hybridisation, mutagenesis and somaclonal variation can have a much larger impact on the plant genome than genetic engineering (Schnell et al., 2015). Plants generated by conventional breeding have a long history of use, with few documented cases where conventional breeding has resulted in an unacceptable level of a metabolite in a crop (Berkley et al., 1986; Seligman et al., 1987), and no documented reports of conventional breeding leading to the production of a novel toxin or allergen (Steiner et al., 2013). Current practices identify and remove harmful non-GM plants to protect domesticated animals and people (Steiner et al., 2013). Therefore, unintended effects resulting from the process of genetic modification will not be considered further.

2.2 Causal pathway

71. 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), gene product(s) and end products
- potential exposure to the introduced gene(s), gene product(s) and end products from other sources in the environment
- the environment at the site(s) of release
- agronomic management practices for the GMOs
- spread and persistence of the GMOs, (e.g. reproductive characteristics, dispersal pathways and establishment potential)
- tolerance to abiotic conditions (e.g. climate, soil and rainfall patterns)
- tolerance to biotic stressors (e.g. pest, pathogens and weeds)
- tolerance to cultivation management practices
- gene transfer to sexually compatible organisms
- gene transfer by horizontal gene transfer (HGT) and
- unauthorised activities.

72. Although all of these factors are taken into account, some are not included in risk scenarios because they are either regulated by other agencies or have been considered in previous RARMPs.

73. The potential for horizontal gene transfer (HGT) and any possible adverse outcomes has been reviewed in the literature (Keese, 2008) and assessed in previous RARMPs. HGT was most recently considered in the RARMP for DIR 108 (OGTR, 2011). HGT events rarely occur and the wild-type gene sequences are already present in the environment and available for transfer via demonstrated natural mechanisms. Therefore, risks from HGT will not be assessed further.

74. Previous RARMPs have considered the potential for unauthorised activities to lead to an adverse outcome. The Act provides substantial penalties for unauthorised dealings with GMOs or non-compliance with licence conditions, and also requires the Regulator to have regard to the suitability of an applicant to hold a licence prior to the issuing of the licence. These legislative provisions are considered sufficient to minimise risks from unauthorised activities. Therefore, risks from unauthorised activities will not be considered further.

2.3 Potential harm

75. 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 or yield of desirable plants
- reduced products or services from the land use
- restricted movement of people, animals, vehicles, machinery and/or water
- reduced quality of the biotic environment (e.g. providing food or shelter for pests or pathogens) or abiotic environment (e.g. negative effects on fire regimes, nutrient levels, soil salinity, soil stability or soil water table).

76. These harms are based on those used to assess risk from weeds (Standards Australia et al., 2006; Keese et al., 2014). Judgements of what is considered harm depend on the management objectives of the land where the GM plant may be present. A plant species may have different weed risk potential in different land uses such as dryland cropping or nature conservation.

2.4 Postulated risk scenarios

77. Three risk scenarios were postulated and screened to identify substantive risk. These scenarios are summarised in Table 2, and discussed individually below. In the context of the activities proposed by the applicant and considering both the short and long term, none of the three risk scenarios gave rise to a substantive risk.

Table 2 Summary of risk scenarios from the proposed dealings with GM canola

Risk scenario	Risk source	Causal pathway	Potential harm	Substantive risk?	Reason
1	GM canola expressing the introduced *dmo* gene or the *dmo* and *cp4 epsps* genes	Cultivation of GM canola at trial sites ⬇ Expression of the introduced genes in GM plants ⬇ Exposure of people and other desirable organisms to the introduced proteins	Increased toxicity or allergenicity for humans or increased toxicity to other desirable organisms	No	• The proteins encoded by the introduced genes occur naturally in the environment and are not known to be toxic or allergenic to people or toxic to other organisms. • The GM canola would not be used in human food or animal feed. • The limited scale, and other proposed limits and controls minimise exposure of people and other organisms to the GM plants.
2	GM canola expressing the introduced *dmo* gene or the *dmo* and *cp4 epsps* genes	Cultivation of GM canola at trial sites ⬇ Dispersal of GM seed outside trial limits ⬇ Establishment of populations of volunteer GM plants expressing the introduced genes in the environment	Increased toxicity or allergenicity for humans or increased toxicity to other desirable organisms OR Reduced establishment or yield of	No	• The genetic modification is expected to increase the fitness of GM canola plants in managed environments, but only when the corresponding herbicide is being applied. • The genetic modification is not expected to alter the response of the GM canola to biotic and abiotic stresses that

Risk scenario	Risk source	Causal pathway	Potential harm	Substantive risk?	Reason
			desirable plants		naturally limit the geographical distribution of non-GM canola. • The limited scale and other proposed controls minimise the spread and persistence of the GM canola seeds outside the trial limits. • Risk scenario 1 did not identify toxicity or allergenicity of the GMOs as a substantive risk.
3	GM canola expressing the introduced *dmo* gene or the *dmo* and *cp4 epsps* genes	Cultivation of GM canola at trial sites ⬇ GM canola pollen flow outside the trial sites ⬇ Outcrossing with other sexually compatible plants, including other herbicide tolerant non-GM and GM canola ⬇ Establishment of populations of hybrid GM plants expressing the introduced genes in the environment	Increased toxicity or allergenicity for humans or increased toxicity to other desirable organisms OR Reduced establishment or yield of desirable plants	No	• The proposed limits and controls would minimise pollen flow to sexually compatible plants outside the trial sites. • Multiple-herbicide tolerant individuals are as susceptible to alternative herbicides as single-herbicide tolerant canola plants or their non-GM counterparts. • Risk scenarios 1 and 2 did not identify toxicity, allergenicity or weediness of the GMOs as substantive risks. Hybrids with sexually compatible plants are unlikely to differ.

Risk scenario 1

Risk source	GM canola expressing the introduced *dmo* gene or the *dmo* and *cp4 epsps* genes
Causal pathway	⬇ Cultivation of GM canola at trial sites ⬇ Expression of the introduced genes in GM plants ⬇ Exposure of people and other desirable organisms to the introduced proteins ⬇
Potential harm	Increased toxicity or allergenicity for humans or increased toxicity to other desirable organisms

Risk source

78. The source of potential harm for this risk scenario is GM canola expressing the introduced *dmo* gene or the *dmo* and *cp4 epsps* genes for herbicide tolerance.

Causal pathway

79. GM canola expressing introduced *dmo* gene or the *dmo* and *cp4 epsps* genes would be cultivated at trial sites. The DMO protein may be expressed in various tissues at all developmental stages. People and other desirable organisms could be exposed to the GM plant material.

80. Workers would be exposed to the GM plant material while cultivating, harvesting, transporting, experimenting or conducting other dealings with GM canola. As the applicant proposes that only authorised personnel can deal with the GM canola, other people are not expected to be exposed to the GM plants or plant material. Potential pathways of exposure to the introduced protein are ingestion, inhalation or dermal contact. There is little potential for exposure of the public to GM plant material as no GM plant material would be used for human food as part of this field trial. There is a small likelihood of GM canola pollen occurring in honey from nearby hives, but proposed isolation measures to limit gene flow through pollen movement will minimise this. Furthermore, commercial procedures used for honey processing (e.g. sieving and filtering) will reduce the presence of GM canola pollen in honey (reviewed in RARMP for DIR 123, (OGTR, 2013c)).

81. Non-human organisms may be exposed directly to the introduced protein through ingesting the GM plants, or exposed indirectly through the food chain, or exposed through contact with dead plant material. Livestock would not be expected to ingest the introduced protein as the GM plant material is not to be used as animal feed. In the event that a site is in close proximity to grazing animals, the applicant has proposed to fence the site to restrict their access.

82. Other desirable organisms that could also be exposed to the DMO protein and resultant metabolites include wild animals and birds, which could enter trial sites and feed on GM canola seed or other plant parts, and pollinators such as honeybees, which would be exposed to nectar and pollen from the GM canola. Soil organisms such as earthworms would contact root exudates or decomposing plant material after harvest.

83. At the end of the trial, the applicant proposes to destroy GM canola not required for further research purposes. The proposed limits and controls would restrict the potential for exposure of the desirable organisms to the GM canola.

Potential harm

84. Toxicity is the adverse effect(s) of exposure to a dose of a substance as a result of direct cellular or tissue injury, or through the inhibition of normal physiological processes (Felsot, 2000). Allergenicity is defined as the potential of a substance to cause an immunological reaction following its ingestion, dermal contact or inhalation, which may lead to tissue inflammation and organ dysfunction (Arts et al., 2006).

85. Potentially, people exposed to the DMO protein expressed in the GM canola plants or plant material may show increased toxic or allergic reactions compared to those exposed to non-GM canola or commercially approved GM canola. Similarly, other desirable organisms exposed to the GM plants or plant material may show an increased toxic reaction.

86. While no toxicity or allergenicity studies have been performed on the plant material of the DT canola line, the DMO protein is well characterised. As detailed in (Chapter 1, Section 5.3), the DMO protein has been assessed by FSANZ in GM soybean, cotton and corn: based on all available information, the protein is not known to be toxic or allergenic and does not share relevant sequence homology with known toxins or allergens, nor is it involved in biochemical pathways that produce toxic or allergenic products.

87. For the stacked line, the DMO and CP4 EPSPS proteins that confer tolerance to dicamba and glyphosate, respectively, operate through independent, unrelated biochemical mechanisms. The possibility that synergistic effects may increase the toxicity or allergenicity of these two proteins in combination has been assessed for GM cotton in the RARMP for DIR 120 (OGTR, 2013b) and no new or increased risks relating to human health and safety or the environment were identified. Similarly, comparison of the levels of the DMO and CP4 EPSPS proteins expressed in stacked GM soybean MON87708 × MON89788 and the corresponding single events did not reveal an interaction at protein level, and no interactions between the events for the biological functions of the two proteins were identified from the molecular characterisation (EFSA, 2015). Therefore, this is expected to be the same for the DT×MON88302 canola line with the same stacked traits.

Conclusion

88. Risk scenario 1 is not identified as a substantive risk due to the lack of toxicity or allergenicity of the introduced *dmo* gene and encoded DMO protein or the stacked genes to humans and other desirable organisms. Also, the GM plant material would not be used as human food and animal feed, and other proposed limits and controls would restrict exposure of people and animals to the GM plant material. Therefore, this risk could not be greater than negligible and does not warrant further detailed assessment.

Risk scenario 2

Risk source	GM canola expressing the introduced *dmo* gene or the *dmo* and *cp4 epsps* genes
Causal pathway	⬇ Cultivation of GM canola at trial sites ⬇ Dispersal of GM seed outside trial limits ⬇ Establishment of populations of volunteer GM plants expressing the introduced genes in the environment ⬇
Potential harm	Increased toxicity or allergenicity for humans or increased toxicity to other desirable organisms OR Reduced establishment or yield of desirable plants

Risk source

89. The source of potential harm for this postulated risk scenario is GM canola expressing the introduced *dmo* gene or the *dmo* and *cp4 epsps* genes for herbicide tolerance.

Causal pathway

90. GM canola expressing the introduced *dmo* gene or the *dmo* and *cp4 epsps* genes would be cultivated at the trial sites and GM canola seeds could be dispersed outside the trial limits. If GM canola seeds were dispersed outside the trial sites or persisted at a site after completion of the trial, the seed could germinate. These plants could spread and persist and become established in the environment. People and other desirable organisms could then be exposed to the introduced gene and the encoded protein outside trial limits.

Dispersal outside the trial site

91. Dispersal of viable GM canola seed outside the trial site could occur in a variety of ways, including movement of seeds by human activity, animal activity and endozoochory (dispersal through ingestion by animals), or spread of residual harvest seeds by high winds or flooding. During the period between harvest and cleaning, residual seed on the soil surface would be susceptible to dispersal by animal predation and water runoff after rainfall.

Potential dispersal by human activity

92. As discussed in the RARMP for DIR 123, human activity is considered the most significant method of long-distance seed dispersal for canola outside the trial limits (OGTR 2013b). It is possible for volunteer canola populations to establish due to seed spillage along the transport route and during the use of agricultural equipment (OGTR, 2017). To reduce dispersal of GM plant material by humans, the applicant has proposed that trial site access will be only granted to trained and authorised personnel. Dispersal of GM plant material by authorised people entering the proposed trial site would be minimised by cleaning all equipment used, including clothing. All GM plant material would be transported in accordance with the Regulator's transport guidelines to reduce the opportunity for its dispersal.

Potential dispersal by animal activity or endozoochory

93. Canola seeds are not sticky, and lack burrs and hooks that can contribute to seed dispersal by attaching to animal fur or feathers (Howe & Smallwood 1982). These characteristics are not expected to be altered in the GMOs.

94. As discussed in the RARMP for DIR 123 (OGTR 2013b), animals such as kangaroos, feral pigs, emus or other birds may occasionally eat canola. Dispersal of viable canola seed into intensive use areas or nature reserves by endozoochory (consumption and excretion of seed) by wild mammals or birds is possible at very low levels (Twigg et al., 2008; Twigg et al., 2009). The information on viability of canola seed after passing through the digestive gut of animals is limited, but some studies suggest that the number of viable seeds after digestion is very low (Stanton et al., 2003; Wiedemann et al., 2009). A study of several species of native doves, ducks and finches fed on canola found that only wood ducks (*Chenonetta jubata*) excreted intact seed, representing less than 0.01% of the seed ingested (Twigg et al., 2008). From those seeds, the germination potential was reduced to less than 50%. These results indicate that less than 0.005% viable canola is likely to be spread by the species studied.

Potential dispersal by flooding or high winds

95. Canola seeds also lack specialised structures that would assist their dispersal by wind. However, canola may be windrowed prior to harvesting, and under strong wind conditions plant material could disperse beyond trial boundaries. Establishment of monitoring zones around trial sites, which are inspected during and after trials, and post-harvest cleaning of all areas onto which GM canola seeds may have been dispersed would manage potential for dispersal of GM canola seeds.

96. It is also possible that heavy rains or flooding could transport GM canola seeds away from trial sites (OGTR, 2017). Canola seedlings are sensitive to waterlogged soil, but if the flooding does not occur over an extended time period, the GM canola could survive. However, canola needs continued irrigation or rainfall to persist. The applicant has proposed to locate the trial sites at least 50 m from permanent natural waterways to minimise the potential for seed dispersal during flooding.

97. Non-GM canola is a poor competitor and feral populations rely on recurrent spillages to persist (Yoshimura et al., 2006). It is also not a significant weed, and it is not likely to become invasive (Busi and Powles, 2016). The expression of the introduced *dmo* gene or the *dmo* and *cp4 epsps* genes in combination are not expected to increase canola survival under natural conditions in the environment, including conditions such as drought stress or reduced nutrient availability. Canola growth and yield depends on water availability and canola has a higher requirement for nitrogen, phosphorus and sulphur than cereals and other crops (OGTR, 2017). It is proposed to trial the GM canola across a range of geographical locations, but in the event that GM canola plants were present outside the trial limits, their ability to spread and persist would be restricted by the same biotic and abiotic stresses that naturally limit the geographical distribution of non-GM canola plants (Chapter 1 Sections 6.1 and 6.2).

Persistence at the trial sites

98. Persistence of GMOs at the trial sites after the field experiment is finished could occur if seeds in the seed bank were dormant. Canola generally does not exhibit primary dormancy, but secondary dormancy has been described (OGTR, 2017). A study carried out in western Canada revealed that secondary seed dormancy prolonged persistence of volunteer canola plants (Gulden et al., 2003). Persisting canola seed banks have been shown to significantly contribute to the dynamics of feral canola populations (Pivard et al., 2008). A long-term monitoring study in Germany detected GM canola volunteers in arable fields for up to fifteen years after the field trial concluded, but did not detect spatial dispersion (Belter, 2016). In Australia, volunteers can be found for up to 3 years after growing canola due to persistence in seed banks, though the majority of volunteer seedlings emerge the year following a canola crop (AOF, 2014).

99. The applicant proposes a number of control measures to manage persistence of the GM canola post-harvest, including: destroying all plant materials not required for further analysis or future

planting, cultivating planting areas after harvest to encourage decomposition or germination of remaining seed and post-harvest monitoring of each trial site for at least 24 months and destruction of volunteers. It is not expected that the genetic modification for herbicide tolerance would increase the ability of the GM canola to survive these standard control measures.

Potential harm

100. If the GM seeds germinated and gave rise to volunteers expressing the introduced gene, these could spread and establish in the environment. If GM volunteers spread and establish in the environment, there could be adverse environmental impacts on native or other desirable vegetation due to weediness of the GM volunteers or due to increased populations of canola pests. People and other desirable organisms exposed to the introduced gene(s) and protein(s) may show increased toxic or allergic reactions compared to those exposed to non-GM canola.

101. As discussed in Risk scenario 1, the introduced DMO protein or combination of DMO and CP4 EPSPS proteins in the GM canola lines are not expected to have increased toxicity or allergenicity for humans or increased toxicity to other desirable organisms.

102. Volunteer GM canola could spread and persist as a weed in nature reserves, displacing native vegetation. However, even if a spillage occurs, GM canola in Australia has low likelihood to become invasive, and volunteers can be effectively controlled by current weed management practices, including a mixture of herbicide modes of action (Busi and Powles, 2016).

103. The GM canola lines proposed for release contain the *dmo* gene which confers tolerance to dicamba herbicide. Expression of this gene will confer a selective advantage over non-GM counterparts in environments in which dicamba herbicide is applied, such as agricultural settings and along roadsides. However, the GM canola plants could be managed by the application of alternative herbicides or by the use of other agricultural practices such as cultivation. MON88701 cotton containing the same *dmo* gene has been assessed by the OGTR in the RARMPs for DIR 120 (OGTR, 2013b) and DIR 145 (OGTR, 2016b), and no increased weediness from the introduced *dmo* gene was identified. USDA-APHIS has also assessed MON88701 cotton, together with MON87708 soybean containing the same *dmo* gene, and concluded that they are unlikely to pose plant pest risks comparing with their non-GM counterparts (USDA-APHIS, 2014). The GM canola lines expressing the *dmo* gene or the *dmo* and *cp4 epsps* genes are expected to behave similarly. Therefore, establishment of the GM canola outside the trial limits would not be expected to lead to greater reduction in the establishment or yield of desirable plants compared to non-GM canola.

Conclusion

104. Risk scenario 2 is not identified as a substantive risk due to the limited ability of canola to spread and persist outside cultivation, and that the genetic modification is not expected to change this, and the proposed limits and controls designed to restrict dispersal of the GM canola. Therefore, this risk could not be greater than negligible and does not warrant further detailed assessment.

Risk scenario 3

Risk source	GM canola expressing the introduced *dmo* gene or the *dmo* and *cp4 epsps* genes
Causal pathway	⬇ Cultivation of GM canola at trial sites ⬇ GM canola pollen flow outside the trial site ⬇ Outcrossing with other sexually compatible plants, including other herbicide tolerant non-GM and GM canola ⬇ Establishment of populations of hybrid GM plants expressing the introduced genes in the environment ⬇

Potential harm	Increased toxicity or allergenicity for humans or increased toxicity to other desirable organisms OR Reduced establishment or yield of desirable plants

Risk source

105. The source of potential harm for this postulated risk scenario is GM canola expressing the introduced *dmo* gene or the *dmo* and *cp4 epsps* genes for herbicide tolerance.

Causal pathway

106. GM canola expressing the *dmo* gene or the *dmo* and *cp4 epsps* genes would be cultivated at the trial sites. Pollen from the GM canola could be transferred outside the trial sites and fertilise sexually compatible plants, either non-GM canola, GM canola authorised for commercial release or plants from another sexually compatible species. Hybrid plants carrying the introduced *dmo* gene or the *dmo* and *cp4 epsps* genes could form the basis for the spread of the gene in other canola or other sexually compatible species and persist and become established in the environment. People and other desirable organisms could be exposed to the introduced gene and protein outside trial limits.

107. It should be noted that vertical gene flow *per se* is not considered an adverse outcome, but may be a link in a chain of events that may lead to an adverse outcome.

108. Although canola is predominantly self-pollinating, up to 30% of seeds can result from cross-pollination (OGTR, 2017). Thus, gene flow via pollen is possible if pollen from the GM plants proposed for release fertilise other canola or sexually compatible plants or crops. Pollen can be transported by physical contact, wind or insect pollinators. Outcrossing occurs at low levels and decreases rapidly with distance, with the majority of cross-pollination occurring in less than 10 m (OGTR, 2017). It is not expected that the introduced *dmo* gene or the *dmo* and *cp4 epsps* genes for herbicide tolerance would alter the pollen dispersal characteristics of the GM canola.

109. As stated in Chapter 1, Section 6.4, if there is synchronicity of flowering, canola can hybridise under natural conditions with sexually compatible species, including commercial plantings of other GM and non-GM canola (OGTR, 2017). The GM canola lines proposed for release could cross with commercially approved GM canola varieties that also carry introduced herbicide tolerance genes. These include Roundup Ready® (containing the same *cp4 epsps* gene under the control of a different promoter and a *gox* gene for glyphosate tolerance), Optimum™ GLY (containing a *gat4621* gene for glyphosate tolerance) and InVigor® (containing a *bar* gene for glufosinate tolerance). The GM canola lines proposed for release could also cross with commercial non-GM herbicide tolerant canola such as the TT or Clearfield® varieties. Although InVigor® canola has only been grown in a small scale for research purposes, the stacking of genes for tolerance to up to five different herbicide groups is a possibility.

110. Hybrids between *B. napus* and *B. juncea* have been observed in the field, are fertile, and often have high fitness (Liu et al., 2010). Cross-pollination between *B. napus* and *B. rapa* has been found in agricultural land and along roads in Canada, confirming the possibility of hybridisation between these two Brassica species under natural conditions (Yoshimura et al., 2006; Warwick et al., 2007), and the hybrids are vigorous and fertile, although with reduced pollen viability (Warwick et al., 2003). Hybrids between *B. napus* and *B. oleracea* have also been detected in wild populations (Ford et al., 2006). However, the frequency of hybridisation between GM canola and other Brassica species is expected to occur at low or very low levels.

111. The applicant has proposed control measures to restrict the potential for pollen flow and gene transfer to sexually compatible plants (Chapter 1, Section 3.2) as well as the persistence of hybrids. These include options of surrounding each trial site with a 50 m monitoring zone, with or without a pollen trap of non-GM canola, in combination with an isolation zone within which canola crops will not be grown. These measures will further reduce the likelihood of hybridisation occurring between the GM canola and compatible species. Control measures such as treating pollen trap plants as if they were the GMO would reduce the likelihood of any hybrids persisting.

Potential harm

112. In the event of gene transfer to a sexually compatible plant, it is possible that expression of the introduced *dmo* gene or the *dmo* and *cp4 epsps* genes could lead to toxicity or allergenicity in people or toxicity in desirable organisms, or reduced establishment or yield of desirable plants through increased spread and persistence of GM hybrids.

113. However, as discussed in Risk scenario 1, the introduced DMO protein or combination of DMO and CP4 EPSPS proteins in the GM canola lines are not expected to have increased toxicity or allergenicity for humans or increased toxicity to other desirable organisms. The same considerations as discussed in Risk Scenario 1 would apply if the introduced DMO protein or combination of DMO and CP4 EPSPS proteins expressed in hybrids with non-GM or commercially released GM canola.

114. If the GM canola lines proposed for release cross with commercial GM or non-GM canola varieties with different herbicide tolerance genes, it could theoretically result in accumulation or 'stacking' of genes for tolerance to up to five different herbicide groups within the same plant. This would have implications for herbicide choices for the control of canola volunteers. However, this is likely to occur at only extremely low frequency, since several hybridisation events would be necessary to create canola with multiple stacked traits. Also, multiple-herbicide tolerant individuals are as susceptible to alternative herbicides as single-herbicide tolerant canola plants or their non-GM counterparts (Senior et al., 2002; Beckie et al., 2004; Dietz-Pfeilstetter and Zwerger, 2009). Under greenhouse conditions, multiple-herbicide tolerant canola plants were no more competitive than single-herbicide tolerant controls (Simard et al., 2005). Therefore, if multiple-herbicide tolerant canola plants were to occur, they are unlikely to be more invasive or persistent than non-herbicide tolerant canola plants and could be controlled by other herbicides, such as those in groups B, I, G, L and Q (AOF, 2014), or other agricultural practices.

115. The potential for the GM canola to reduce establishment or yield of desirable plants was discussed in Risk Scenario 2. Canola plants, including hybrids, expressing the introduced DMO protein are unlikely to spread and persist in nature reserves or to survive standard weed management practices for canola volunteers in agricultural settings.

Conclusion

116. Risk scenario 3 is not identified as a substantive risk due to the proposed limits and controls designed to restrict pollen flow as well as the limited capacity of canola to outcross. GM hybrids are not likely to differ from the GM canola, for which Risk scenarios 1 did not identify toxicity, allergenicity or weediness as substantive risks. Therefore, this risk could not be greater than negligible and does not warrant further detailed assessment.

Section 3 Uncertainty

117. Uncertainty is an intrinsic property of risk analysis and is present in all aspects of risk analysis[2].

118. There are several types of uncertainty in risk analysis (Clark and Brinkley, 2001; Hayes, 2004; Bammer and Smithson, 2008). 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:

[2] A more detailed discussion of uncertainty is contained in the Regulator's *Risk Analysis Framework* available from the OGTR website or via Free call 1800 181 030.

- 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.

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

120. As field trials of GMOs are designed to gather data, there are generally data gaps when assessing the risks of a field trial application. However, field trial applications are required to be limited and controlled. Even if there is uncertainty about the characteristics of a GMO, limits and controls restrict exposure to the GMO, and thus decrease the likelihood of harm.

121. For DIR 164, uncertainty is noted particularly in relation to potential for increased weediness of the GM canola lines.

122. Additional data, including information to address these uncertainties, may be required to assess possible future applications with reduced limits and controls, such as a larger scale trial or the commercial release of these GMOs.

123. Chapter 3, Section 4, discusses information that may be required for future release.

Section 4 Risk evaluation

124. 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.

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

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

126. Three risk scenarios were postulated whereby the proposed dealings might give rise to harm to people or the environment. In the context of the limits and controls proposed by the applicant, and considering both the short and long term, none of these scenarios were identified as substantive risks. The principal reasons for these conclusions are summarised in Table 2, and include:

- none of the GM plant material would enter human food or animal feed
- the DMO protein encoded by the introduced *dmo* gene is not known to be toxic or allergenic
- the GM canola plants have limited ability to establish populations outside cultivation
- limits on the size, locations and duration of the release would be imposed, and
- the suitability of controls proposed by the applicant to restrict the spread and persistence of the GM canola and its genetic material will be assessed and, if necessary amended.

127. Therefore, risks to the health and safety of people, or the environment, from the proposed release of the GM canola plants into the environment are considered to be negligible. The *Risk Analysis Framework* (OGTR, 2013a) which guides the risk assessment and risk management process, defines negligible risks as risks of no discernible concern with no present need to invoke actions for mitigation. Therefore, no additional controls are required to treat these negligible risks. Hence, the

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

Chapter 3 Risk management plan

Section 1 Background

128. Risk management is used to protect the health and safety of people and to protect the environment by controlling or mitigating risk. The risk management plan addresses risks evaluated as requiring treatment and considers limits and controls proposed by the applicant, as well as general risk management measures. The risk management plan informs the Regulator's decision-making process and is given effect through licence conditions.

129. 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.

130. 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.

131. 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. In addition, the Regulator has extensive powers to monitor compliance with licence conditions under Section 152 of the Act.

Section 2 Risk treatment measures for substantive risks

132. The risk assessment of risk scenarios listed in Chapter 2 concluded that there are negligible risks to people or the environment from the proposed field trial of GM canola. These risk scenarios were considered in the context of the scale of the proposed release (Chapter 1, Section 3.1), the proposed control measures (Chapter 1, Section 3.2), and the receiving environment (Chapter 1, Section 6), and considering both the short and the long term. The risk evaluation concluded that no specific risk treatment measures are required to treat these negligible risks. Limits and controls proposed by the applicant and other general risk management measures are discussed below.

Section 3 General risk management

133. The limits and controls proposed in the application were important in establishing the context for the risk assessment and in reaching the conclusion that the risks posed to people and the environment are negligible. Therefore, to maintain the risk context, licence conditions have been imposed to limit the release to the proposed size, location and duration, and to restrict the spread and persistence of the GMOs and their genetic material in the environment. The conditions are discussed and summarised in this Chapter and listed in full in the licence.

3.1 Licence conditions to limit and control the release

3.1.1 Consideration of limits and controls proposed by Monsanto

134. Sections 3.1 and 3.2 of Chapter 1 provide details of the limits and controls proposed by Monsanto in the application. These are taken into account in the three risk scenarios postulated for the proposed release in Chapter 2. Many of the proposed control measures are considered standard for GM crop trials and have been imposed by the Regulator in previous DIR licences. The appropriateness of these controls is considered further below.

Limits

135. The applicant proposes that the duration of the field trial would be confined to four years, with up to 15 trial sites during the first two years with a maximum combined planting area of 30 ha per year, up to 20 sites for the third and fourth years with a maximum planting area of 50 ha and 100 ha, respectively. Each site would be a maximum area of 2 ha in the first two years, 5 ha in the third year and 20 ha in the fourth year. Sites are to be selected from 140 possible LGAs in NSW, Queensland, SA, Victoria and WA. The limited size and duration of the trial would limit the potential exposure of humans and other organisms to the GMOs (Risk Scenario 1).

136. The applicant proposes that only trained and authorised staff would be permitted to deal with the GMOs. Standard licence conditions require all people dealing with the GMOs to be informed of relevant licence conditions. These measures would limit the potential exposure of people to the GMOs (Risk scenario 1).

137. The GM canola has not been assessed for food use by FSANZ. The applicant proposes that no GM plant material from the field trial would be used for human food or animal feed. This would minimise exposure of people or desirable animals to the GM canola by consumption (Risk scenarios 1 and 2).

Controls for dispersal and persistence

138. The applicant proposes that any non-GM canola plants grown in the trial sites would be treated as if they were GMOs. A number of GM canola varieties have been approved for commercial production and the applicant may also use any of these at the trial sites, including use as a pollen trap plant. Thus non-GM canola or commercially approved GM canola may be mingled with or fertilised by the GM canola for this release and it is therefore necessary to treat all these plants as if they were the GMOs to be released. This standard licence condition will reduce the likelihood of dispersal of GM material (Risk Scenario 2).

139. As discussed in Chapter 1 Section 6.4, canola pollen is transferred by both insects and wind. The applicant has proposed a number of measures to control pollen-mediated gene flow, including the use of monitoring zones, isolation zones and pollen traps.

140. The applicant proposes that all trial sites would be surrounded by monitoring zones in which sexually compatible species would be removed prior to flowering. The monitoring zones would be 50 m wide. As experimental evidence suggests that the rate of out-crossing is greatly reduced beyond 30 m from the pollen source, and as most *Brassicaceous* weeds hybridise inefficiently with canola (Chapter 1, Section 6.4), a 50 m wide monitoring zone would restrict pollen-mediated gene flow to other *Brassicaceous* species (Risk Scenario 3).

141. The applicant has also proposed to maintain an isolation zone between the GM canola plants and any other canola crops or other sexually compatible crop species. The isolation zone would be 400 m from the outer edge of the pollen trap if used, or 1 km from the edge of the planting area where GMOs are grown if no pollen trap is used.

142. The applicant has proposed that, if used, the pollen trap will be 15 m wide and composed of non-GM canola. Pollen traps are an effective means of reducing pollen-mediated gene flow (Staniland et al., 2000) and are more effective at reducing gene flow than leaving the area barren (Morris et al., 1994; Reboud, 2003). Pollen traps function by absorbing the majority of pollen dispersed by the wind or insect vectors. In the case of pollinating insects, the presence of pollen trap plants flowering synchronously with the GM canola may provide sufficient forage for incoming pollinating insects without them needing to visit the GM plants within. Alternatively, pollen trap plants may absorb the pollen deposited by visiting insects as they exit the trial site (Williams, 2001). Therefore, a condition that the pollen trap plants are flowering at the same time as the GM canola plants is also included in the licence.

143. The isolation distances proposed exceed those mandated for trials of GM canola overseas, which generally require an isolation distance of 50-400 m (Salisbury, 2002). Moreover, they exceed the isolation distances required in Australia for the production of non-GM certified canola seed. Production of basic canola seed requires an isolation distance of 100 m from the nearest *Brassica* crop and the seed must contain no more than 0.3 % off-types, whereas production of certified seed requires an isolation distance of 200 m and must contain no more than 0.1 % off-types (Australian Seeds Authority Ltd., 2006; OECD, 2008). Therefore, the proposed isolation zones and pollen containment measures are considered an effective means of restricting pollen-mediated gene flow to any other canola crops or other sexually compatible crop species being grown for breeding, commercial or research purposes (Risk Scenario 3), and are consistent with the recently issued canola licences for limited and controlled release.

144. As discussed in Risk Scenario 2, human activities play the greatest role in spread of canola seed. There is potential for dispersal of seed during sowing, harvesting and threshing (mechanical dispersal). Sowing and harvesting activities may lead to dispersal of seed into the area immediately around the trial, including the monitoring zone. To minimise such seed dispersal, the applicant proposes to clean equipment used with the GMOs before removal from the site and to transport and store any plant material taken off-site for experimental analysis according to the Regulator's *Guidelines for the Transport, Storage and Disposal of GMOs* (http://www.ogtr.gov.au/). These are standard protocols for the handling of GMOs to minimise exposure of people and other organisms to the GMOs (Risk scenario 1), dispersal into the environment (Risk scenario 2), and gene transfer (Risk scenario 3). These cleaning and transport measures are included as licence conditions. A licence condition is also included requiring the GM canola be harvested separately from other crop to prevent GM canola seed mixing with other seed.

145. There is also a possibility of seed dispersal via movement of plant material under strong winds. As discussed in Risk scenario 2, there is potential for dispersal of material from windrows in an unusually strong wind event, or under flooding conditions. A licence condition requires the licence holder to notify the Regulator in writing of the intended method of harvest for each trial site (eg hand harvesting, direct heading or windrowing). In addition, another licence condition requires the applicant to use appropriate measures to minimise likelihood of dispersal of windrowed plant material by wind or water. Appropriate measures may include: high density planting and growth of the canola prior to windrowing, ensuring that windrows are thick and heavy so as to minimise the likelihood of their movement off-site; cutting/windrowing to allow maximum stubble height, as longer stubble helps anchor the windrows; site selection to avoid flood or wind-prone areas; and/or use of a windrow roller, which has proven effective in forming tight, compact windrows that are resistant to wind. A further licence condition requires the applicant to provide details of the measures used to the Regulator.

146. The applicant proposes to clean the GMO planting area after harvest by cultivation. During sowing and harvesting, plant material could be scattered into the area immediately surrounding the trial, so there is potential for residual seed to be present in both the planting area and the monitoring zone. As discussed in Risk scenario 2, residual seed on the soil surface could be dispersed by animal predation and water runoff after rainfall during the period between harvest and cleaning. Therefore, it is appropriate to require that cleaning occurs shortly after harvest. A licence condition requires that GMO planting areas, their associated monitoring zones and other areas where GM plant material may have dispersed must be cleaned within 14 days after harvest of the GMOs. The applicant has proposed burial of excess seed as one of the destruction methods. Deep burial of seed is considered an effective method of destruction, therefore conditions allowing deep burial, with requirements for monitoring of burial sites, have been included in the licence.

147. The applicant proposes, in line with a standard DIR licence condition, that trial sites be located at least 50 m from natural waterways to minimise the chance of viable plant material being washed away from the sites. An additional licence condition has also been included requiring immediate notification of any extreme weather conditions such as strong winds or flooding, and of any

movement of harvested plant material off the site. This would facilitate monitoring of the release by the Regulator and help to ensure that if any dispersal occurs it is appropriately managed.

148. The applicant proposes post-harvest monitoring of the trial site, pollen trap area and any areas used to clean equipment or to bury seed every 35 days for at least 24 months, and destroying any volunteer canola plants detected until no volunteers are observed in the most recent 12 month period. These monitoring arrangements are in line with recent canola licences for limited and controlled release and their effectiveness is supported by data collected during monitoring of the previous releases. The 50 m monitoring zone around the trial site would also be subject to this post-harvest monitoring. Records must be kept of monitoring activities and findings, including number and location of volunteers, which will allow the Regulator to assess the ongoing suitability of these measures and provide additional information for future assessments.

3.1.2 Summary of licence conditions to be implemented to limit and control the release

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

- limit the release to up to 15 sites per year in the first two years and 20 sites per year in the third and fourth years in nominated local government areas in New South Wales, Queensland, South Australia, Victoria and Western Australia between January 2020 and January 2024
- limit each trial site to a maximum of 2 ha with a maximum combined area of 30 ha per year in 2020 and 2021, 5 ha with a maximum combined area of 50 ha in 2022 and 20 ha with a maximum combined area of 100 ha in 2023
- locate the proposed trial sites at least 50 m away from the nearest natural waterway
- restrict gene flow via pollen from the trial sites using one of the following measures:
  a. surrounding the Planting Area with a 50 m Monitoring Zone and maintain an Isolation Zone of at least 1 km to other canola crops; or
  b. surrounding the Planting Area with a 15 m Pollen trap of non-GM canola and a 50 m Monitoring Zone and maintain a 400 m Isolation Zone to other canola crops
- ensure that the 50 m Monitoring Zone is kept free of related species
- treat all non-GM plants or commercially authorised GM canola used in the trial as if they were the GM canola proposed for release
- harvest the GM canola plant material separately from other canola crops
- clean equipment prior to use for other purpose
- clean the planting areas and other adjacent areas on which viable material may be present (such as clean down areas) following harvest
- transport and store GM plant material in accordance with the current Regulator's Guidelines for the Transport, Storage and Disposal of GMOs
- destroy all plant material from the trial not required for further evaluation or future trials
- post-harvest monitor the trial site at least once every 35 days for at least 24 months and until the site is free of volunteer plants for 12 consecutive months, and destroy any volunteer canola plants before flowering
- not allow the GM plant materials or products to be used for human food or animal feed.

3.2 Other risk management considerations

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

- applicant suitability
- contingency plans
- identification of the persons or classes of persons covered by the licence
- reporting requirements
- access for the purpose of monitoring for compliance.

3.2.1 Applicant suitability

151. 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, for either an individual applicant or a body corporate, include:

- any relevant convictions of the applicant
- 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.

152. The conditions of the licence include a requirement for the licence holder to inform the Regulator of any information that would affect their suitability.

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

3.2.2 Contingency plan

154. Monsanto is required to submit a contingency plan to the Regulator before planting the GMOs. This plan would detail measures to be undertaken in the event of any unintended presence of the GM canola outside permitted areas.

155. Monsanto is also required to provide the Regulator with a method to reliably detect the GMOs or the presence of the genetic modifications in a recipient organism. This methodology is required before planting the GMOs.

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

156. The persons covered by the licence are the licence holder and employees, agents or contractors of the licence holder and other persons who are, or have been, engaged or otherwise authorised by the licence holder to undertake any activity in connection with the dealings authorised by the licence. Prior to growing the GMOs, Monsanto would be required to provide a list of people and organisations that will be covered by the licence, or the function or position where names are not known at the time.

3.2.4 Reporting requirements

157. The licence requires the licence holder to immediately report any of the following to the Regulator:

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

158. A number of written notices are also required under the licence to assist the Regulator in designing and implementing a monitoring program for all licensed dealings. The notices include:

- expected and actual dates of planting
- details of areas planted to the GMOs
- expected dates of flowering

- expected and actual dates of harvest and cleaning after harvest
- details of inspection activities.

3.2.5 Monitoring for compliance

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

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

161. In cases of non-compliance with licence conditions, the Regulator may instigate an investigation to determine the nature and extent of non-compliance. The Act provides for criminal sanctions of large fines and/or imprisonment for failing to abide by the legislation, conditions of the licence or directions from the Regulator, especially where significant damage to health and safety of people or the environment could result.

Section 4 Issues to be addressed for future releases

162. Additional information has been identified that may be required to assess an application for a commercial release of these GM canola lines, or to justify a reduction in limits and controls. This includes additional phenotypic characterisation of the GM canola plants, particularly with respect to traits that may contribute to weediness or persistence.

Section 5 Conclusions of the consultation RARMP

163. The RARMP concludes that this limited and controlled release of GM canola poses negligible risks to the health and safety of people or the environment as a result of gene technology, and that these negligible risks do not require specific risk treatment measures.

164. Conditions have been imposed to limit the release to the proposed size, location and duration, and to restrict the spread and persistence of the GMOs and their genetic material in the environment, as these were important considerations in establishing the context for assessing the risks.

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Appendix A Summary of submissions from prescribed experts, agencies and authorities

Advice received by the Regulator from prescribed experts, agencies and authorities[3] on the consultation RARMP is summarised below. 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.

Submission	Summary of issues raised	Comment
1	One member commented that the RARMP seems to be dependent on the limited release areas, restricting the use of oilseed produced, cleaning up the surplus plants and checking the growing sites. While these are all necessary components, it does not actually address real risks in this application. The real risks are potential allergenicity of the GM seed-which will be used in the long-term as human and stock feed, and hence need careful animal and human testing, the potential weediness of the GM crop which will not be able to be controlled by dicamba or glyphosate, and the mobility of the genetic elements in cross-breeding with non-GM strains. It is expected that all these aspects have been addressed at a prior stage, but a detailed risk assessment is not present in the material that has been circulated. To rely on a very limited agricultural trial as a negligible risk assessment on the ground that it is limited, appears to be just a soothing statement with no real content.	This licence application is for a limited and controlled field trial of the GMOs. As such, the main focus of the risk assessment is whether or not the limits and containment measures are adequate to minimise exposure of people and animals to the GM plant material from the trial and contain the GMOs to the trial sites. As described in the RARMP, draft licence conditions include requirements to: limit the duration of the trial (5 years) limit the number and size of the sites restrict pollen mediated gene flow (a number of measures) restrict seed dispersal (a number of measures) ensure all plants are destroyed at the completion of the trial monitor for at least two years after harvest to ensure the site is free of volunteers not allow the GM plant materials or products to be used for human food or animal feed The RARMP concluded that these measures would minimise exposure of people and animals to the GM plant material from the trial and contain the GMOs to the trial sites. Were the applicant to propose a general release of the GMOs, a new licence application would be required, including detailed data to address the potential for increased toxicity, allergenicity and weediness of the GMOs. This may include data from human and animal feeding studies, seed composition data and agronomic data associated with potential weediness. Approval from FSANZ would be required for food use of the GMOs.
	Although the RARMP points out that regulation of herbicide usage is a matter for the APVMA rather than the OGTR, it cannot be agreed that	Australia's regulatory system for gene technology involves a number of agencies/authorities and where possible,

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

Submission	Summary of issues raised	Comment
	the two can so easily be separated and the OGTR takes no responsibility for risk assessment of any herbicide usage that might be associated with the growth of GM plants covered by DIR 164. If the GM plants covered by this application are to be treated with glyphosate during the proposed trials then it can be considered a potential risk to the health and safety of the personnel carrying out the treatments arising as a direct consequence of the deployment of the glyphosate resistance gene. Whilst Monsanto and the APVMA maintain that glyphosate is a safe herbicide to handle, the World Health Organisation's International Agency for Research on Cancer (IARC) has assessed glyphosate as a probable human carcinogen. Moreover, the APVMA has not conducted a formal re-assessment of glyphosate biosafety in more than 20 years. Without making any judgement about the safety or otherwise of glyphosate, it would seem that a precautionary approach should be taken to protect the health and safety of workers charged with the application of glyphosate if any is intended in the proposed trials. In the absence of an integrated OGTR/APVMA risk assessment (i.e. one that includes herbicide application as one of the proposed dealings with GM canola) or the provision of information by the APVMA on the required use of personal protective equipment (PPE) by workers involved, it would seem a part of the OGTR's duty of care to the workers dealing with glyphosate-resistant GM canola to find out (e.g. from the APVMA) whether workers health and safety is being protected by the use of appropriate PPE or to insist that appropriate PPE is used. The same argument applies to dicamba resistant GM canola or any other herbicide resistant GM plant being risk-assessed by the OGTR.	duplication is avoided. OGTR and APVMA are required by their respective legislation to assess specific aspects of GM plants and products. Issues relating to the safety and use of herbicides are assessed and managed by the APVMA, and the OGTR has no authority to regulate in this area. Information regarding the safety of glyphosate usage, including a response to the IARC assessment, can be found at https://apvma.gov.au/node/13891. The APVMA is required to be satisfied in relation to the safety of agricultural chemicals before issuing a research permit or registering formulations and issuing labels for approved products. Permits and labels contain all information for using the products, including safety instructions. For this field trial, the applicant will be using dicamba under a research permit issued by APVMA and using glyphosate with formulations already registered with the APVMA for MON88302 canola.
2	Agrees with the overall conclusions of the RARMP.	Noted.
	The Regulator should consider clarifying whether any new or additional information has been considered in relation to the *cp4 epsps* gene and any possible interactions with the *dmo* gene.	Amendments have been made in Chapter 1, Section 5.3.2, Chapter 2, Section 2.1 and Risk scenario 1 for clarification.
3	Agrees with the overall conclusions of the RARMP that the risks to the environment are negligible.	Noted.
	It is recognised that pollen or seed dispersed outside the trial site is unlikely to lead to harm as canola is not a weedy species in Australia and the GM traits are unlikely to increase weediness potential of the GM plants or weedy relatives, in the unlikely event that gene flow to weedy	Noted.

Submission	Summary of issues raised	Comment
	species occurs.	
	There is negligible likelihood of pollen-mediated gene flow to weedy relatives (risk scenario 3) due to controls in place to limit pollen dispersal such as pollen traps and large isolation zones. It is recognised that pollen dispersal can be minimised with effective controls but canola seed dispersal may be more difficult to manage (Banks, G. 2014).	Noted. As this is a limited and controlled field trial, seed dispersal will be effectively managed by imposed licence conditions for equipment use, post-harvest trial site cleaning and monitoring, and transport, storage and disposal for GMOs.
	Canola seed dispersal can occur through wind, water, spillage of seed during transportation or activities of seed-eating birds and mammalian herbivores (CFIA 2017). The RARMP notes that the likelihood of endozoochory by wild animals or birds is possible at very low levels and some studies support that seeds are unlikely to be viable after digestion (Paragraph 93). The RARMP would benefit from including references for these studies.	Paragraph 93 has been amended and additional references added.
4	Overall, Monsanto's application has negligible risks to the health and safety of people and the environment. Specifically, satisfied that the measures taken to manage the short and long term risks of the application are adequate.	Noted.
5	Considered the RARMP and have no comments.	Noted.
6	Supports the conclusion that DIR 164 poses negligible risk of harm to human health and safety and the environment.	Noted.
	It states on Page 21, Paragraph 110 that "In the **unlikely** event of gene transfer to a sexually compatible plant, it is possible that expression of the introduced *dmo* gene ….". The word 'unlikely' should be removed. The reason is that on Page 9, Paragraph 45, it is noted that movement of genes has been demonstrated to 2 km and the indicative buffer zones in the RARMP are 1 km or 400 m, The population of canola in these trials are probably at least comparable to the number of plants examined where 2 km movement was found, so it is arguable that the chance of at least one spread event occurring in at least one of the trials is not unlikely.	The RARMP has been amended accordingly.
	These proposed GM herbicide tolerance lines may reduce the likelihood of broad leaf weed tolerance to glyphosate.	Noted.
7	No comments on the RARMP and no objection to the issue of a licence for DIR 164.	Noted.
8	For Risk scenario 1, noted that workers could be exposed to the plant material or expressed proteins either through dermal, inhalation and ingestion pathways. General public could be	Noted. Licence condition 17 requires the licence holder to inform the Regulator if the licence holder becomes aware of additional information as to any risks to the health and

Submission	Summary of issues raised	Comment
	exposed to expressed protein through inhalation or ingestion pathways (honey). Ingestion pathway can be excluded as produced canola will not be used as human consumption or animal feed. Suggests that as the toxicity and allergenicity studies related to dicamba-tolerant canola line are not available, the applicant should keep a record of any adverse reactions (both dermal and inhalational) in workers and inform the regulator as part of the license conditions.	safety of people or any unintended effects associated with the dealings authorised by the licence.

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

The Regulator received nine submissions from the public on the consultation RARMP. The issues raised in the submissions are summarised in the table below. All issues 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.

Submission	Summary of issues raised	Comment
1	This is nothing to do with a trial. This is all about spreading Monsanto's Trojan Horse GM pollution to the point where there are no GM free areas left in Australia. To talk of a "limited and controlled release" is a nonsense as there is no way to ensure such. The effects of GM crops and Roundup on the human microbiome are profound.	Monsanto has applied to the Gene Technology Regulator to conduct a limited and controlled trial of GM canola. The RARMP concluded that the field trial of the GM canola poses negligible risks to the health and safety of people and the environment. The licence imposes conditions to limit the spread and persistence of the GM canola in the environment, including cleaning of trial sites after harvest and monitoring trial sites for at least 2 years, during which any volunteers found will be destroyed and until the Regulator is satisfied that no GMOs remain. The licence also prohibits GM plant material from being used for human food or animal feed. 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. The APVMA considers risks to human health, animals and the environment in assessing agricultural chemicals for registration.
2	Requests to not allow in Australia what has happened to the food chain in the USA. Asserts that Monsanto is a monster and will poison people through spraying crops with poison, and that the poison will build-up in the human body over time. The science from Monsanto is not the full story and the Regulator needs to look into it. Already stopped buying anything with canola oil in it as the OGTR is even considering this idiocy and asks to reconsider what we leave future generations to clean up.	This application is for a limited and controlled release (field trial). No products from this GM canola trial will be allowed to enter the human food supply. The Regulator has prepared a comprehensive RARMP, in accordance with the requirements of the Act, and includes a comprehensive and critical assessment of data supplied by the applicant, together with a thorough review of other relevant national and international scientific literature. Advice is also taken from prescribed experts, Australian Government authorities and agencies, State and Territory Governments, the Minister for the Environment and the public prior to making the decision. See comments for Submission 1 regarding issues relating to use of agricultural chemicals.
3	Requests that this proposal is not given government approval. Has concerns that weeds will develop resistance to the herbicides used to spray GM	Issues relating to the development of herbicide resistant weeds by herbicide usage are considered by the APVMA in assessing herbicides for registration. In addition, there is a high level

Submission	Summary of issues raised	Comment
	crops and then stronger chemicals will need to be used, and the cycle expands until people are consuming more herbicides in human food.	of awareness of herbicide resistance issues in Australian cropping (both GM and non-GM), with research, industry and extension representatives collaborating on a number of management initiatives. This is a limited and controlled trial and no products from this GM canola trial will be allowed to enter the human food supply.
4	Does not believe that it is possible to identify all the risks posed by genetic engineering of life forms. Setting up a body such as the Gene Technology Regulator with a limited scope merely legitimates actions which may harm ecological balance and human society. Protests against allowing Monsanto to run DIR 164 field trial as it is premature to test agronomic performance when the health and ecological effects are un-tested and may be untest-able.	Australia's regulatory system for gene technology involves a number of agencies/authorities including OGTR, FSANZ and APVMA, which are required by their respective legislation to assess specific aspects of GM plants and products. 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 Regulator must not issue a licence unless risks can be managed to protect the health and safety of people and the environment. The RARMP concluded that risks to human health and safety and the environment are negligible as a result of this field trial. The licence requires that any unintended effects must be reported to the Regulator.
5	Does not think it is a good idea to give licence, even limited licence to use the GM to trial the canola fields for the safety of the environment. Understands this trial is not for human consumption or animal feed, but questions the purpose of the trial if not for human consumption and animal feed in the long run.	The purpose of the field trial is to assess the agronomic performance of the GMOs under field conditions and all plant material produced from the trial not for further experimentation must be destroyed. Following the field trial, if the applicant decides to apply for commercial release of the GMOs, they will need to submit a new licence application for commercial release and provide more detailed data to address any issues related to human health and the environment. They will also need to obtain approval from FSANZ for food use of the GMOs.
6	As an organic/biodynamic dairy, beef and cropping farmer who has extensive experience in conventional farming, does not want any GM canola sites allocated around their farm or in South Australia. Encourages the state to uphold the SA GM moratorium till at least 2025. Has concerns that if the GM moratorium is lifted in South Australia, organic farmers' choice of livelihoods will be removed due to contamination of seeds from nearby farms that grow GM crops and their income will be destroyed. Notes that individual farms that sue for compensation for loss of their organic status due to contamination of GM plants from neighbouring farms have in the past lost their	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 and the GM moratorium in SA is for this purpose. 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.

Submission	Summary of issues raised	Comment
	case (eg the Marshall case in WA), asserting that the neighbouring farm's legal fight was financially supported directly or indirectly by the chemical companies. Suggests that organic farmers would then have to find alternatives against whom to form a class action.	
	Comments that increasing weed resistance to glyphosate-based herbicides is a huge problem and conventional farmers are choosing to reduce usage where they can. So the roundup ready crops may be of no advantage - if there is any - within the near future. In WA GM crops have declined from 30% to 20% in past 12 months. Truflex canola allows higher rates of Roundup to be sprayed more often and for longer, questions if this will increase glyphosate residues in soil, water and food. Asserts that that there is an increase in herbicide glyphosate usage around the world where GM crops are grown. The IARC report has found that glyphosate products are likely cause of certain cancers.	See comments for Submission 3 regarding issues relating to herbicide resistant weeds. The APVMA considers risks to human health, animals and the environment in assessing herbicides for registration. The APVMA has assessed the safety of the application for use of glyphosate on Truflex canola before issuing/amending the label. Information regarding the safety of glyphosate usage, including an APVMA's response to the IARC assessment, can be found at https://apvma.gov.au/node/13891.
7	Finds the RARMP to be well-prepared and comprehensive and the proposed limits and controls are expected to minimise potential harm. Supports the conclusions of the RARMP.	Noted.
	Asks if an alternative plan will be sought for water unavailability (eg irrigation systems). Suggests that this would assist in monitoring volunteers in the long-term. Also asks what contingencies are in place in the event of unforeseen circumstances (eg. natural calamities) affecting the trial and the reporting mechanisms in case of a breach.	During the course of the field trial, the licence holder is required to report to the Regulator any issues that may affect the trial. A licence condition requires that the licence holder must provide to the Regulator a contingency plan prior to conducting any dealings with the GMOs and notify the Regulator any adverse event that could cause or has led to the dispersal of GMOs beyond areas requiring cleaning during the trial. The licence also has a provision requiring the licence holder to inform the Regulator any event or circumstances occurring after the commencement of this licence that would affect the capacity of the licence holder to meet the conditions.
8	As a commercial beekeeper with apiary sites in country South Australia, sells honey primarily to a packer interstate. Knowing that the South Australian genetically modified food crop moratorium is in place and is due to expire on 1 September 2025, has an interest in the direction GM crops are taking as it represents a potential source of contamination to honey. This may negatively	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. The States and Territories that have imposed restrictions on the growing of GM crops for marketing reasons may allow trials of GM crops subject to conditions unrelated to human health and safety and the

Submission	Summary of issues raised	Comment
	affect the landowners where apiary sites are located, noting that there is clearly an identified market demand for GM free honey. The current GM moratorium exists for "trade and market access purposes" (PIRSA "GM Review"). Introduction of GM sites as "trials" will negatively affect sales in GM free honey market. A trial site near apiary sites will reduce product acceptance by the market place. Locating GM canola sites near organic farms will jeopardise their organic status and their very existence as a recognised organic producer. It leaves them no choice in the matter of genetic interference in their farming practice.	environment. This is an application for limited and controlled field trial of GM canola. The limits and containment measures imposed by the licence are intended to minimise dispersal of the GM plant material from the field trial.
	The DIR 164 RARMP indicates that there is consideration of pollen transfer to non-GM canola crops. A 1 km "isolation zone" from non-GM crops is described in the trial sites. A study by Dr Mary Rieger (Grains Research and Development Corporation) indicates there is pollen transfer up to 3 km from the source. The trial's 1 km zone is insufficient to ensure gene transfer via pollen does not occur. Prefers to have zero gene transfer. This can be achieved by not allowing the trials to take place. There is a need for more independent and extended research where trials are not carried out by a group who have a vested interest in the result. Monsanto/Bayer has an emerging poor record of valid research in this area. Australia is a country with an identified "green" image in relation to its food production and we need to exercise extreme caution in allowing Monsanto/Bayer to use Australia as a testing ground.	Rieger et al (2002) was considered in preparation of the RARMP, and referenced there. The study, which indicates that there is a small amount of pollen-mediated gene movement up to 3 km from a source field, was carried out with large commercial canola field. As noted by Rieger et al, the large size may contribute to the randomness of long-distance pollination events. In contrast, this application is for a field trial of limited size and duration and containment measures imposed in the licence, including the use of pollen trap, monitoring zone and isolation zone, are considered adequate for controlling pollen transfer from the trial sites. In regards to how to consider data provided by the applicant, please see comments for Submission 2 regarding how this RARMP is prepared. Issues such as marketing, trade, and motives of biotechnology companies, are outside the scope of responsibility of the Regulator.
9	Supports the RARMP and the Regulators priority to protect the health and safety of people and the environment by controlling and mitigating risk. Notes that the proposed GM canola trial has several advantages: If approved for trial, the GM variety may reduce reliance on the herbicide glyphosate and allow greater crop rotation with glyphosate resistant canola and this may reduce selection pressure for glyphosate-resistant weeds. If found to be plausible at the end of the trial period, these factors will be of great benefit to Australian grain growers.	Noted.