Australian Government
Department of Health
Office of the Gene Technology Regulator

February 2022

Risk Assessment and Risk Management Plan (consultation version)

for

Register 003

Inclusion of dealings with MON-ØØØ73-7 canola, genetically modified for herbicide tolerance, on the GMO Register

This RARMP is open for consultation until 31 March 2022

Written comments on the risks to human health and safety and the environment posed by this initiative 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

Section 1 *Legislation*

1. The *Gene Technology Act 2000* (the Act) contains a number of requirements related to the GMO Register. There must be a Register (The Register) which must be maintained by the Gene Technology Regulator (the Regulator) (s76). For any dealing included on The Register, the Regulator must specify a description of the dealing with the genetically modified organism (GMO); and any condition to which the dealing is subject (s77).

2. The Regulator may, by a legislative instrument, determine that a dealing with a GMO is to be included on the GMO Register. To do so, the Regulator must be satisfied that the dealing is, or has been, authorised by a GMO licence; or the GMO concerned is a genetically modified (GM) product and is a GMO only because of regulations made under the definition (s10) of ***genetically modified organism***. This decision may be made in response to an application by the licence holder or on the initiative of the Regulator (s78(2)). The decision to include dealings on the GMO Register comes into effect on the day specified in the decision (s78(3)).

3. The Regulator must not decide to include dealings with a GMO on the GMO Register unless satisfied that any risks posed by the dealing are minimal; and that it is not necessary for persons undertaking the dealing to hold, or be covered by a GMO licence, in order to protect the health and safety of people or to protect the environment (s79(1)).

4. The Regulator must consider any available data about adverse effects posed by the dealing; other information as to risks associated with the dealing including information provided to the Regulator by a licence holder (s65) or by another person (s66); whether there is a need for the dealing to be subject to conditions; any other information in relation to whether the dealing should be authorised by a GMO licence (s79(2)). The Regulator may have regard to other matters they consider relevant (s79(3)).

5. Currently there are two entries in the GMO Register - Register 001/2004 and Register 002. Register 001/2004 authorises dealings for commercial release of four lines of colour modified GM carnations. The dealings included on the Register are: conducting experiments with the GMO; making, developing, producing or manufacturing, breeding and propagating the GMO; using the GMO in the course of manufacture of a thing that is not the GMO; growing, raising or culturing, importing, transporting and disposing of the GMO; and the possession, supply or use of the GMO for the purpose of, or in the course of, a dealing mentioned. Register 002 authorises dealings with cut flowers from three lines of colour modified GM carnations including import, transport and disposal, and possession or supply of the GMO in the course of any of those dealings.

6. The consideration of Register 003 to include the MON-ØØØ73-7 canola in the GMO Register is on the initiative of the Regulator (s78(2)(b)).

Section 2 *Background*

2.1 MON-ØØØ73-7 canola

7. The GM canola is genetically modified for glyphosate herbicide tolerance. It is known by the unique identifier MON-ØØØ73-7 assigned by the Organisation for Economic Co-operation and Development (OECD), and also known as Roundup Ready® canola, event GT73 (RT73), RT73 canola or oilseed rape GT73.

8. MON-ØØØ73-7 canola is currently authorised for commercial release in Australia under licence DIR 020/2002, issued in 2003 to Monsanto Australia Limited. The dealings permitted include: conducting experiments with the GMO; making, developing, producing or manufacturing, breeding and propagating the GMO; using the GMO in the course of manufacture of a thing that is not the GMO; growing, raising or culturing, importing, transporting and disposing of the GMO; and the possession, supply or use of the GMO

for the purpose of, or in the course of, a dealing mentioned. The Risk Assessment and Risk Management Plan (RARMP) for DIR 020/2002 was published in December 2003.

9. MON-ØØØ73-7 canola was most recently assessed in the RARMP for licence DIR 108, which authorises the commercial release of InVigor® × Roundup Ready® canola. The RARMP for DIR 108 was published in December 2011. Prior to this, InVigor® × Roundup Ready® canola was authorised for limited and controlled release (field trial) under the licence DIR 104.

10. This RARMP, prepared as part of the consideration to include dealings with MON-ØØØ73-7 canola on the GMO Register, provides background information on the GMO, outlines the conclusions of the RARMPs for DIR 020/2002 and DIR 108, surveys relevant information about the GMO that has emerged since the DIR 108 RARMP was published in 2011, and assesses whether this information indicates any new risks or increased levels of risk from GMO. The purpose of this RARMP is to provide information for the Regulator to decide whether the level of risk is such that it is not necessary for persons undertaking the dealings to hold, or be covered by a GMO licence, in order to protect the health and safety of people and the environment. If the Regulator decides that this is the case, then inclusion of dealings with MON-ØØØ73-7 canola on the GMO Register is appropriate.

2.2 The genetic modifications

11. MON-ØØØ73-7 canola was genetically modified to express two genes conferring tolerance to the herbicide glyphosate. The two introduced genes, *goxv247* and *cp4 epsps*, as well as other genetic elements and source organisms, are listed in Table 1.

Table 1 Introduced genes and other genetic elements in MON-ØØØ73-7 canola

Gene (source)	Promoter (source)	Terminator (source)	Additional elements (source)	Protein produced	Protein function
cp4 epsps (*Agrobacterium* sp. strain CP4)	*P- CMoVb* (Figwort mosaic virus)	*E9 3'* (*P. sativum*)	AEPSPS/CTP2 *(Arabidopsis thaliana*)	CP4 EPSPS	Reduced affinity to glyphosate
goxv247 (Ochrobactrum anthropi strain LBAA)	P-CMoVb (Figwort mosaic virus)	*E9 3'* (*P. sativum*)	SSU1A/CTP1 (*Arabidopsis thaliana*)	GOX	Detoxifying glyphosate

12. The detailed descriptions of the two introduced genes and other genetic elements can be found in the RARMPs for DIR 020/2002 and DIR 108.

2.3 Experience with cultivation of MON-ØØØ73-7 canola

2.3.1 Cultivation of canola

13. Canola (*Brassica napus L.*) is exotic to Australia and has been grown in Australia as an agricultural crop since the 1970s. Canola is cultivated mainly for its seed, to produce canola oil for human consumption as cooking oil or food ingredient, and canola meal as animal feed (GRDC, 2017).

14. The area sown to canola in Australia increased considerably in the 1990s with the introduction of improved varieties, agronomic developments and good prices (Colton and Potter, 1999), peaking in 2013 with over 3.27 million hectares (ha) harvested (FAOSTAT website, accessed November 2021). The total Australian canola planting area, including both GM and non-GM canola, was 2.03 million ha in 2020 and is estimated to have increased to 2.45 million ha in 2021 (ABARES, 2021).

2.3.2 Approvals for MON-ØØØ73-7 canola

15. Canada was the first country to commercially plant MON-ØØØ73-7 canola in 1996 (Canola Council of Canada) and Australia started commercially growing MON-ØØØ73-7 canola in 2008 (Salisbury et al., 2016). In addition, MON-ØØØ73-7 canola has been commercially grown in the USA (Fernandez-Cornejo et al., 2016), with cultivation also approved in Japan (ISAAA, 2018). However, no GM crops are commercially cultivated in Japan (Matsushita et al., 2020). Globally, GM canola, including MON-ØØØ73-7, was grown on 10.1 million hectares in 2018, which accounted for 29% of all canola production in that year (ISAAA, 2018). Authorisations of MON-ØØØ73-7 canola globally for food and feed use and for commercial cultivation are summarised in Table 2 below.

Table 2 International approvals of MON-ØØØ73-7 canola*

Country	Food	Feed	Cultivation
Canada	1994	1995	1995
China	2002	2002	
European Union	1997	2007	
Iran	2019		
Japan	2001	2003	2006
Malaysia	2020	2020	
Mexico	1996		
New Zealand	2000		
Philippines	2003	2003	
Singapore	2014	2014	
South Korea	2003	2005	
Taiwan	2015		
USA	1995	1995	1999
Vietnam	2020	2020	

*Information from GMO databases: ISAAA GMO database; Biosafety Clearing House database; EU GMO Register; Biotrack Product Database. The years of approval refer only to the initial approvals; authorisation renewal years are not shown.

16. In Australia to date, all production of MON-ØØØ73-7 canola is carried out under licence DIR 020/2002. There has been no commercial production of GM canola with the GT73 event under licence DIR-108 (OGTR, 2021). The area of MON-ØØØ73-7 canola planted annually in Australia since first plantings in 2008, is presented in Table 3, with data collected from the annual briefs on the global status of commercialised biotech/GM Crops (ISAAA) and annual reports submitted to the OGTR by the licence holder as part of DIR 020/2002 licence conditions.

17. Food from MON-ØØØ73-7 canola has been approved for human consumption by Food Standards Australia New Zealand (FSANZ) (ANZFA, 2000).

Table 3 Areas of MON-ØØØ73-7 canola planted in Australia since 2008

Year	Hectares	Year	Hectares
2008	9,500	2015	443,069
2009	41,200	2016	446,226
2010	133,330	2017	491,528
2011	139,150	2018	499,000
2012	181,030	2019	529,600*
2013	222,361	2020	434200*
2014	342,000		

*Information provided by the Monsanto Australia Ltd in annual reports, available on the OGTR website. As only the amount of seed planted (kg) was provided in the reports, these approximate planted area figures were derived using the seeding rate of 2kg seed/ha (OGTR, 2017).

2.3.3 Previous Risk Assessments

18. The weed risk potential of canola has been assessed using methodology based on the *National Post-Border Weed Risk Management Protocol* (see Appendix 1, OGTR, 2017). As a volunteer (rather than as a crop), non-GM canola is considered to exhibit the following potential to cause harm:

- low potential to negatively affect the health of animals and/or people
- limited ability to reduce the establishment or yield of desired plants
- low ability to reduce the quality of products or services obtained from land uses
- moderate potential to act as a reservoir for pests or pathogens (OGTR, 2017).

19. The RARMPs for DIR 020/2002 and DIR 108 both concluded that the commercial release of the GM canola varieties containing the GT73 event (MON-ØØØ73-7) posed negligible risks to human health and safety and the environment and as such no specific risk treatment measures were imposed.

20. The RARMPs for DIR 020/2002 and DIR 108 considered information on the introduced *goxv247* and *cp4 epsps* genes and the pathways in which they are involved, the proteins encoded by the genes, the stability of the transgenes, detailed molecular characterisation and phenotypic characterisation. Credible pathways to harm considered in the RARMPs included exposure of people or other organisms through contact with or ingestion of GM canola, spread and persistence of GM canola plants in agricultural areas and in undisturbed natural habitats, gene transfer to other canola plants and related species (including weedy species), leading to increased toxicity or allergenicity in people or increased toxicity in other desirable organisms, reduced establishment, yield and/or quality of desirable plants, and impact on biodiversity.

21. The principal reasons for the conclusion of negligible risks were:

- the introduced proteins are not considered toxic or allergenic to people, or toxic to other desirable organisms
- the GM canola and other GM crops containing the introduced *goxv247* and *cp4 epsps* genes have a history of safe use in Australia and overseas
- the same or similar proteins encoded by the introduced genes are widespread in the environment

- the GM canola and its progeny can be controlled using integrated weed management practices
- the GM canola has limited capacity to survive in undisturbed natural habitats.

22. In addition, food made from the GM canola has been assessed and approved by FSANZ as safe for human consumption (ANZFA, 2000).

Section 3 *Risk assessment: evaluation of new information*

3.1 Information received as part of DIR 020/2002 licence conditions

23. DIR licence conditions require reporting by the licence holder of any information about any adverse impacts, unintended effects, or new information relating to risks to human health and safety or the environment caused by the GMOs or material from the GMOs. There have been no reports of any adverse or unintended effects from commercial cultivation of MON-ØØØ73-7 canola in the Annual Reports for DIR 020/2002 since 2008, when MON-ØØØ73-7 canola was first planted in Australia.

24. Since licence DIR 020/2002 was issued in 2003 and planting commenced under this licence in 2008, the Regulator has not received any other reports of adverse impacts, unintended effects, or new information relating to risks, to human health and safety or the environment caused by commercial cultivation of MON-ØØØ73-7 canola or material from the GM canola containing the GT73 event.

3.2 Plant database searches

25. Despite a long history of commercial cultivation, *Brassica napus* is not a significant weedy species in Australia. It is not recorded in the *Weeds of National Significance* list (Weeds Australia website, accessed November 2021), the *National Environmental Alert List* (Weeds Australia website, accessed November 2021) or the Noxious Weed List for Australian States and Territories (Invasive Plants and Animals Committee, 2015). The introduction of GM canola (mainly herbicide tolerant varieties) in the Australian cropping system has not changed this status. The Western Australian Department of Parks and Wildlife lists feral canola as one of 60 weeds that threaten rail and roadside vegetation by lowering the biodiversity and aesthetic value of the verge, and recommends that management of these weeds be a priority along roads of high conservation value (Roadside Conservation Committee, 2014). However, a latest national weeds data collection survey conducted by ABARES showed that canola is not listed as an established weed causing agricultural, social or environmental impacts by weed managers around Australia (Ng et al., 2021), indicating that feral canola was not a weed of national concern.

26. The following plant databases were also accessed in November 2021 to search for records of *B. napus* in Australia during the period from 2003 (the licence for DIR 020/2002 was issued in December 2003) to 2021:

- Global Biodiversity Information Facility (GBIF) Backbone Taxonomy. (GBIF Secretariat - https://doi.org/10.15468/39omei Accessed via https://www.gbif.org/occurrence/search?continent=OCEANIA&taxon_key=3042636&year=2003,2021). Four occurrences listed for *B. napus* from 2003 to 2021 in Oceania.
- Atlas of Living Australia (ALA - https://www.ala.org.au/) showed over 400 records across all states in Australia except for Northern Territory without indication of weedy populations.
- The Australasian Virtual Herbarium (AVH - https://avh.chah.org.au/) contained over 250 records across all states in Australia except for Northern Territory without indication of weedy populations.
- Individual state floral databases of NSW, Victoria, South Australia, Queensland and Western Australia (many of which feed into AVH and ALA) record *B. napus* as naturalised.

27. The information available across these databases confirms that *B. napus* has naturalised in all states in Australia, other than Northern Territory, mainly as a result of occasional escape from cultivation. However, it is apparent that no weedy populations have established in Australia since the previous review made under DIR 020/2002 and the presence of such populations is considered in each RARMP for canola.

3.3 Evaluation of new information regarding risk

28. Literature searches to find information published since 2011 were conducted mainly in Google Scholar, but also in Semantic Scholar, NAL Online - AGRICOLA, Proquest (Agriculture and Environment), and Science Direct using the following key words (and combinations of these): canola, rapeseed, oilseed rape, GT73, RT73, MON-ØØØ73-7, roundup ready canola, glyphosate tolerant canola, glyphosate resistant canola, cp4 epsps, goxv247, toxicity, adverse effects, environmental impacts and human health.

3.3.1 Risks to health and safety of people and animals

29. The literature searches did not produce new evidence to support negative effects to human health as a result of growing and consuming MON-ØØØ73-7 canola worldwide. No credible evidence was found to suggest that MON-ØØØ73-7 canola is harmful to humans or livestock or other grazing animals, nor were there any credible reports of any adverse effects from human consumption of oil derived from MON-ØØØ73-7 canola or feeding MON-ØØØ73-7 canola to livestock since its commercialisation in Canada in 1996.

30. There is some recent literature about herbicide use associated with growing glyphosate-tolerant crops. However, issues regarding effects of herbicides on human health, including glyphosate residues present in GM herbicide-tolerant crops (such as MON-ØØØ73-7 canola) following cultivation, are outside the scope of the Act, and come under the regulatory oversight of the Australian Pesticides and Veterinary Medicines Authority (APVMA). Further information on the use of glyphosate is available on the APVMA website.

3.3.2 Weediness

31. In Australia, a study of roadside canola plants found that under favourable climatic conditions and in circumstances where other roadside weeds are controlled by glyphosate, roadside populations of glyphosate-tolerant (GT) canola (identified as MON-ØØØ73-7) could persist for at least three years, but no hybrids between GT canola and conventionally bred canola tolerant to triazines or imidazolinone were found (Busi and Powles, 2016). The study also found that when GT canola seeds were dispersed into two natural areas, feral canola populations survived for 0 and 3 years, respectively, prior to extinction. This is consistent with the fact that canola is not a persistent weed in natural undisturbed habitats, so when GT canola was found in bushland, no fitness advantage was conferred by the introduced transgenes. The GT canola volunteers in agricultural areas have been controlled using integrated weed management practices, which include using a variety of other herbicides assessed and approved by the APVMA, as well as nonchemical management methods currently used to control non-GM canola, such as mowing, grazing or cultivation (Australian Oilseeds Federation, 2019).

32. Experience in Canada after 15 years of growing herbicide-tolerant (HT) canola, including GT canola, was that management of canola volunteers was no more of a problem with GM HT cultivars than non-HT cultivars and no increase in herbicide costs were associated with management of HT canola volunteers. However, management of HT canola was the same as any other option for managing weeds and, as part of the overall strategy, HT canola need to be managed carefully in rotations with herbicide use to avoid increasing pressure for selection of herbicide resistance weeds (Beckie et al., 2011). Also, no invasions of natural areas were reported (Beckie et al., 2011).

33. In the USA, following commercial cultivation of GM HT cultivars, including MON-ØØØ73-7 canola, the presence of large, widespread populations of feral GT canola along roadsides in canola-growing regions was confirmed, which indicated the dispersal of GM canola outside cultivation (Schafer et al., 2011; Munier et al., 2012). In addition, hybridisation or stacking of glyphosate tolerance genes with a glufosinate-tolerance gene was observed in feral canola populations (Schafer et al., 2011). Secondary dormancy of canola seed through shallow burial and tolerance to glyphosate made GT canola volunteers weedier in certain regions where there are restrictions on phenoxy herbicide use (Munier et al., 2012).

34. In the European Union (EU) and many other countries listed in Table 2, MON-ØØØ73-7 canola seed is authorised to be imported for processing and use as human food and/or animal feed but not for cultivation. However, volunteer or feral GT canola, including MON-ØØØ73-7, has been reported in countries such as Austria, Switzerland, Latvia, Japan and South Korea, established through various means including inadvertent seed import spills (dispersal from unloading, handling and transportation) and as seed contaminants in other seed imports (Hecht et al., 2014; Schulze et al., 2014; Pascher et al., 2017; Grantina-Ievina et al., 2019; Rostoks et al., 2019; Umurzokov et al., 2019; Chen et al., 2020). While canola has characteristics such as secondary dormancy and small seed size that enable it to persist and be redistributed in the landscape, the presence of feral canola, including HT canola such as MON-ØØØ73-7, is not in itself an environmental or economic problem in Europe (Devos et al., 2012).

35. In Argentina, GM canola is banned from importation and cultivation, but MON-ØØØ73-7 canola has been found to invade the fields of other crops, such as GT soybeans (Pandolfo et al., 2016). Also, gene flow of HT genes have been shown to occur between MON-ØØØ73-7 canola and *Brassica rapa* (Pandolfo et al., 2018). However, these GT plants can be controlled by integrated weed management practices, including the use of alternative herbicides in various situations and crops.

36. Based on the available information and experience, it can be concluded that while MON-ØØØ73-7 plants can be considered a weed in certain contexts, it is not considered to be invasive or problematic weed outside agricultural systems. MON-ØØØ73-7 plants can persist under favourable conditions and may at times require management, particularly when they volunteer in subsequent crops. However, no reports were found indicating that volunteer MON-ØØØ73-7 canola was difficult to control in the environment under either agricultural or natural conditions.

3.3.3 Glyphosate resistant weeds

37. Some concerns have been raised regarding the potential increase of glyphosate resistant weeds as a result of gene flow from GT crops (Mallory-Smith and Zapiola, 2008).

38. In Australia, there are at least 21 glyphosate resistant weed species recorded (Heap, 2020). The list of herbicide resistant weeds in Australia prepared by CropLife Australia (accessed November 2021), indicates that the most commonly found glyphosate-resistant weeds are mostly grass weeds and some broadleaf weeds such as sowthistle and fleabane. Among the related Brassicaceae weeds including wild radish (*Raphanus raphanistrum*), Buchan weed (*Hirschfeldia incana*) and charlock (*Sinapis arvensis*), only three populations of glyphosate-resistant wild radish are recorded on the list. However, there has been no published evidence of gene flow occurring from MON-ØØØ73-7 canola to any weedy plant species in Australia.

39. In Canada, no evidence of gene flow from HT canola to related crucifers was reported. However, herbicide resistance was transmitted to its close relative, bird's rape (*Brassica rapa*), in the wild but that well-managed planting of HT canola would not promote herbicide-resistant weeds (Beckie et al., 2011).

3.3.4 International risk assessments published

40. Since the licence DIR 020/2002 was issued, the European Food Safety Authority (EFSA) has assessed oilseed rape GT73 (MON-ØØØ73-7) and concluded that it was as safe as conventional oilseed rape for

humans and animals, and for the environment in the context of the proposed use (EFSA, 2004). The European Union authorised the import, processing and use of oilseed rape GT73 and derived products for animal feed in 2005, with a validity period of 10 years[1]. For renewal of this authorisation, EFSA assessed all available new data in 2020 and concluded that there is no evidence of any new hazards, modified exposure or scientific uncertainties that would change the conclusions of the original risk assessment on oilseed rape GT73 made in 2004 (EFSA, 2020). The EU renewed the authorisation in 2021 for 10 years[2]. In addition, EFSA has also assessed oilseed rape GT73 for renewal of the authorisation for continued marketing of existing food and feed ingredients, feed materials, feed additives and food additives produced from oilseed rape GT73 (EFSA, 2009), and for food containing or consisting of, and food produced from, or containing ingredients produced from, oilseed rape GT73 (EFSA, 2013). Each of these assessments concluded that there is no direct harm to human and animal health as a consequence of consuming food or feed produced from or containing oilseed rape GT73.

41. Decision and consent documents relating to authorisation for grain import into the EU, and processing and food and feed use of the oilseed rape GT73 can be found on the European Commission (EC) website (Community register of GM food and feed).

42. The Philippines issued a new Biosafety Permit in 2019 following a new biosafety assessment for direct use as food, feed or for processing of RT73 canola (MON-ØØØ73-7). Malaysia also approved importation of RT73 canola for sale/placing on the market for direct use as food, feed and for processing in 2020 following a risk assessment by its Genetic Modification Advisory Committee. Although the published information from these assessments is brief, the risk assessments did not identify any new risks, and concluded that RT73 canola is as safe for human food and animal feed, and the environment as its conventional counterpart.

43. Following the approval for unconfined release of GT73 canola (MON-ØØØ73-7) into the environment, including feed use, by the Canadian Food Inspection Agency in 1995 and the approval for food use of GT73 canola by Health Canada in 1999, no further assessments on GT73 canola have been carried out by the Canadian authorities. Likewise, following the approval for food and feed use by the US Food and Drug Administration in 1995 and the deregulation of GT73 canola by the Animal and Plant Health Inspection Services, US Department of Agriculture in 1999, no further assessments on GT73 canola have been carried out by the US authorities.

3.4 Conclusion of the risk assessment

44. Based on available information, there is no indication that any adverse or unexpected events have occurred either in Australia or in other countries where cultivation and/or import and distribution of MON-ØØØ73-7 canola has been authorised. No information was found in the literature review or from plant databases to indicate altered or increased risks to human health and safety or to the environment from MON-ØØØ73-7 canola. The conclusion of the risk assessment for DIR 020/2002 remains valid.

45. Thus, the dealings with MON-ØØØ73-7 canola represent minimal risk to human health and the environment.

Section 4 Risk management plan

46. 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.

[1] Commission Decision 2005/635/EC of 31 August 2005.
[2] Commission Decision (EU) 2021/1385 of 17 August 2021.

47. Under Section 79(1) of the Act, the Regulator must not decide to include dealings with a GMO on the GMO Register unless satisfied that any risks posed by the dealing are minimal; and it is not necessary for persons undertaking the dealing to hold, or be covered by a GMO licence, in order to protect the health and safety of people or to protect the environment.

48. A licence is not considered necessary for the proposed dealings with MON-ØØØ73-7 canola, because:

- the risk was assessed as negligible, and previous experience in dealing with MON-ØØØ73-7 canola demonstrated safe use, which indicates minimal risk as a result of gene technology; and
- neither statutory (s65 and s66 of the Act) nor application-specific licence conditions (DIR 020/2002) resulted in a finding that would justify continued licensing to manage this minimal risk.

49. If the Regulator makes a determination to include dealings with a GMO on the Register, under Section 77(b) specific conditions might be included on the GM Register to manage risks. Based on the risk assessment presented here, specific conditions to manage risks are not considered necessary.

Section 5 Conclusions of the consultation Risk Assessment and Risk Management Plan

50. The dealings with MON-ØØØ73-7 canola as authorised under the DIR 020/2002 licence pose minimal risk to the health and safety of people or the environment as a result of gene technology. No conditions are proposed if the Regulator makes a determination to include those dealings on the Register.

Section 6 Literature Cited

ABARES (2021). Australian Crop Report No. 199: September 2021. (Canberra, Australia: Australian Bureau of Agricultural and Resource Economics and Sciences).

ANZFA (2000). Final risk analysis report - Application A363: Food produced from glyphosate-tolerant canola line GT73. (Canberra, Australia: Australia New Zealand Food Authority).

Australian Oilseeds Federation (2019). Canola volunteer control 2019.

Beckie, H.J., Harker, K.N., Légère, A., Morrison, M.J., Séguin-Swartz, G., and Falk, K.C. (2011). GM canola: The Canadian experience. Farm Policy Journal *8*, 43-49.

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.

Chen, R., Shimono, A., Aono, M., Nakajima, N., Ohsawa, R., and Yoshioka, Y. (2020). Genetic diversity and population structure of feral rapeseed (Brassica napus L.) in Japan. PLoS One *15*, e0227990.

Colton, B., and Potter, T.D. (1999). History. In Canola in Australia: the first 30 years, P.A. Salisbury, T.D. Potter, G. McDonald, and A.G. Green, eds. (Organising Committee of the 10th International Rapeseed Congress).

Devos, Y., Hails, R.S., Messean, A., Perry, J.N., and Squire, G.R. (2012). Feral genetically modified herbicide tolerant oilseed rape from seed import spills: are concerns scientifically justified? Transgenic Res *21*, 1-21.

EFSA (2004). Opinion of the Scientific Panel on Genetically Modified Organisms on a request from the Commission related to the Notification (Reference C/NL/98/11) for the placing on the market of herbicide-tolerant oilseed rape GT73, for import and processing, under Part C of Directive 2001/18/EC from Monsanto. EFSA Journal *29*, 1-19.

EFSA (2009). Scientific Opinion on applications (EFSA-GMO-RX-GT73[8.1.a] and EFSA-GMO-RX-GT73[8.1.b/20.1.b]) for renewal of the authorisation for continued marketing of existing (1) food and food ingredients produced from oilseed rape GT73; and of (2) feed materials, feed additives and food additives produced from oilseed rape GT73, all under Regulation (EC) No 1829/2003 from Monsanto. EFSA Journal *7*, 1417.

EFSA (2013). Scientific opinion on applications (EFSA-GMO-NL-2010-87) for the placing on the market of genetically modified herbicide tolerant oilseed rape GT73 for food containing or consist of, and food produced from or containing ingredients produced from, oilseed rape GT73 (with the exception of refined oil and food additives) under Regulation (EC) No 1829/2003 from Monsanto. EFSA Journal *11*, 3079.

EFSA (2020). Assessment of genetically modified oilseed rape GT73 for renewal authorisation under Regulation (EC) No 1829/2003 (application EFSA-GMO-RX-002). EFSA Journal *18*, e06199.

Fernandez-Cornejo, J., Wechsler, S., and Milkove, D. (2016). The adoption of genetically engineered alfalfa, canola, and sugarbeets in the United States. Economic Information Bulletin No. 163. (U.S. Department of Agriculture, Economic Research Service).

Grantina-Ievina, L., Ievina, B., Evelone, V., Berga, S., Kovalcuka, L., Bergspica, I., Jakovele, A.*, et al.* (2019). Potential risk evaluation for unintended entry of genetically modified plant propagating material in Europe through import of seeds and animal feed - the experience of Latvia. GM Crops & Food *10*, 159-169.

GRDC (2017). GRDC Canola GrowNotes: Northern. (Grains Research and Development Corporation).

Heap, I. (2020). The International Survey of Herbicide Resistant Weeds. (Available online, accessed 14 December 2020).

Hecht, M., Oehen, B., Schulze, J., Brodmann, P., and Bagutti, C. (2014). Detection of feral GT73 transgenic oilseed rape (Brassica napus) along railway lines on entry routes to oilseed factories in Switzerland. Environ Sci Pollut Res Int *21*, 1455-1465.

Invasive Plants and Animals Committee (2015). Noxious weed list for Australian states and territories.

ISAAA (2018). Global Status of Commercialized Biotech/GM Crops in 2018: Biotech Crops Continue to Help Meet the Challenges of Increased Population and Climate Change. *ISAAA Brief No. 54*. (ISAAA: Ithaca, NY.).

Mallory-Smith, C., and Zapiola, M. (2008). Gene flow from glyphosate-resistant crops. Pest Management Science *64*, 428-440.

Matsushita, A., Goto, H., Takahashi, Y., Tsuda, M., and Ohsawa, R. (2020). Consideration of familiarity accumulated in the confined field trials for environmental risk assessment of genetically modified soybean (Glycine max) in Japan. Transgenic Res *29*, 229-242.

Munier, D.J., Brittan, K.L., and Lanini, W.T. (2012). Seed bank persistence of genetically modified canola in California. Environ Sci Pollut Res Int *19*, 2281-2284.

Ng, K., Raphael, B., Maloney, L., Evans, J., and Parsons, S. (2021). The state of weeds data collection in Australia. (Canberra, Australia: Australian Bureau of Agricultural and Resource Economics and Sciences).

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 (2021). Risk Assessment and Risk Management Plan for DIR 178 - Commercial release of canola genetically modified for herbicide tolerance and a hybrid breeding system (MS11 × RF3 and MS11 × RF3 × MON 88302). (Canberra, Australia: Office of the Gene Technology Regulator).

Pandolfo, C.E., Presotto, A., Carbonell, F.T., Ureta, S., Poverene, M., and Cantamutto, M. (2016). Transgenic glyphosate-resistant oilseed rape (Brassica napus) as an invasive weed in Argentina: detection, characterization, and control alternatives. Environ Sci Pollut Res Int *23*, 24081-24091.

Pandolfo, C.E., Presotto, A., Carbonell, F.T., Ureta, S., Poverene, M., and Cantamutto, M. (2018). Transgene escape and persistence in an agroecosystem: the case of glyphosate-resistant Brassica rapa L. in central Argentina. Environ Sci Pollut Res Int *25*, 6251-6264.

Pascher, K., Hainz-Renetzeder, C., Gollmann, G., and Schneeweiss, G.M. (2017). Spillage of viable seeds of oilseed rape along transportation routes: Ecological risk assessment and perspectives on management efforts. Frontiers in Ecology and Evolution *5*.

Roadside Conservation Committee (2014). Roadside Environmental Weeds List. (Department of Parks and Wildlife, Western Australia).

Rostoks, N., Grantiņa-Ieviņa, L., Ieviņa, B., Evelone, V., Valciņa, O., and Aleksejeva, I. (2019). Genetically modified seeds and plant propagating material in Europe: potential routes of entrance and current status. Heliyon *5*, e01242.

Salisbury, P.A., Cowling, W.A., and Potter, T.D. (2016). Continuing innovation in Australian canola breeding. Crop and Pasture Science *67*, 266-272.

Schafer, M.G., Ross, A.A., Londo, J.P., Burdick, C.A., Lee, E.H., Travers, S.E., Van de Water, P.K., *et al.* (2011). The establishment of genetically engineered canola populations in the U.S. PLoS One *6*, e25736.

Schulze, J., Frauenknecht, T., Brodmann, P., and Bagutti, C. (2014). Unexpected diversity of feral genetically modified oilseed rape (*Brassica napus* L.) despite a cultivation and import ban in Switzerland. PLoS One *9*, e114477.

Umurzokov, M., Jeong, I.H., Ruziev, F., Bo, A.B., Jia, W., Hien, L.T.T., Khaitov, B., *et al.* (2019). Alternative herbicides to manage unintentionally released transgenic canola. Weed & Turfgrass Science *8*, 123-130.

Section 7 Appendix – Literature reviewed in preparation of the consultation RARMP

References found through the literature searches described in the body of this document, but not subsequently cited directly are provided in this list. References are grouped generally, but some may have relevance to more than one area.

1. Methods for detection of introduced gene(s) in MON-ØØØ73-7 canola

Ben Ali, S.-E., Madi, Z.E., Hochegger, R., Quist, D., Prewein, B., Haslberger, A.G., and Brandes, C. (2014). Mutation Scanning in a Single and a Stacked Genetically Modified (GM) Event by Real-Time PCR and High Resolution Melting (HRM) Analysis. International Journal of Molecular Sciences *15*, 19898-19923.

Demeke, T., Eng, M., Holigroski, M., and Lee, S.-J. (2021). Effect of amount of DNA on digital pcr assessment of genetically engineered canola and soybean events. Food Analytical Methods *14*, 372-379.

Kim, I.R., Lim, H.S., Choi, W., Kang, D.I., Lee, S.Y., and Lee, J.R. (2020). Monitoring living modified canola using an efficient multiplex PCR assay in natural environments in South Korea. Applied Sciences *10*, 7721.

Mazur, M., Sieradzki, Z., Król, B., and Kwiatek, K. (2017). Multiplex PCR assays for qualitative detection and identification of the GT73, Ms8, Rf3 and T45 varieties of genetically modified oilseed rape. Journal of Animal and Feed Sciences *26*, 148-156.

2. Weediness of GM plants including herbicide-tolerant canola

Bauer-Panskus, A., Breckling, B., Hamberger, S., and Then, C. (2013). Cultivation-independent establishment of genetically engineered plants in natural populations: current evidence and implications for EU regulation. Environmental Sciences Europe *25*, 34.

Bauer-Panskus, A., Miyazaki, J., Kawall, K., and Then, C. (2020). Risk assessment of genetically engineered plants that can persist and propagate in the environment. Environmental Sciences Europe *32*, 32.

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.

Ellstrand, N.C. (2018). "Born to Run"? Not Necessarily: Species and Trait Bias in Persistent Free-Living Transgenic Plants. Front Bioeng Biotechnol *6*, 88.

Tsatsakis, A.M., Nawaz, M.A., Tutelyan, V.A., Golokhvast, K.S., Kalantzi, O.-I., Chung, D.H., Kang, S.J., *et al.* (2017). Impact on environment, ecosystem, diversity and health from culturing and using GMOs as feed and food. Food and Chemical Toxicology *107*, 108-121.

3. Safety assessment of CP4 EPSPS and GOXV247 proteins

ILSI (2012). A review of the environmental safety of the CP4 EPSPS protein. Environmental Biosafety Research *10*, 5-25.

Salisu, I.B., Shahid, A.A., Yaqoob, A., Rao, A.Q., and Husnain, T. (2019). Effect of dietary supplementation of recombinant Cry and Cp4 epsps proteins on haematological indices of growing rabbits. Journal of Animal Physiology and Animal Nutrition *103*, 305-316.

Shi, Z., Zou, S., Lu, C., Wu, B., Huang, K., Zhao, C., and He, X. (2019). Evaluation of the effects of feeding glyphosate-tolerant soybeans (CP4 EPSPS) on the testis of male Sprague-Dawley rats. GM Crops Food *10*, 181-190.

Zdziarski, I.M., Edwards, J.W., Carman, J.A., and Haynes, J.I. (2014). GM crops and the rat digestive tract: A critical review. Environment International *73*, 423-433.

4. Socio-economic considerations of GM crops

Biden, S., Smyth, S.J., and Hudson, D. (2018). The economic and environmental cost of delayed GM crop adoption: The case of Australia's GM canola moratorium. GM Crops & Food *9*, 13-20.

5. Herbicide use associated with herbicide-tolerant GM crops

Bøhn, T., Cuhra, M., Traavik, T., Sanden, M., Fagan, J., and Primicerio, R. (2014). Compositional differences in soybeans on the market: Glyphosate accumulates in Roundup Ready GM soybeans. Food Chemistry *153*, 207-215.

Cuhra, M. (2015). Review of GMO safety assessment studies: glyphosate residues in Roundup Ready crops is an ignored issue. Environmental Sciences Europe *27*, 20.

Cuhra, M., Bøhn, T., and Cuhra, P. (2016). Glyphosate: Too much of a good thing? Frontiers in Environmental Science *4*.

Guyton, K.Z., Loomis, D., Grosse, Y., El Ghissassi, F., Benbrahim-Tallaa, L., Guha, N., Scoccianti, C.*, et al.* (2015). Carcinogenicity of tetrachlorvinphos, parathion, malathion, diazinon, and glyphosate. The Lancet Oncology *16*, 490-491.

Herman, R.A., and Price, W.D. (2013). Unintended compositional changes in genetically modified (GM) crops: 20 years of research. Journal of Agricultural and Food Chemistry *61*, 11695-11701.