Australian Government
Department of Health
Office of the Gene Technology Regulator

September 2018

Risk Assessment and Risk Management Plan
(consultation version)
for

DIR 164

Limited and controlled release of canola genetically modified for herbicide tolerance

Applicant – Monsanto Australia Limited

This RARMP is open for consultation until 22 October 2018.

Written comments on the risks to human health and safety and the environment posed by this proposed release are invited. You may make your submission

via mail to: The Office of the Gene Technology Regulator
MDP 54, GPO Box 9848, Canberra ACT 2601 or
via email to: ogtr@health.gov.au

Please note that issues regarding food safety and labelling, the use of agricultural chemicals, and marketing and trade implications do **not** fall within the scope of these evaluations as they are the responsibilities of other agencies and authorities.

PAGE INTENTIONALLY LEFT BLANK

Summary of the Risk Assessment and Risk Management Plan (Consultation Version)

for

Licence Application No. DIR 164

Introduction

The Gene Technology Regulator (the Regulator) has received a licence application for the intentional release of a genetically modified organism (GMO) into the environment. It qualifies as a limited and controlled release application under the *Gene Technology Act 2000* (the Act). The Regulator has prepared a Risk Assessment and Risk Management Plan (RARMP) for this application, which concludes that the proposed field trial poses negligible risks to human health and safety and the environment. Licence conditions have been drafted for the proposed field trial. The Regulator invites submissions on the RARMP, including draft licence conditions, to inform the decision on whether or not to issue a licence.

The application

Application number	DIR 164
Applicant	Monsanto Australia Limited (Monsanto)
Project title	Limited and controlled release of canola 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. Draft licence conditions are detailed in Chapter 4 of the RARMP.

As the level of risk is considered negligible, specific risk treatment is not required. However, since this is a limited and controlled release, the draft 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.

Table of Contents

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).

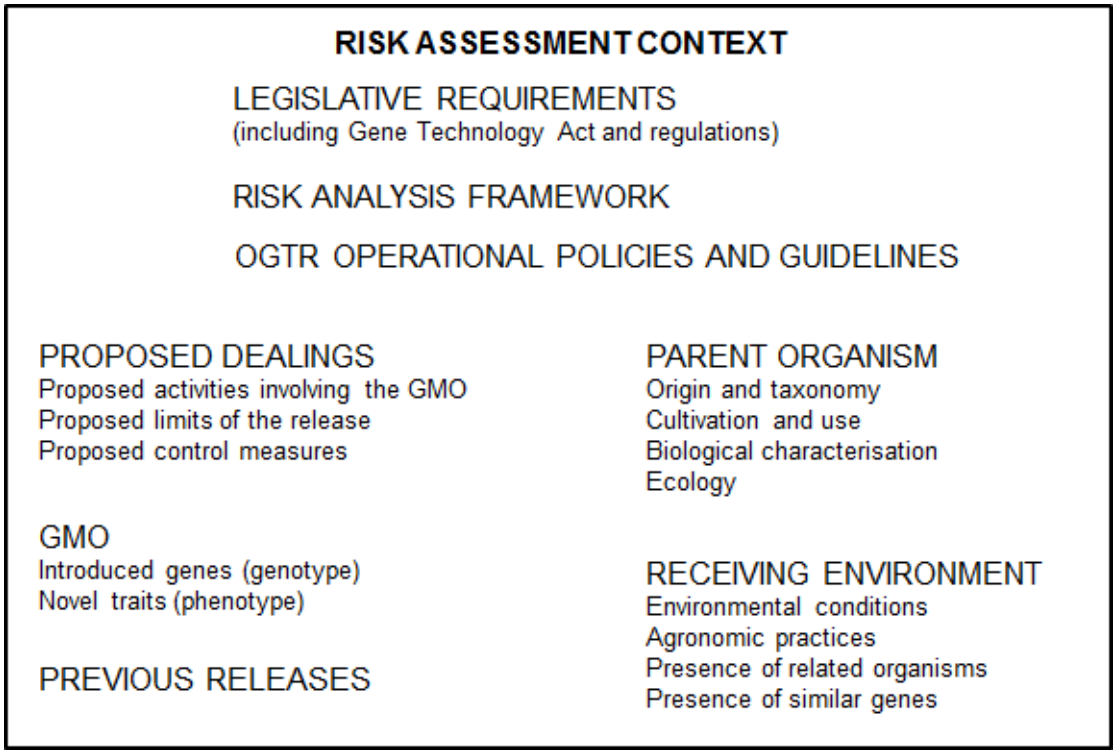

Figure 1 Summary of parameters used to establish the risk assessment context

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.

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 Limited (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
Wellington				Wagin
Young				Wandering

New South Wales	Victoria	South Australia	Queensland	Western Australia
				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 will be 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).

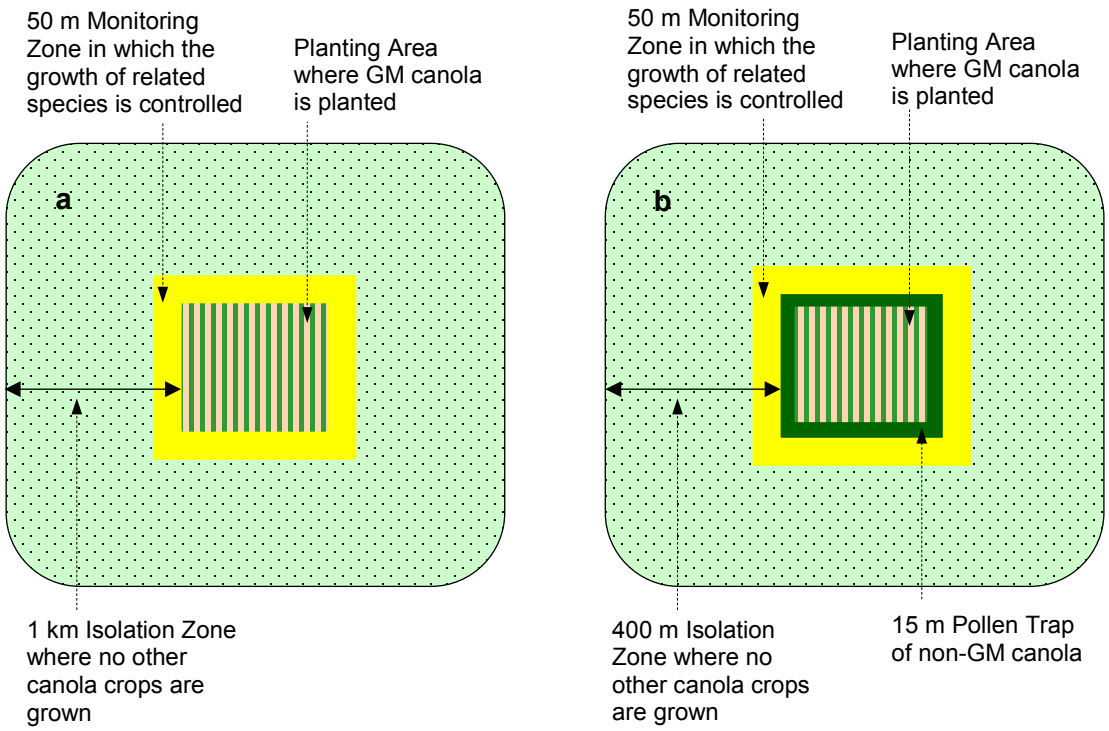

Figure 2 Proposed trial layout, including some of the controls (not to scale)

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

DMO protein

26. The *dmo* gene and encoded protein DMO 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 the 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.

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 EPSPS lacks toxicity to humans or animals, or allergenicity to humans.

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. 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

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

document *The Biology of Brassica napus L. (canola) and Brassica juncea (L.) Czern. & Coss. (Indian mustard)* (OGTR, 2017).

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

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

58. 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). Risks are identified within the context established for the risk assessment (see Chapter 1), taking into account current scientific and technical knowledge. A consideration of uncertainty, in particular knowledge gaps, occurs throughout the risk assessment process.

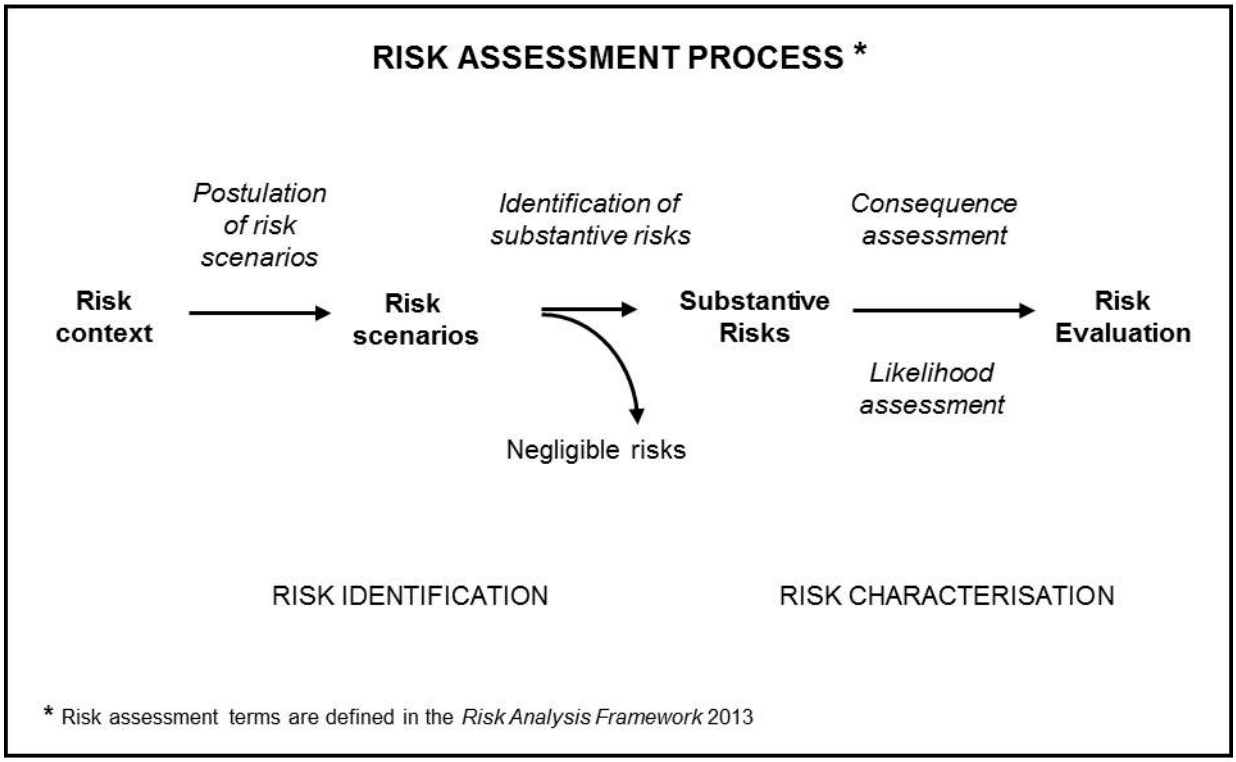

Figure 3 The risk assessment process

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

60. 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.

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

Section 2 Risk identification

63. Postulated risk scenarios are comprised of three components:

i. the source of potential harm (risk source)

ii. a plausible causal linkage to potential harm (causal pathway)

iii. potential harm to an object of value (people or the environment).

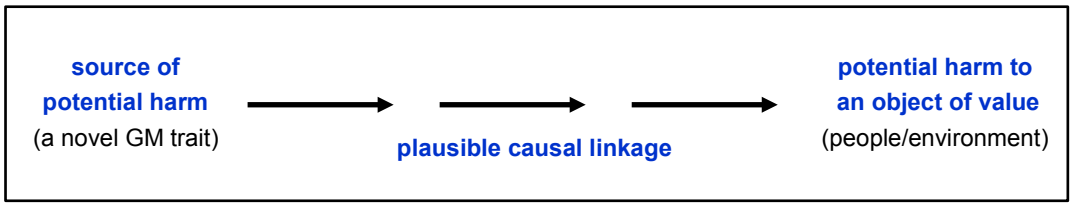

Figure 4 Components of a risk scenario.

64. When postulating relevant risk scenarios, the risk context is taken into account, including:

- 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

65. 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.

66. 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.

67. 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 (OGTR, 2014) 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. In light of the previous assessments, *cp4 epsps* alone will not be considered further as potential source of risk.

68. 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.

69. 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

70. 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.

71. 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.

72. 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.

73. 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

74. 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).

75. These harms are based on those used to assess risk from weeds (Keese et al. 2013; Standards Australia Ltd et al. 2006). 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

76. 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 occurs 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 desirable plants	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 naturally limit the geographical distribution of non-GM canola. • The limited scale and other proposed controls

Risk scenario	Risk source	Causal pathway	Potential harm	Substantive risk?	Reason
					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 site ⬇ Outcrossing with other sexually compatible plants, including other herbicide tolerant non GM and GM canolas ⬇ 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

77. 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

78. 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.

79. 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)).

80. 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 and. 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.

81. 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.

82. 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

83. 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).

84. 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.

85. 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.

86. 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. This is expected to be the same for the DT×MON88302 canola line with the same stacked traits.

Conclusion

87. 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

88. 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

89. 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

90. 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

91. 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

92. 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.

93. 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 viability of canola seed

after passing through the digestive gut of animals is poorly understood, but some studies support that seeds are unlikely to be viable after digestion. 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

94. 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.

95. 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.

96. 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

97. 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).

The applicant proposes a number of control measures to manage persistence of the GM canola post-harvest, including: destruction of 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

98. 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.

99. 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.

100. 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).

101. 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

102. 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 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

103. 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

104. 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.

105. 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.

106. 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.

107. 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.

108. 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.

109. 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

110. In the unlikely 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.

111. 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.

112. 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.

113. 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

114. 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

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

116. 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:
  - 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.

117. 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

[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.

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.

118. 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.

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

120. 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.

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

Section 4 Risk evaluation

122. 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.

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

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

124. 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.

125. 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[3].

[3] As none of the proposed dealings are considered to pose a significant risk to people or the environment, section 52(2)(d)(ii) of the Act mandates a minimum period of 30 days for consultation on the RARMP. However, the Regulator has allowed 6 weeks for the receipt of submissions from prescribed experts, agencies and authorities, and the public.

Chapter 3 Risk management plan

Section 1 Background

126. 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.

127. 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.

128. 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.

129. 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

130. 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

131. 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 proposed 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 detail in Chapter 4 (the draft licence).

3.1 Draft licence conditions to limit and control the release

3.1.1 Consideration of limits and controls proposed by Monsanto

132. 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

133. 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).

134. 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).

135. 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

136. 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).

137. 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.

138. 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).

139. 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.

140. 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 draft licence.

141. 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.

142. 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 draft licence conditions. A draft licence condition is also included requiring the GM canola be harvested separately from other crop to prevent GM canola seed mixing with other seed.

143. 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 draft 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 draft 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 draft licence condition requires the applicant to provide details of the measures used to the Regulator.

144. 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 draft 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 monitoring of burial sites, have been included in the draft licence.

145. 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 draft 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.

146. 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. 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 draft licence conditions to be implemented to limit and control the release

147. A number of licence conditions have been drafted 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 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 allow the GM plant materials or products to be used for human food or animal feed.

3.2 Other risk management considerations

148. 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

149. 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.

150. If a licence were issued, the conditions would include a requirement for the licence holder to inform the Regulator of any information that would affect their suitability.

151. 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

152. If a licence were issued, Monsanto would be 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.

153. Monsanto would also be 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 would be required before planting the GMOs.

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

154. If a licence were issued, the persons covered by the licence would be 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

155. If issued, the licence would require 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.

156. A number of written notices would also be required under the licence to assist the Regulator in designing and implementing a monitoring program for all licensed dealings. The notices would 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

157. 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.

158. 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.

159. 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

160. 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

161. The RARMP concludes that the proposed 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.

162. If a licence were issued, conditions would be 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.

Chapter 4 Proposed licence conditions

Section 1 Interpretations and Definitions

1. In this licence:

    a. unless defined otherwise, words and phrases used in this licence have the same meaning as they do in the Act and the Regulations;

    b. words importing a gender include any other gender;

    c. words in the singular include the plural and words in the plural include the singular;

    d. words importing persons include a partnership and a body whether corporate or otherwise;

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

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

    g. specific conditions prevail over standard conditions to the extent of any inconsistency.

2. In this licence:

'Act' means the *Gene Technology Act 2000* (Commonwealth) or the corresponding State legislation under which this licence is issued.

'Burial Site' means a place where the GMO is Destroyed by burial.

'Canola' means plants of the species *Brassica napus* L.

'Clean' (or **'Cleaned'**) means, as the case requires:

a. in relation to an area specified in this licence as requiring Cleaning, the Destruction of the GMOs in that area, to the reasonable satisfaction of the Regulator; or

b. in relation to Equipment, the removal and/or Destruction of the GMOs from the Equipment, to the reasonable satisfaction of the Regulator.

'Contingency Plan' means a written plan detailing measures to be taken in the event of the unintended presence of the GMOs outside an area that must be inspected. A Contingency Plan must include procedures to:

a. ensure the Regulator is notified immediately if the licence holder becomes aware of the event; and

b. recover and/or Destroy the GMOs to the reasonable satisfaction of the Regulator; and

c. inspect for and Destroy any Volunteers that may exist as a result of the event to the reasonable satisfaction of the Regulator.

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

a. cutting;

b. shredding/mulching;

c. treatment with herbicide;

d. burning/incineration;

e. burial, but only subject to the conditions of this licence;

f. Tillage, but only subject to the conditions of this licence;

g. autoclaving;

h. in the case of a Facility, removal of the GMOs; or

i. a method approved in writing by the Regulator.

Note: 'As the case requires' has the effect that, depending on the circumstances, one or more of these techniques may not be appropriate. For example, used individually, treatment by cutting or mowing may not be sufficient to kill the GMO remaining after harvest and additional treatment(s) may be required.

'Equipment' includes, but is not limited to, seeders, harvesters, storage equipment, transport equipment (e.g. bags, containers, trucks), clothing, footwear and tools.

'Extreme Weather Event' includes, but is not limited to, fires, flooding, cyclones, earthquakes, torrential rain that could disperse GMOs.

'Facility' means a facility approved in writing by the Regulator.

'Flowering' is taken to begin when any plant of the class of plants referred to in a particular condition first flowers, and is taken to end when all plants in the class of plants no longer have flowers.

'GM' means genetically modified.

'GMOs' means the genetically modified organisms that are the subject of the dealings authorised by this licence. GMOs include live plants and viable seed.

'Isolation Zone' means an area of land extending outwards from the outer edge of the Planting Area, or the outer edge of the Pollen Trap with respect to a Planting Area when a Pollen Trap is employed. The Isolation Zone must be kept free of deliberately planted Related Species while the GMOs are growing in the Planting Area.

'Logbook' means a written or electronic record containing information required to be collected and maintained by this licence and which is able to be presented to the Regulator on request.

'Monitoring Zone' means an area of land extending outwards from the outer edge of the Planting Area, as indicated in Figure 1.

'OGTR' means the Office of the Gene Technology Regulator.

'Personal Information' means information or an opinion about an identified individual, or an individual who is reasonably identifiable:

a. whether the information or opinion is true or not; and

b. whether the information or opinion is recorded in a material form or not.

'Planting Area' means an area of land where GM and non-GM canola plants are intentionally planted and grown pursuant to this licence, but does not include the Pollen Trap.

'Plant Material' means any part of the GM or non-GM canola plants grown in a Planting Area or in the Pollen Trap with respect to a Planting Area, whether viable or not, including but not limited to seed, stubble and pollen, whether from the plant itself or derived from or produced by the plant.

'Pollen Trap' means an area of land extending at least 15 m in all directions from the outer edge of a Planting Area.

'Regulator' means the Gene Technology Regulator.

'Related Species' means plants of the species *Brassica napus*, *B. rapa*, *B. juncea*, *B. oleracea*, *Hirschfeldia incana*, *Raphanus raphanistrum* or *Sinapis arvensis*, but does not include the GMO or non-GM Canola plants planted and grown according to this licence.

'Sign-off' means a notice in writing from the Regulator, in respect of an area, that post-harvest obligations no longer apply in respect of that area.

'**Tillage**' (or '**Tilled'** or '**Tilling'**) means the use of any technique to disturb the soil.

'Volunteers' means GM or non-GM Canola plants, which have not been intentionally grown.

'Waterways' means all permanent natural waterways and man-made waterways that flow into natural waterways.

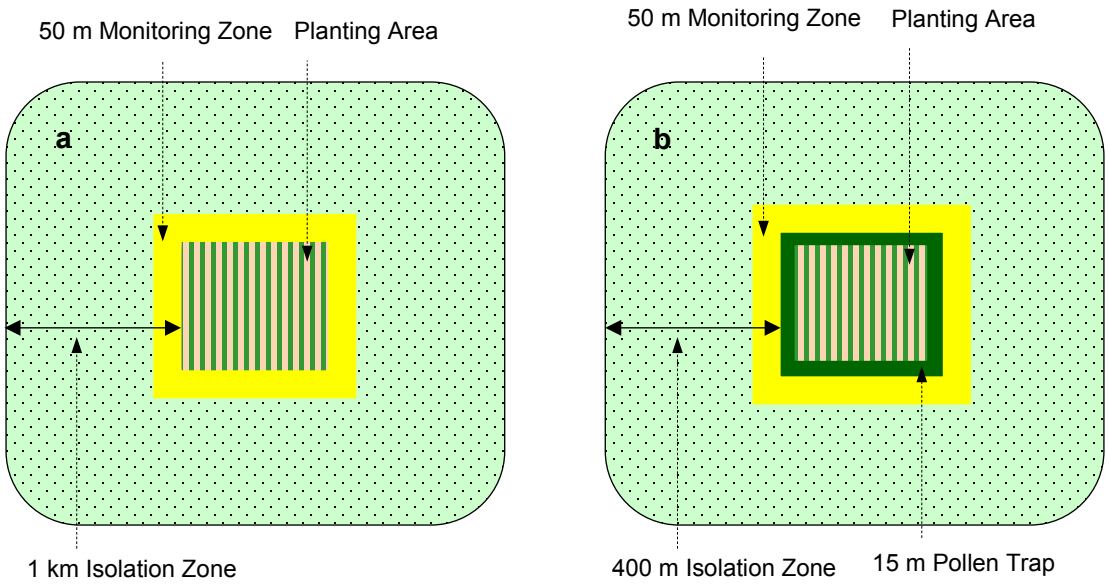

Figure 1. Diagrams showing the relationship between a Planting Area, a Pollen Trap, a Monitoring Zone and an Isolation Zone (not drawn to scale).
Site-layout: (a) without Pollen Trap; (b) with Pollen Trap. Monitoring and Isolation Zones must be kept free of related species (Conditions 30, 31 and 32).

Section 2 General conditions and obligations

3. This licence does not authorise dealings with GMOs that are otherwise prohibited as a result of the operation of State legislation recognising areas as designated for the purpose of preserving the identity of GM crops, non-GM crops, or both GM crops and non-GM crops, for marketing purposes.

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

5. The licence holder is Monsanto Australia Limited (Monsanto).

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

7. The only permitted dealings authorised by this licence are to conduct experiments with the GMOs, breed, propagate, grow, culture, import, transport and dispose of the GMOs, and the possession, supply and use of the GMOs in the course of any of these dealings.

Obligations of the Licence Holder

8. The licence holder must notify the Regulator in writing as soon as practically possible if any of the contact details of the project supervisor change from that notified in the licence application or subsequently.

Note: please address correspondence to ogtr.applications@health.gov.au.

Prior to issuing a licence, the Regulator considers suitability of the applicant to hold a licence. The following conditions address ongoing suitability of the licence holder.

9. The licence holder must, at all times, remain an accredited organisation in accordance with the Act and must comply with its instrument of accreditation.

10. The licence holder must:

a. inform the Regulator immediately in writing, of:

i. any relevant conviction of the licence holder occurring after the commencement of this licence; and

ii. any revocation or suspension of a licence or permit held by the licence holder under a law of the Australian Government, a State or a foreign country, being a law relating to the health and safety of people or the environment; and

iii. any event or circumstances occurring after the commencement of this licence that would affect the capacity of the licence holder to meet the conditions in it; and

b. provide any information related to the licence holder's ongoing suitability to hold a licence, if requested by the Regulator, within the stipulated timeframe.

11. The licence holder must be able to access and control all Planting Areas, Pollen Traps, Monitoring Zones, Isolation Zones and approved facilities to the extent necessary to comply with this licence, for the duration of the life of the licence.

The following conditions seek to ensure that persons conducting the dealings are aware of the licence conditions and appropriate processes are in place to inform people of their obligations.

12. Prior to conducting any dealings with the GMOs, the licence holder must provide to the Regulator:

a. names of all organisations and persons or functions or positions of the persons who will be covered by the licence, with a description of their responsibilities; and

Note: Examples of functions or positions are 'Project supervisor', 'Site manager', 'Farm labourer' etc.

b. detail of how the persons covered by the licence will be informed of licence conditions; and

c. detail of how the licence holder will access and control the Planting Areas, Pollen Traps, Monitoring Zones, Isolation Zones and approved facilities for the duration of the licence; and

Note: this may include a description of any contracts, agreements, or other enforceable arrangements.

d. written methodology to reliably detect the GMO, and the presence of the genetic modifications described in this licence in a recipient organism. The detection method must be capable of identifying, to the satisfaction of the Regulator, each genetic modification event described in this licence; and

e. a Contingency Plan to respond to inadvertent presence of the GMOs outside an area that must be inspected.

13. Any changes to the information provided under the immediately preceding condition must be communicated in writing to the Regulator within 14 days of the changes occurring.

14. The licence holder must inform any person covered by this licence, to whom a particular condition of the licence applies, of the following:

a. the particular condition (including any variations of it); and

b. the cancellation or suspension of the licence; and

c. the surrender of the licence.

15. The licence holder must not permit a person covered by this licence to conduct any dealing unless:

a. the person has been informed of any applicable licence conditions, including any variation of them; and

b. the licence holder has obtained from the person a signed and dated statement that the person:

i. has been informed by the licence holder of the licence conditions including any variation of them; and

ii. has understood and agreed to be bound by the licence conditions, or variation.

16. The licence holder must:

a. inform the persons covered by this licence that any Personal Information relevant to the administration and/or enforcement of the licence may be released to the Regulator; and

b. provide the Regulator, if requested, with copies of the signed and dated statements referred to in the immediately preceding condition.

Provision of new information to the Regulator

Licence conditions are based on the risk assessment and risk management plan developed in relation to the application using information available at the time of assessment. The following condition requires that any new information that may affect the risk assessment is communicated to the Regulator.

17. The licence holder must inform the Regulator if the licence holder becomes aware of:

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

b. any contraventions of the licence by a person covered by the licence; or

c. any unintended effects of the dealings authorised by the licence.

Note: The Act requires, for the purposes of the above condition, that:

a. *the licence holder will be taken to have become aware of additional information of a kind mentioned in paragraph 17(a) if he or she was reckless as to whether such information existed; and*

b. *the licence holder will be taken to have become aware of contraventions, or unintended effects, of a kind mentioned in paragraph 17(b) and 17(c), if he or she was reckless as to whether such contraventions had occurred, or such unintended effects existed.*

Note: Contraventions of the licence may occur through the action or inaction of a person. For example if it is a condition of the licence that volunteers are destroyed prior to flowering and a volunteer flowers, then the person responsible for controlling volunteers will have contravened that licence condition.

18. If the licence holder is required to inform the Regulator under the immediately preceding condition, the Regulator must be informed without delay.

Note: An example of informing without delay is contact made within a day of the incident via the OGTR free call phone number 1800 181 030, which provides emergency numbers for incidents that occur out of business hours. Notification without delay will allow the OGTR to conduct a risk assessment on the incident and attend the location, if required.

19. If the licence holder informs the Regulator under the immediately preceding condition and the Regulator requests further information, such information must be provided in a manner, and within the time period, stipulated by the Regulator.

Obligations of persons covered by the licence

20. Persons covered by this licence must not deal with the GMOs except as expressly permitted by this licence.

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

Note: Under the Act a place, including an area of land, is defined as a premises.

Section 3 Limits and Control Measures

Limits on the release

The following licence conditions maintain the risk assessment context within which the application was assessed, by imposing limits on where and when the GMOs may be grown, and on other activities that can be undertaken.

22. The only plants that may be intentionally grown at a Planting Area are:

    a. the GMOs covered by this licence as described in Attachment A of the licence;

    b. non-GM canola plants; and

    c. plants approved in writing by the Regulator.

Note: Attachment A is not included in the draft licence as the plants are described in the Risk Assessment and Risk Management Plan.

23. Planting and growing of the GMOs may only occur within the following limits:

    a. Up to 20 sites, with a total maximum Planting Area of 100 ha per year, as listed in the table below:

Area and duration

Maximum size of each Planting Area	Maximum combined size of Planting Area per year	Maximum number of Planting Areas per year	Period
2 ha	30 ha	15	2020 - 2021
5 ha	50 ha	20	2022
20 ha	100 ha	20	2023

    b. sites may be located in the following local government areas:

Local Government Areas in which Planting Areas may be located

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
Wellington				Wagin
Young				Wandering

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

24. Plant Material must not be used, sold or otherwise disposed of for any purpose which would involve or result in its use as food for humans or feed for animals.

Control measures

The following licence conditions maintain the risk assessment context within which the application was assessed by restricting spread and persistence of the GMOs.

Controls to minimise pollen and seed dispersal during cultivation

25. The outer edge of a Planting Area, or a Pollen Trap if employed, must be at least 50 m away from Waterways and be confined to areas not subject to flooding.

26. For each Planting Area, one of the following measures to limit gene flow must be adopted:

    a. surround the Planting Area by an Isolation Zone of at least 1 km (Figure 1a); or

    b. surround the Planting Area by a Pollen Trap and an Isolation Zone of at least 400 m (Figure 1b).

27. If a Pollen Trap surrounds a Planting Area:

    a. the Pollen Trap must be planted only to non-GM canola or GM canola approved for commercial release by the Regulator and maintained in such a way as to:

        i. have a reasonably dense and vigorous growth; and

        ii. be Flowering at the same time as the GMOs; and

        iii. form a continuous barrier at least 15 m wide around the Planting Area while the GMOs are Flowering, with the exception of a path of up to 3 m in width in order to access the Planting Area and for wheel tracks from large irrigation equipment; and

    b. Plant Material from the Pollen Trap must be handled and controlled as if they were the GMOs or Plant Material from the GMOs.

28. A Planting Area, or a Pollen Trap if employed, must be surrounded by a Monitoring Zone.

29. The Monitoring Zone means an area of land extending outwards:

    a. at least 50 m in all directions from the outer edge of a Planting Area without a Pollen Trap (Figure 1a); or

    b. at least 50 m in all directions from the outer edge of a Pollen Trap with respect to a Planting Area when a Pollen Trap is employed (Figure 1b).

30. The Monitoring Zone must be maintained in a manner appropriate to allow the identification and/or Destruction of Volunteers and Related Species whilst the GMOs are growing in the Planting Area and until the Planting Area is Cleaned.

Note: Measures to achieve this could include maintaining the area free of vegetation and/or keeping vegetation mown. Condition 51(d) of this licence requires details of current land use and recent land management practices to be recorded upon inspection of the Monitoring Zone.

31. The GMOs must not be planted or be growing in a Planting Area if any Related Species are being grown at the same time in the Monitoring or Isolation Zones.

Note: Refer to Condition 11 and 12(c) regarding access and control of areas

32. While the GMOs are growing in a Planting Area, associated areas must be inspected by people trained to recognise plants of Related Species, and actions taken, as follows:

Area	Period of inspection	Inspection frequency	Inspect for	Action
Planting Area and Pollen Trap (if applicable)	**From** 14 days prior to the expected commencement of Flowering of any GMOs* **until** the Planting Area, Pollen Trap and Monitoring Zone are Cleaned	At least once every 35 days	Related Species	Destroy before Flowering or prevent from Flowering
Monitoring Zone	**From** 14 days prior to the expected commencement of Flowering of any GMOs* **until** the Planting Area, Pollen Trap and Monitoring Zone are Cleaned	At least once every 35 days	Volunteers and Related Species	Destroy before Flowering or prevent from Flowering or Destroy the GMOs in the Planting Area
Isolation Zone	**From** 14 days prior to the expected commencement of Flowering of any GMOs* **until** all GMOs in the Planting Area have finished Flowering	At least once every 35 days	Intentionally planted Related Species	Destroy before Flowering or prevent from Flowering or Destroy the GMOs in the Planting Area

**Condition 57(a) requires the licence holder to provide information to the Regulator on the expected Flowering period, however the inspection period should be based on the observed development of the GMOs, so that inspections commence prior to Flowering of any GMOs.*

Note: Details of any inspection activity must be recorded in a Logbook as detailed in Condition 51.

33. If conditions regarding the area of the Isolation Zone defined as the Monitoring Zone are inconsistent with the requirements regarding the Isolation Zone, then the conditions for the Monitoring Zone prevail.

34. Non-GM Canola grown in a Planting Area must be handled as if it were the GMO.

35. The licence holder must notify the Regulator in writing as soon as reasonably practicable of any Extreme Weather Event that could cause or has led to the dispersal of GMOs beyond areas requiring Cleaning.

Note: The Contingency Plan must be implemented if the GMOs are detected beyond areas requiring Cleaning (Condition 55).

Controls during processing or experimentation with GMOs

36. If not conducted in accordance with NLRD requirements, the following activities with the GMOs may only be undertaken within:

a. a Planting Area, Pollen Trap or Monitoring Zone prior to post-harvest Cleaning: experimentation, analysis, threshing or processing; or

b. a Facility approved in writing by the Regulator: experimentation, analysis, storage, threshing or processing.

Note: Dealings conducted in accordance with Notifiable Low Risk Dealings (*NLRD) requirements must be assessed by an institutional biosafety committee (IBC) before commencement and must comply with the requirements of the Gene Technology Regulations 2001.*

37. Within a Facility approved under the preceding conditions, any area that is used for experimentation, analysis, threshing, storage or processing of the GMOs must be Cleaned as soon as practicable and before use for any other purpose.

38. GMOs not required for further experimentation or future planting under this licence must be Destroyed as soon as practicable.

Controls to minimise dispersal during harvest

39. GMOs must be harvested separately from any other crop.

40. Harvesting must be conducted in a manner that minimises the likelihood of dispersal of GMOs outside the Planting Area.

41. If windrowing is employed, the licence holder must take, or have taken, measures to minimise the likelihood of dispersal of the GMOs by wind or rain. Appropriate measures may include:

a. ensuring high density planting and growth of the Canola prior to windrowing; or

b. cutting/windrowing to allow maximum stubble height; or

c. use of windrow roller; or

d. appropriate site selection.

Note: Appropriate site selection includes avoidance of flood or wind-prone areas.

42. If all GMOs growing/planted in a Planting Area are Destroyed, they are taken to have been harvested for the purposes of this licence and all conditions applying to post-harvest apply equally to post-Destruction.

Controls during transport or storage of the GMOs

43. If transport or storage of the GMOs is not conducted in accordance with NLRD requirements, such activities must:

a. only occur to the extent necessary to conduct the dealings permitted by this licence or other valid authorisation; and

b. be in accordance with the Regulator's Guidelines for the Transport, Storage and Disposal of GMOs for PC2 GM plants as current at the time of transportation or storage; and

c. comply with all other conditions of this licence.

Note: Dealings conducted in accordance with NLRD requirements must be assessed by an IBC before commencement, must comply with the requirements of the Gene Technology Regulations 2001, and are not subject to the conditions of this licence.
Note: Condition 15 requires signed statements for persons transporting or disposing of the GMOs.

44. Methods and procedures used for any transportation of GMOs must be recorded, and must be provided to the Regulator, if requested.

Note: The Contingency Plan must be implemented if the GMOs are detected outside areas under inspection (Condition 55).

Conditions relating to Cleaning

45. Areas of land used in connection with the GMOs must be Cleaned as follows:

Areas to be Cleaned	When
a. Planting Area, Pollen Trap and Monitoring Zone	Within 14 days after harvest of the GMOs

b.	any area where the GMOs have dispersed during planting, growing, harvesting or burial	As soon as practicable
c.	any area used to Clean any Equipment used in connection with the GMOs	
d.	any area used to Destroy any GMOs	
e.	any Facility used to store or experiment with the GMO	As soon as practicable and before use for any other purpose

Note: Areas of land that have been Cleaned are also subject to inspections (Condition 50), and Cleaning activities must be recorded and provided to the Regulator [Condition 57(e)].

46. Any Equipment used in connection with the GMOs must be Cleaned as soon as practicable and before use for any other purpose.

Note: If GM seeds are or might have been dispersed around the burial pit during burial, this area will require cleaning under Condition 45, and post-cleaning licence conditions will apply.

Conditions relating to Destruction by burial

47. Burial must be conducted in a manner that minimises the likelihood of dispersal of GMOs outside the Burial Site.

48. If Destruction of the GMOs occurs by burial:

a. the GMOs must be buried in a pit and covered by a layer of soil at least 1 m in depth, the top of which is no higher than the soil surface surrounding the Burial Site;

b. seeds should be sufficiently irrigated at time of burial to encourage decomposition;

c. within 14 days of burial, the Regulator must be provided a written notice with the precise location of the Burial Site (GPS coordinates and either a street address or other directions), the date on which burial occurred and a broad description of the GMOs buried (Planting Area and year the GMOs were planted);

d. the Burial Site must not be intentionally disturbed for a period of at least 2 years from the date of burial; and

e. the Burial Site must be inspected during this period to identify any significant disturbance, and, if disturbance is identified, take appropriate remedial action and notify the Regulator of the disturbance and the remedial action taken.

Note: Results of inspection activities are required to be recorded in a Logbook and provided to the Regulator (Condition 51).

49. Monitoring and Sign-off of the Burial Site is not required if burial takes place at a Municipal or commercial land fill and the Regulator is provided with a written notice from the manager of the land fill undertaking:

a. to bury the GMOs on the day of delivery; and

b. not to disturb the Burial Site for a period of at least 2 years from the date of burial; and

c. to notify both the licence holder and the Regulator in writing of any significant disturbance of the Burial Site within the 2 years.

Note: The Licence cannot be surrendered until Burial site conditions have been satisfied.

Controls to restrict persistence of the GMOs post-Cleaning

50. Post-Cleaning, areas of land must be inspected by people trained to recognise Volunteers. Inspections must cover the entirety of areas to be inspected. Actions must be taken as follows:

Area	Period of inspection	Inspection frequency	Inspect for	Action
Planting Area, Pollen Trap, Monitoring Zone, and other areas of land that have been Cleaned (except Facilities used for storage or experimentation)	From the day of Cleaning, until: i. the area is replanted with the GMOs; or ii. the Regulator has issued a Sign-off for the area	At least once every 35 days	Volunteers	Destroy before Flowering
Fence, if used,	During any period when livestock are grazing in the Monitoring Zone	Weekly	Damage	Repair as soon as practical to maintain exclusion of livestock

51. Details of any inspection activity must be recorded in a Logbook and must include:

    a. date of the inspections;

    b. name of the person(s) conducting the inspections;

    c. details of the experience, training or qualification that enables the person(s) to recognise Volunteers, if not already recorded in the logbook;

    d. details of areas inspected including current land use (including details of any post-harvest crops), presence of livestock and recent management practices applied (including Tillage events);

       Note: this may also include spraying or maintenance measures used to facilitate inspections for Volunteers

    e. details of the developmental stage of the GMOs while they are being grown;

    f. details of any post-harvest rainfall events including measurements at or near the area, or any irrigation events;

    g. details of any Volunteers observed during inspections or during land-management activities, including number, developmental stage and approximate position of the Volunteers within each area inspected[†];

    h. date(s) and method(s) of Destruction of or preventing Flowering of any Volunteers, including destruction of Volunteers during land-management activities; and

    i. details of any damage and any repairs to the fence (if used).

[†] Examples of acceptable ways to record the positional information for Volunteers in the Logbook include:
- descriptive text
- marking on a diagram
- indicating grid references on corresponding map/sketch.

Note: Details of Inspection activities must be provided to the Regulator [Condition 57(h)].The Regulator has developed a standardised proforma for recording inspection activities. This can be made available on request.

Use of areas post-Cleaning

52. While post-Cleaning inspection requirements apply to an area:

a. the area must be maintained in a manner appropriate to allow identification of Volunteers; and

b. the following areas must be Tilled within 60 days of harvest of the GMO at a Planting Area, unless otherwise approved in writing by the Regulator:

i. the Planting Area;

ii. the Pollen Trap, if any;

iii. 5 m around each Planting Area, or around the Pollen Trap, if used;

iv. any areas of land used to Clean Equipment used in connection with the GMO;

v. any other areas of land onto which the GMOs were dispersed;

vi. any areas used to Destroy the GMO, other than a Burial Site; and

Note: Delaying the first Tillage until at least 28 days after harvest may result in reduced persistence of seed in the soil, but Tillage may be carried out earlier.

c. any Tillage of an area must not bury the GMO to a depth of more than 5 cm; and

d. all areas requiring Tillage according to Condition 52(b) must also be Tilled at least once within the 12 months prior to submission of a Sign-off application. This Tillage must occur in conditions where germination of Volunteers is reasonably likely to ensue (e.g. immediately before or after rain or irrigation); and

Note: A period of natural rainfall may be taken as irrigation only with the agreement of the Regulator. Evidence (such as rainfall measurements, photos etc.) that the rainfall has been sufficient to promote germination should be provided.
Note: Additional Tillage [other than that required by Condition 52(d)] need not be undertaken when conditions are conducive to germination. However, Tillage in conditions of adequate soil moisture will promote germination of residual seed and reduce the size of the soil seed bank.

e. no plants may be intentionally grown in the area unless:

i. the plants are those specified in Condition 22 and planted in accordance with the conditions of this licence; or

ii. the plants are plants that are listed as post-harvest crops permitted for GM Brassica field trial sites in the OGTR Policy on Post Harvest Crops as current at the time of planting and satisfy Condition 52(a); or

iii. written approval is given by the Regulator for the plants to be grown in the area; or

iv. the Regulator has issued a Sign-off for the area.

Note: The OGTR's Policy on Post Harvest Crops can be found on the OGTR website.

53. Subject to Condition 54, livestock may be introduced for grazing only if:

a. a fence at least 1 metre high capable of excluding livestock surrounds the following areas:

i. the Planting Area plus 5 m around the Planting Area; and

ii. the Pollen Trap, if any, plus 5 m around the Pollen Trap; and

iii. any area which required cleaning under Condition 45; and

b. any gates in the fence are secured so as to exclude livestock.

Note: Grazing of the Monitoring Zone post-harvest may delay Site Sign-off (see the note for Condition 56). Fencing must also be inspected (Condition 50). Notices must be provided to the Regulator in relation to grazing of the Monitoring Zone [Condition 57(g)].

54. Livestock must not be permitted:

a. within the Monitoring Zone during the period from 2 weeks prior to the projected flowering of GMO in the Planting Area until the Planting Area, Pollen Trap and Monitoring Zone have been Cleaned; and

b. in the Planting Area or Pollen Trap at any time prior to the Regulator issuing a Sign-off for these areas.

Contingency plan

55. If any unintentional presence of the GMOs is detected beyond the areas requiring Cleaning, the Contingency Plan must be implemented.

Section 4 Sign off

56. The licence holder may make written application to the Regulator that planting restrictions and inspection requirements no longer apply to the Planting Area and other areas requiring Cleaning if:

a. all post-Cleaning inspection activities have been conducted for at least 24 months on the area,

b. conditions have been conducive for germination and detection of Volunteers; and

c. no Volunteers have been detected on this area for at least 12 months of the inspection period immediately prior to the Sign off request.

Note: A Planting Area and the aggregate of all other areas of land requiring Cleaning will be signed-off as a group rather than individually. Licence conditions require two Tillage events prior to a Sign-off application (see Condition 52).

The Regulator will take into account the management and inspection history for the Planting Area and other areas required cleaning, including post-harvest crops planted (if any), Tillage, irrigation, rainfall, application of herbicide and occurrence of volunteers, in deciding whether or not further inspections are required to manage persistence of the GMOs. Additionally, as stock grazing in the Monitoring Zone may remove Volunteers before they are observed, a site will generally not be signed off if grazing has occurred in the required 12 month Volunteer-free period.

Section 5 Reporting and Documentation

The following licence conditions are imposed to demonstrate compliance with other conditions, facilitate monitoring of compliance by staff of the OGTR, and emphasise appropriate selection of the Planting Area.

57. Notifications must be sent to the Regulator as follows:

Notice	Content of notice	Timeframe
a. Intention to Plant	i. Details of the Planting Area including size, the local government area, GPS coordinates, a street address, a diagrammatical representation of the trial sites (e.g. Google Maps) and any other descriptions. ii. The measures intended to manage pollen movement (e.g. use of pollen trap, size of the Monitoring and Isolation Zones) for each Planting Area iii. Identity of the GMOs to be planted at the Planting Area (e.g. lines or construct details). iv. Date on which the GMOs will be planted. v. Period when the GMOs and Pollen Traps are expected to Flower. vi. Period when windrowing (if applicable) and harvesting are expected to commence and the likely method of	At least 7 days prior to each planting (to be updated immediately if the notified details change)

Notice	Content of notice	Timeframe
	harvesting. vii. How all areas requiring post-Cleaning inspections are intended to be used until sign-off, including the proposed post-harvest crop(s) (if any). viii. Details of how the inspection activities will be managed, including strategies for the detection and destruction of volunteer GMOs. ix. History of how the site has been used for the previous two years.	
b. Planting	i. Actual date(s) of planting the GMOs. ii. Any changes to the details provided under part (a) of this condition.	Within 7 days of any planting
c. Windrowing (if applicable)	i. Actual date(s) of windrowing and details of measures used to minimise dispersal of the GMOs during windrowing and harvesting (Condition 41).	Within 7 days of commencement of windrowing
d. Harvest	i. Actual date(s) of harvesting the GMOs.	Within 7 days of commencement of any harvesting
e. Cleaning	i. Actual date(s) on which any areas needing Cleaning were Cleaned. ii. Method of Cleaning.	Within 7 days of completion of any Cleaning
f. Burial	i. Actual date(s) and precise location of Burial. ii. Broad description of the GMOs buried [Condition 48(c)]. iii. Record of any disturbance to the Burial Site and remedial actions taken.	Within 14 days of any burial As soon as practicable
g. Grazing (if applicable)	i. Actual date(s) on which grazing commenced or ceased.	Within 7 days of commencement and within 7 days of cessation of grazing in a Monitoring Zone
h. Inspection activities	i. Information recorded in a Logbook as per the inspection requirement table.	Within 35 days of Inspection

Note: Other reports and documents that may need to be sent to the Regulator are listed in an attachment to the licence, should the Regulator decide to issue a licence.

References

ABARES (2018). Australian Crop Report No.185, February 2018. Report No. 182. (Canberra, Australia: Department of Agriculture and Water Resources).

AOF (2014). Canola volunteer control. (New South Wales, Australia: Australian Oilseeds Federation).

Arts, J.H.E., Mommers, C., and de Heer, C. (2006). Dose-response relationships and threshold levels in skin and respiratory allergy. Critical Reviews in Toxicology *36*, 219-251.

Australian Seeds Authority Ltd. (2006). ASA technical standard for the accreditation of seed certification agencies implementing the Australian Seed Certification Scheme. (Australian Seeds Authority Ltd).

Bammer, G., and Smithson, M. (2008). Uncertainty and risk: Multidisciplinary perspectives (London: Earthscan).

Beckie, H.J., Séguin-Swartz, G., Warwick, S.I., and Johnson, E. (2004). Multiple herbicide–resistant canola can be controlled by alternative herbicides. Weed Science *52*, 152-157.

Belter, A. (2016). Long-term monitoring of field trial sites with genetically modified oilseed rape (*Brassica napus* L.) in saxony-Anhalt, Germany. Fifteen years persistence to date but no spatial dispersion. Genes *7*, 1-13.

Berkley, S.F., Hightower, A.W., Beier, R.C., Fleming, D.W., Brokopp, C.D., Ivie, G.W., and Broome, C.V. (1986). Dermatitis in grocery workers associated with high natural concentrations of furanocoumarins in celery. Annals of Internal Medicine *105*, 351-355.

Busi, R., and Powles, S.B. (2016). Transgenic glyphosate-resistant canola (*Brassica napus*) can persist outside agricultural fields in Australia. Agriculture, Ecosystems & Environment *220*, 28-34.

Cai, L., Zhou, B., Guo, X., Dong, C., Hu, X., Hou, M., and Liu, S. (2008). Pollen-mediated gene flow in Chinese commercial fields of glufosinate-resistant canola (*Brassica napus*). Chinese Science Bulletin *53*, 2333.

Clark, A.J., and Brinkley, T. (2001). Risk management: for climate, agriculture and policy. (Canberra: Commonwealth of Australia).

Cox, C. (1994). Herbicide factsheet - Dicamba. Journal of Pesticide Reform *14*, 30 - 35.

CropLife Australia (2015). Herbicide mode of action groups. (CropLife Australia) Accessed.

Darmency, H., and Fleury, A. (2000). Mating system in *Hirschfeldia incana* and hybridisation to oilseed rape. Weed Research *40*, 231-238.

Darmency, H., Lefol, E., and Fleury, A. (1998). Spontaneous hybridisations between oilseed rape and wild radish. Molecular Ecology *7*, 1467-1473.

Dietz-Pfeilstetter, A., and Zwerger, P. (2009). In-field frequencies and characteristics of oilseed rape with double herbicide resistance. Environmental Biosafety Research *8*, 101-111.

DPI NSW (2013). Winter crop variety sowing guide 2013. (Department of Primary Industries, NSW, Australia).

EFSA (2013). Scientific opinion on application EFSA-GMO-NL-2011- 93 for the placing on the market of the herbicide-tolerant genetically modified soybean MON 87708 for food and feed uses, import and processing under Regulation (EC) No 1829/2003 from Monsanto. EFSA Journal *11(10)*, 3355.

Felsot, A.S. (2000). Insecticidal genes part 2: Human health hoopla. Agrichemical & Environmental News *168*, 1-7.

Ford, C.S., Allainguillaume, J., Grilli-Chantler, P., Cuccato, G., Allender, C.J., and Wilkinson, M.J. (2006). Spontaneous gene flow from rapeseed (*Brassica napus*) to wild *Brassica oleracea*. Proceedings of the Royal Society B: Biological Sciences *273*, 3111-3115.

FSANZ (2012). Approval Report A1063 - Food derived from herbicide tolerant soybean line MON 87708. (Canberra: Food Standards Australia New Zealand).

FSANZ (2013a). Approval report - Application A1080. Food derived from herbicide-tolerant cotton line MON 88701. (Canberra: Food Standards Australia New Zealand).

FSANZ (2013b). Safety assessment - Application A1071 (Approval): Food derived from herbicide-tolerant canola line MON88302. (Food Standard Australia New Zealand.).

FSANZ (2016). Approval Report – Application A1118: Food derived from herbicide-tolerant corn line MON87419. (Canberra, Australia: Food Standards Australia New Zealand).

Funk, T., Wenzel, G., and Schwarz, G. (2006). Outcrossing frequencies and distribution of transgenic oilseed rape (*Brassica napus* L.) in the nearest neighbourhood. European Journal of Agronomy *24*, 26-34.

GRDC (2009). Canola best practice management guide for south-eastern Australia. (Canberra, Australia: Grains Research & Development Corporation).

GRDC (2017). GRDC Northern Canola GrowNotes. (Canberra, Australia: Grains Research & Development Corporation).

Gulden, R.H., Shirtliffe, S.J., and Thomas, A.G. (2003). Secondary seed dormancy prolongs persistence of volunteer canola in western Canada. Weed Science *51*, 904-913.

Hayes, K.R. (2004). Ecological implications of GMOs: robust methodologies for ecological risk assessment. Best practice and current practice in ecological risk assessment for genetically modified organisms. (Tasmania: CSIRO Division of Marine Research).

Herman, P.L., Behrens, M., Chakraborty, S., Chrastil, B.M., Barycki, J., and Weeks, D.P. (2005). A three-component Dicamba *O*-demethylase from *Pseudomonas maltophilia*, Strain DI-6: Gene isolation, characterisation and heterologous expression. Journal of Biological Chemistry *280*, 24759-24767.

Howlett, B., Ballinger, D., and Barbetti, M. (1999). Diseases of Canola. In Canola in Australia: The first thirty years, P.A. Salisbury, T.D. Potter, G. McDonald, and A.G. Green, eds. (Australian Oilseeds Federation), pp. 47-52.

Hüsken, A., and Dietz-Pfeilstetter, A. (2007). Pollen-mediated intraspecific gene flow from herbicide resistant oilseed rape (*Brassica napus* L.). Transgenic Research *16*, 557-569.

Keese, P.K., Robold, A.V., Myers, R.C., Weisman, S., and Smith, J. (2014). Applying a weed risk assessment approach to GM crops. Transgenic Research *23*, 957-969.

Liu, Y.B., Wei, W., Ma, K.P., and Darmency, H. (2010). Backcrosses to *Brassica napus* of hybrids between *B. juncea* and *B. napus* as a source of herbicide-resistant volunteer-like feral populations. Plant Science *179*, 459-465.

Miles, M., and McDonald, G. (1999). Insect Pests. In Canola in Australia: The First Thirty Years, P.A. Salisbury, T.D. Potter, G. McDonald, and A.G. Green, eds., pp. 53-58.

Morris, W., Kareiva, P., and Raymer, P.L. (1994). Do barren zones and pollen traps reduce gene escape from transgenic crops? Ecological Applications *4*, 157-165.

OECD (2008). OECD Seed Schemes 2008. (Organisation for Economic Co-operation and Development).

OECD (2011). Revised consensus document on compositional considerations for new varieties of low erucic acid rapeseed (canola): Key food and feed nutrients, anti-nutrients and toxicants. Report No. ENV/JM/MONO(2011)55, Organisation for Economic Cooperation and Development (OECD).

OGTR (2011). Risk Assessment and Risk Management Plan for DIR 108: Commercial release of canola genetically modified for herbicide tolerance and a hybrid breeding system (InVigor® x Roundup Ready® canola). (Canberra, Australia: Office of Gene Technology Regulator).

OGTR (2013a). Risk Analysis Framework 2013, 4th edn (Canberra: Office of the Gene Technology Regulator).

OGTR (2013b). Risk Assessment and Risk Management Plan for DIR 120: Limited and controlled release of cotton genetically modified for insect resistance and herbicide tolerance. (Canberra, Australia: Office of the Gene Technology Regulator).

OGTR (2014). Risk Assessment and Risk Management Plan for DIR 127: Commercial release of canola genetically modified for herbicide tolerance (MON 88302).

OGTR (2016a). Risk Assessment and Risk Management Plan for DIR 138: Commercial release of canola genetically modified for dual herbicide tolerance and a hybrid breeding system (InVigor® x TruFlex™ Roundup Ready®). (Canberra, Australia: Office of the Gene Technology Regulator).

OGTR (2016b). Risk Assessment and Risk Management Plan for DIR 145: Commercial release of cotton genetically modified for insect resistance and herbicide tolerance [Bollgard® 3 XtendFlex™ (SYN-IR102-7 x MON 15985-7 x MON-88913-8 x MON 88701-3) and XtendFlex™ (MON-88913-8 x MON 88701-3) cotton]. (Canberra, Australia: Office of the Gene Technology Regulator).

OGTR (2017). The Biology of *Brassica napus* L. (canola) and *Brassica juncea* (L.) Czern. & Coss. (Indian mustard). (Canberra, Australia: Office of the Gene Technology Regulator).

OGTR (2018a). Risk Assessment and Risk Management Plan for DIR 155: Commercial release of canola genetically modified for omega-3 oil content (DHA canola NS-B5ØØ27-4). (Canberra, Australia: Office of the Gene Technology Regulator).

OGTR (2018b). Risk assessment reference: Methods of plant genetic modification. (Canberra, Australia: Office of the gene Technology Regulator).

Pivard, S., Adamczyk, K., Lecomte, J., Lavigne, C., Bouvier, A., Deville, A., Gouyon, P.H.*, et al.* (2008). Where do the feral oilseed rape populations come from? A large-scale study of their possible origin in a farmland area. Journal of Applied Ecology *45*, 476-485.

Reboud, X. (2003). Effect of a gap on gene flow between otherwise adjacent transgenic *Brassica napus* crops. Theoretical and Applied Genetics *106*, 1048-1058.

Rieger, M.A., Lamond, M., Preston, C., Powles, S.B., and Roush, R. (2002). Pollen-mediated movement of herbicide resistance between commercial canola fields. Science *296*, 2386-2388.

Ryan, R.P., Monchy, S., Cardinale, M., Taghavi, S., Crossman, L., Avison, M.B., Berg, G.*, et al.* (2009). The versatility and adaptation of bacteria from the genus Stenotrophomonas. Nat Rev Microbiol *7*, 514-525.

Salisbury, P.A. (2002). Genetically modified canola in Australia: agronomic and environmental considerations (Australian Oilseed Federation, Melbourne, Australia).

Schnell, J., Steele, M., Bean, J., Neuspiel, M., Girard, C., Dormann, N., Pearson, C.*, et al.* (2015). A comparative analysis of insertional effects in genetically engineered plants: considerations for pre-market assessments. Transgenic Research *24*, 1-17.

Seligman, P.J., Mathias, C.G.T., O'Malley, M.A., Beier, R.C., Fehrs, L.J., Serrill, W.S., and Halperin, W.E. (1987). Phytophotodermatitis from celery among grocery store workers. Archives of Dermatology *123*, 1478-1482.

Senior, I.J., Moyes, C., and Dale, P.J. (2002). Herbicide sensitivity of transgenic multiple herbicide-tolerant oilseed rape. Pest Management Science *58*, 405-412.

Simard, M.J., Legere, A., Seguin-Swartz, G., and Nair, H. (2005). Fitness of double vs. single herbicide-resistant canola. Weed Science *53*, 489-498.

Society of Toxicology (2003). Society of Toxicology position paper: The safety of genetically modified foods produced through biotechnology. Toxicological Sciences *71*, 2-8.

Standards Australia, Standards New Zealand, and CRC for Australian Weed Management (2006). HB 294:2006 National Post-Border Weed Risk Management Protocol (Standards Australia and Standards New Zealand).

Staniland, B.K., McVetty, P.B.E., Friesen, L.F., Yarrow, S., Freyssinet, G., and Freyssinet, M. (2000). Effectiveness of border areas in confining the spread of transgenic *Brassica napus* pollen. Canadian Journal of Plant Science *80*, 521-526.

Steiner, H.Y., Halpin, C., Jez, J.M., Kough, J., Parrott, W., Underhill, L., Weber, N.*, et al.* (2013). Evaluating the potential for adverse interactions within genetically engineered breeding stacks. Plant Physiology *161*, 1587-1594.

Twigg, L.E., Lowe, T.J., Taylor, C.M., Calver, M.C., Martin, G.R., Stevenson, C., and How, R. (2009). The potential of seed-eating birds to spread viable seeds of weeds and other undesirable plants. Austral Ecology *34*, 805-820.

Twigg, L.E., Taylor, C.M., Lowe, T.J., and Calver, M.C. (2008). Can seed-eating birds spread viable canola seed? Pacific Conservation Biology *14*, 119-127.

USDA-APHIS (2014). Monsanto petitions (10-188-01p and 12-185-01p) for determination of nonregulated status of dicamba-resistant soybean and cotton varieities. Final Environmental Impact Statement. (United States Department of Agriculture Animal and Plant Health Inspection Service).

USDA-APHIS (2016). Monsanto petition (15-113-01p) for determination of nonregulated status of dicamba and glufosinate herbicide-resistant MON 87419 maize - Plant pest risk assessment. (Washington, USA: U.S. Department of Agriculture).

Walton, G., Mendham, M., Robertson, M., and Potter, T. (1999). Phenology, physiology and agronomy. In Canola in Australia: the first thirty years, P. Salisbury, T. Potter, G. McDonald, and A.G. Green, eds. (10th International Rapeseed Congress Organising Committee), pp. 9-14.

Wang, C., Glenn, K.C., Kessenich, C., Bell, E., Burzio, L.A., Koch, M.S., Li, B.*, et al.* (2016). Safety assessment of dicamba mono-oxygenases that confer dicamba tolerance to various crops. Regul Toxicol Pharmacol *81*, 171-182.

Warwick, S.I., Legere, A., Simard, M.J., and James, T. (2007). Do escaped transgenes persist in nature? The case of an herbicide resistance transgene in a weedy Brassica rapa population. Mol Ecol *17*, 1387-1395.

Warwick, S.I., Simard, M.J., Légère, A., Beckie, H.J., Braun, L., Zhu, B., Mason, P.*, et al.* (2003). Hybridization between transgenic *Brassica napus* L. and its wild relatives: *Brassica rapa* L., *Raphanus raphanistrum* L., *Sinapis arvensis* L., and *Erucastrum gallicum* (Willd.) O.E. Schulz. Theoretical and Applied Genetics *107*, 528-539.

Williams, I.H. (2001). Bee-mediated pollen and gene flow from GM plants. Acta Horticulturae *561*, 25-33.

Yoshimura, Y., Beckie, H.J., and Matsuo, K. (2006). Transgenic oilseed rape along transportation routes and port of Vancouver in western Canada. Environmental and Biosafety Research *5*, 67-75.