Australian Government
Department of Health and Aged Care
Office of the Gene Technology Regulator

Risk Assessment and Risk Management Plan

for

Register 003

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

August 2024

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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 is 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 the GMO, 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). The canola growing area peaked in 2013 with over 3.25 million hectares (ha) harvested, but fluctuated in the following years, and increased back to 3.25 million ha in 2022 (FAOSTAT website, accessed February 2024). The total canola planting area, including both GM and non-GM canola, was estimated to reach 3.9 million ha in 2023 (ABARES, 2023).

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 United States of America (USA) (Fernandez-Cornejo et al., 2016). Cultivation was also approved in Japan in 2006 (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	2016	446,226
2009	41,200	2017	491,528
2010	133,330	2018	498,897
2011	139,150	2019	529,610*
2012	181,030	2020	434,150*
2013	222,361	2021	618,950**
2014	342,000	2022	781,600**
2015	443,069	2023	668,890**

*Information provided by Monsanto Australia Ltd in annual reports, available on the OGTR website.;
**information provided by Monsanto Australia Ltd in unpublished reports. 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, 2024).

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 the Appendix, OGTR, 2024). 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, 2024).

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 July 2024), the *National Environmental Alert List* (Weeds Australia website, accessed July 2024) 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 later 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 February 2024 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 2024:

- 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=2003,2024). 181 occurrences listed for *B. napus* from 2003 to 2024 in Australia.
- 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 141 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 the 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. Although there are some reports suggesting that over expression of *epsps* genes in *Arabidopsis thaliana* might enhance fecundity of transgenic plants (Beres et al., 2018; Fang et al., 2018), MON-ØØØ73-7 canola expressing the *cp4-epsps* gene does not show substantially different growth characteristics, including seed production, to non-GM canola varieties (refer to the RARMP for DIR 020/2002). 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, and the authors speculated that this could have been due to abiotic (lower rainfall) and biotic (plant herbivory, animal predation and disease) factors in the environment. 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. In addition, for both non-GM and other GM canola, herbicide tolerance traits may be acquired over time by crossing with other herbicide tolerant canola varieties or by natural mutations, but it is no more likely for the MON-ØØØ73-7 canola to acquire the other herbicide tolerance traits than it is for any non-GM or other GM canola if appropriate crop stewardship activities are undertaken.

32. 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). No increased weediness was reported after 14 years of commercial cultivation and use of the GT canola in Australia, and a survey of weed managers from Natural Resource Management groups across Australia did not list canola as an established weed causing agricultural, social or environmental impacts (Ng et al., 2021).

33. 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 was associated with management of HT canola volunteers. Management of HT canola was the same as any other option for managing weeds and, as part of the overall strategy, HT canola needs 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).

34. 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 and the likely persistence beyond single years of GM canola outside cultivation (Schafer et al., 2011; Munier et al., 2012). These populations appeared to occur both in habitats with selection pressure (roadsides sprayed with glyphosate) and also in habitats without obvious selection pressure (Schafer et al., 2011). 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).

35. 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).

36. 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 has 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.

37. 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

38. 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).

39. 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 July 2024), 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.

40. In Canada, no evidence of gene flow from HT canola to related crucifers was reported. Herbicide resistance was transmitted to wild bird's rape (*Brassica rapa*), a close relative, however well-managed planting of HT canola would not promote herbicide-resistant weeds (Beckie et al., 2011). Although *B. rapa* (wild turnip) is considered an agricultural and environmental weed in Australia, glyphosate resistant *B. rapa* has not been reported (Heap, 2020), indicating that in the 12 years of commercial cultivation of glyphosate tolerant canola there has not been gene flow to transfer the introduced genes from canola to weedy *B. rapa*.

3.3.4 International risk assessments published

41. 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. These assessments did not include consideration of risks to the environment for commercial cultivation of oilseed rape GT73.

42. 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 (EU Register of authorised GMOs).

43. The Philippines issued a Biosafety Permit in 2019 following a 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. The Philippines' assessment concluded that the RT73 canola is safe for human food and animal feed and the environment, while the Malaysian assessment concluded that RT73 canola does not endanger biological diversity or human, animal and plant health, when it was used for food, feed and processing in these countries.

44. 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

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

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

45. 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.

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

Section 4 Risk management plan

47. 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.

48. 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.

49. 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.

50. 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

51. 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 (2023). Crop data underpinning Australian Crop Report No. 208: December 2023. (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.

Beres, Z.T., Yang, X., Jin, L., Zhao, W., Mackey, D.M., and Snow, A.A. (2018). Overexpression of a native gene encoding 5-Enolpyruvylshikimate-3-Phosphate Synthase (EPSPS) may enhance fecundity in *Arabidopsis thaliana* in the absence of glyphosate. International Journal of Plant Sciences *179*, 390-401.

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.

Fang, J., Nan, P., Gu, Z., Ge, X., Feng, Y.-Q., and Lu, B. (2018). Overexpressing exogenous 5-enolpyruvylshikimate-3-phosphate synthase (EPSPS) genes increases fecundity and auxin content of transgenic Arabidopsis plants. Frontiers in Plant Science *9*, 233.

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 (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).

OGTR (2024). The Biology of *Brassica napus* L. (canola) and *Brassica juncea* (L.) Czern. & Coss. (Indian mustard) (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 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.

Appendix A: Summary of submissions from prescribed experts, agencies and authorities on the consultation RARMP

The Regulator received a number of submissions from prescribed experts, agencies and authorities[3] on the consultation RARMP. All issues raised in submissions that related to risks to the health and safety of people and the environment were considered in the context of the currently available scientific evidence and were used in finalising the RARMP that formed the basis of the Regulator's decision to include dealings with the GM canola on the GMO Register. Advice received is summarised below.

Submission	Summary of issues raised	Comment
1	Agrees that the conclusions of all relevant previous RARMPs remain valid and considered that the information gathered was sufficient to identify any new risks. Agrees with the overall conclusions of the Reg-003 RARMP and that the dealings pose minimal risk.	Noted.
2	No concerns.	Noted.
3	Supports the inclusion of dealings with MON-ØØØ73-7 canola on the GMO Register. Recommends continued monitoring of weed risk and that any decision to include MON-ØØØ73-7 on the Register be reviewed if new scientific evidence of weediness relating to MON-ØØØ73-7 in Australia is published in the peer-reviewed literature. Suggested that while there have been no reports of adverse effects on human health and safety, or the environment resulting from the dealings licensed under DIR 020/2002, this lack of evidence of any adverse effects is not the same as evidence (via scientific studies) that demonstrates the absence of adverse effects.	Noted. The RARMP considered information on risks to human health and safety and the environment, and the history of safe use. It did not find any evidence of risks that warranted any conditions on the inclusion of dealings with MON-ØØØ73-7 canola on the GMO Register. The OGTR continuously monitors information and scientific literature related to GMOs. If any issues of adverse effects arise with MON-ØØØ73-7 canola in the future, under Section 80 of the *Gene Technology Act 2000* (the Act), the Regulator may, by legislative instrument, vary the GMO Register to (a) remove a dealing from the GMO Register; or (b) revoke or vary conditions to which a dealing on the GMO Register is subject; or (c) impose additional conditions to which a dealing on the GMO Register is subject.
4	Accepts that dealings with the GM canola have negligible risks to the health and safety of people or the environment.	Noted.
5	Noted that MON-ØØØ73-7 canola has a history of safe use in Australia and overseas, and no adverse effects have been reported from cultivation or use as human food and animal feed. Also in a broader	Noted.

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

Submission	Summary of issues raised	Comment
	sense canola is not a persistent weed in natural undisturbed habitats in Australia. Supports the Regulator's conclusion that dealings with MON-ØØØ73-7 canola pose minimal risk to human health and the environment and that MON-ØØØ73-7 canola should be included on the GMO Register.	
	Seeks clarification on the following points: • whether the GM canola to be included on the GMO registry is subject to stewardship and best practice management training provided by seed companies to protect the environment, resistance management and coexistence of GM canola and non-GM farming systems.	Management of GM canola production and coexistence of GM canola and non-GM farming systems are outside the remit of the Regulator. These issues are the responsibility of the States and Territories, and industry. Stewardship and training are expected to be undertaken for MON-ØØØ73-7 as this is best practice for growing and managing any canola variety (GM or non-GM).
	• The resistance to herbicides (non-glyphosate) currently used for management of volunteer populations is possible/likely over time and may exacerbate the persistence and potential spread of the GMO in remnant natural habitats.	Other herbicides from a range of mode of action groups are approved by the Australian Pesticides and Veterinary Medicines Authority (APVMA) for control of the GM canola and it is expected that industry best practice for growing and managing the development of herbicide resistance in any canola variety (GM or non-GM) is adhered to. Text was added to the RARMP to note that herbicide tolerance traits may be acquired over time via crossing or natural mutations, but it is not more likely for the glyphosate-tolerant canola to acquire other herbicide tolerance traits than for any non-GM or other GM canola if appropriate crop stewardship activities are undertaken (par 31). Also note that it is the other factors that determine whether canola will survive in natural habitats (such as rainfall and herbivory) and not whether it is resistant to one or more herbicides.
6	Concerned that the available evidence does not appear sufficient to conclude with certainty that GM canola under widespread cultivation poses minimal risks to the environment. States that GM canola is considered a significant invasive weed of agriculture in some countries and can not only spread and persist outside cultivation but may also transfer herbicide tolerance genes to weedy relatives, reducing the options to control those relatives.	Noted.

Submission	Summary of issues raised	Comment
	Recommends all information relevant to the environmental risk assessment, sufficient to support conclusions and regulatory decisions on risk to the environment be included in the RARMP.	
	Weediness and survival outside cultivation Claims a lack of studies of GM canola in natural habitats, and that GM canola is an invasive problematic weed in natural environments in GM canola growing countries. Suggests information relevant to assessing the risk of weediness of GM canola from Australia, Canada and the US be included in the RARMP as follows:	
	Australia (par 31) Requests inclusion of information from a cited study that abiotic (drought) and biotic (disease) stress were the main reason why the population died out when spread to a natural ecosystem. Notes there is data to indicate that the HT trait may confer an unintended increase in tolerance to abiotic (drought) stress. Has concerns that there is no Australian data on abiotic and biotic stress tolerance in GM and non-GM canola and such data from other countries may not be suitable for environmental risk assessment under Australian conditions.	Some text regarding survival of GM canola in natural habitats has been included in par 31. Discussion of potential for unintended enhanced fitness of GM plants expressing introduced *epsps* genes is also included. In Australia, there is extensive experience in the management of canola in agricultural settings and the management of canola volunteers in natural ecosystems, including GM canola that has been modified for herbicide tolerance. MON-ØØØ73-7 canola has been commercially cultivated for 16 years and no increased weediness status of canola or impact on the natural environment have been recorded in Australia. This extensive practical experience of negligible risk supports the conclusions of previous RARMPs. Furthermore, many areas in Canada and the US have agro-ecological zones that are similar to Australian canola growing regions, and therefore information/data from these countries are relevant to Australian situations (for example, see discussion in the RARMP for DIR 178).
	Canada (par 32) Claims that GM canola has become a significant invasive weed of agricultural areas and multiple stacked herbicide tolerant canola may make their control more challenging in Canada. Requests to clarify that a Canadian study cited only looked at GM canola in agricultural areas rather than natural areas. Considers that the statement in the RARMP that 'no invasions of natural areas were reported' is inaccurate.	MON-ØØØ73-7 canola is only tolerant to glyphosate herbicide and there is no evidence to indicate that multiple stacked herbicide tolerant canola has caused management issues for volunteer canola control in Canada as alternative herbicides can be sought. The text regarding no invasions of HT canola in natural areas was one of the conclusions in the Canadian study cited. It has been deleted as it is agreed that

Submission	Summary of issues raised	Comment
		there is a lack of clear connection between this statement and the information presented in the paper.
	USA (par 33) Requests inclusion of information from a US study that GM canola had widespread distribution and was established and persistence outside cultivated areas, and occurred in habitats with or without glyphosate selection pressure. Believes that other literature cited shows that dormant seed and herbicide resistance have made GM canola a new and difficult weed in California.	Some text was added to par 34 (previously par 33). GM canola becoming a difficult weed in California was mainly due to restrictions on phenoxy herbicide use there, which is made clear in this paragraph.
	Gene flow to weedy relatives States that canola is identified as the riskiest crop for gene flow to weedy relatives and non-GM canola due to crop characteristics that may increase gene flow. States that substantial gene flow from GM canola to the weedy relative *B. rapa* has been reported, but hybridisation rates vary in different countries and that there is a lack of such Australian data. Concerned that *B. rapa* is considered an invasive agricultural weed in Australia, Canada, and the US and is listed as an environmental weed in Victoria. Concerned that gene flow may result in harm or increased weediness of weeds in natural habitats if the gene or trait confers an advantage. States that there is data to suggest that the HT trait may confer an unintended increase in tolerance to abiotic stress in *Arabidopsis,* thus conferring a fitness benefit. Requests discussion of potential risks from gene flow to *B. rapa* and including information to support a conclusion of no risk.	Although gene flow from canola to *B. rapa* can occur under natural conditions, gene flow *per se* does not necessarily lead to harm. With the commercial production of GM canola following stewardship practices for weed management in Australia, the level of such gene flow was found to be very low in cultivation under licence DIR-020/2002. Although *B. rapa* (wild turnip) is considered an agricultural weed in Australia, glyphosate resistant *B. rapa* still has not been reported following 16 years of large-scale commercial cultivation of glyphosate tolerant canola. Discussion of potential for unintended effects on fitness of GM plants expressing introduced *epsps* genes is included in par 31. Discussion of gene flow from glyphosate tolerant canola to wild *B. rapa* has been added to par 40 (previously par 39). The conclusion of the RARMP is minimal risk rather than zero risk. No activity, with GMOs or otherwise can be assessed to have zero risk.
	Lack of environmental risk assessment data Notes that the reports cited (par 40 and 42) assessed safety to humans and animals from use of GM canola as food or feed only and requests that the RARMP clarify that the reports did not assess risks to the environment and therefore cannot be used to conclude on or demonstrate safety to the environment.	Text to reflect this has been included in par 41 (previously par 40).
	Also recommends that the Regulator establishes a mechanism to ensure that any adverse effects, unintended events or new information related to risks are reported to the OGTR, such as through	The OGTR continuously monitors information and scientific literature related to GMOs. If required, the Regulator may vary the GMO Register

Submission	Summary of issues raised	Comment
	conditions on the Register or other means, so that the Regulator remains informed regarding any ongoing potential risks and can respond through potentially amending the listing on the register if needed.	under Section 80 of the Act – see the response to Submission 3 for more detail.
	Proposed condition Agrees that there are no reports on GM canola causing harm in the environment but there is also a lack of studies monitoring or investigating potential spread or impacts into the environment, particularly in Australia. Proposes the condition to '*continue to inform OGTR of any adverse effects, unintended events and any new information relevant to risk'* be kept/added when GM canola is placed on the GMO Register to maintain oversight in light of some uncertainty regarding potential environmental risks.	The RARMP concludes that the dealings with MON-ØØØ73-7 canola represent minimal risk to human health and the environment. As neither the literature nor the practical experience indicates greater than negligible risk, no conditions are imposed at this stage for inclusion of the dealings on the Register.

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

The Regulator received 10 submissions from the public on the consultation RARMP. The issues raised in the submissions are summarised in the table below. All issues that related to risks to the health and safety of people and the environment were considered in the context of currently available scientific evidence in finalising the RARMP that formed the basis of the Regulator's decision to include dealings with the GM canola on the GMO Register.

Submission	Summary of issues raised	Comment
1	Asks whether the safety studies on the mRNA and DNA spike producing vaccines have been done.	The initiative to include dealings on the GMO Register is for a GM canola and not for GM vaccines.
	Asserts that double standards of stifling agricultural development are repulsive to champions in agriculture who would have liked to have seen many more safe biotech traits assist agriculture by now.	Noted.
2	Asks to stop interfering with humans and nature.	Noted.
3	Notes that there is no evidence to suggest any risk to the environment associated with a potential overreliance on MON-ØØØ73-7 canola, or that the use of MON-ØØØ73-7 canola has contributed to any increased occurrence of glyphosate resistant weed populations. Supports the inclusion of MON-ØØØ73-7 canola on the GM register.	Noted.
	Points out that well-developed industry stewardship programs, widely supported by growers for effective management of glyphosate resistance and the continued marketing of Australian canola requiring the segregation of GM and non-GM canola, are currently in place. Believes that there is no evidence that any further stewardship regulations are required or that growers and the wider industry are not capable of managing MON-ØØØ73-7 canola as part of a broader approach to integrated weed management.	Noted.
4	Understands that this is the first agricultural commodity to be included on the GMO Register. Notes that considering a history of safe use, dealings with MON-ØØØ73-7 pose no additional risks to human health and safety or the environment compared to its conventional counterpart.	Noted.
	Also notes that placing certain products on the GMO Register may create complexities regarding ongoing stewardship needs but recognises the Regulator can only undertake a science-based risk assessment for the commercial release of a GMO. Encourages work with the relevant peak industry bodies and grower groups to ensure understanding of product sustainability and trade-related implications of placing agricultural commodities on the GMO Register. Indicates a need to consider notifying key trading partners of the proposed regulatory changes before making them public.	The Act requires the Regulator to identify and manage risks to human health and safety and the environment posed by or as a result of gene technology. The Regulator notifies key stakeholders on all GMO decisions. Marketing and trade issues are outside the matters to which the Regulator may have regard when determining whether to include dealings with a GMO on the GMO Register. These

Submission	Summary of issues raised	Comment
		issues are the responsibility of the States and Territories, and industry.
5	Welcomes the consideration for adding dealings with MON-ØØØ73-7 canola to the GMO Register and agrees that this recognises the history of safe use of this GM canola in Australia. States that a voluntary commitment to the management of risks goes beyond the legal and regulatory requirements in a variety of areas.	Noted.
	Critical stewardship activities	
	Notes continued requirements for implementation of critical stewardship activities (compulsory accreditation requirement, crop management plan, resistance management plan and weed management guide) by growers contribute to the safe and sustainable use of MON-ØØØ73-7 canola. Notes the important role of these activities play in protecting the environment, promoting resistance management, and maintaining coexistence between GM and non-GM commodity markets for international trading.	Noted. See comments to Submission 4 regarding marketing and trade issues. Product sustainability and segregation and coexistence regimes are outside the scope of the Act. These issues are the responsibility of the States and Territories, and industry. Stewardship activities are expected to be undertaken for MON-ØØØ73-7 as this is best practice for growing and managing any canola variety (GM or non GM).
	Ongoing education and support of new growers	
	Notes that role of stewardship programs in maintaining safe and sustainable use of the GM canola and that ongoing education and support to ensure all growers, particularly the many new growers each season, are familiar with the stewardship requirements, is critical for continuing safe and sustainable use. Concerned about the maintenance of practices mandated by current stewardship requirements.	Noted.
	Proposed transition of critical stewardship activities	
	Notes that three of the four critical stewardship activities for MON-ØØØ73-7 canola, are currently compulsory requirements for growers under a License and Stewardship Agreement (LSA), and that this agreement also references conditions of licence DIR 020/2002. Believes that these critical stewardship activities should continue regardless of whether or not MON-ØØØ73-7 is added to the Register. Proposes a two-year transition period from the date of any decision to add MON-ØØØ73-7 to the Register for the industry to appoint an appropriate body to manage ongoing stewardship activities and establish systems to audit accreditation and stewardship issues, after which the DIR 020/2002 licence could be surrendered. Believes such a transition period would allow time to transfer critical activities. Advocates inclusion of conditions requiring compulsory completion of critical stewardship activities by all new growers prior to planting MON-ØØØ73-7 if it is included in the GMO Register.	Noted. Matters related to stewardship activities are outside the scope of the Act. Note that licence DIR 020/2002 does not impose conditions on any stewardship activities to manage risks from commercial dealings with the GMO.

Submission	Summary of issues raised	Comment
	Impacts to trade Recognises that the OGTR, in considering moving MON-ØØØ73-7 to the GMO Register, must only consider human health and the environment but believes that this leaves a concerning gap in the policy settings around the regulation of GMOs, particularly regarding trade. Cites current requirements for export to some trading partners to reference GMO licence numbers and believe that placement on the GMO Register may cause trade uncertainty for commodity traders if not addressed prior to any decision being announced. Also encourages the OGTR to work with relevant government departments, peak industry bodies, and grower groups to ensure that trade matters are fully considered and briefing of key trading partners before any changes to regulation are made public. Welcomes the opportunity to engage further to ensure best-practice stewardship is maintained in all potential regulatory scenarios.	Noted. Trade issues are outside the scope of the Act. The OGTR identifier for this determination, Reg-003, can be referenced like other OGTR identifiers (e.g. DIR, DNIR and NLRD) on importation and exportation documentation for Australia and for other countries.
6	Supports use of the GMO Register for dealings with a history of safe use.	Noted.
	States that moving dealings with MON-ØØØ73-7 onto the Register represents an important step for the plant science industry, as this is the first time that a GM food crop has undergone such a process. Advocates careful consideration of all potential issues and development for each step of the implementation process. States that this is essential not only for this application, but also for potential future use of the GMO Register.	Noted.
	Asserts that beyond licence conditions, companies develop and deliver training, accreditation, and stewardship practices for growers to manage issues related to supply chain and trade issues, and to sustainability. Believes these would be lost if dealings with GM food crops are placed on the Register unless specific conditions are included to mandate accreditation and stewardship, but that conditions defeat the purpose of the Register.	Noted. The RARMP concludes that the dealings with MON-ØØØ73-7 canola represent minimal risk to human health and the environment. As neither the literature nor the practical experience indicates greater than negligible risk, no conditions are imposed at this stage for inclusion of the dealings on the Register. It is expected that stewardship activities will be undertaken by the industry just like for non-GM crops and other authorised GM crops.
	Proposes development of an industry-wide stewardship program to ensure industry best practice in this area. Notes the organisation's long-standing commitment to product stewardship and effective engagement with the farming sector, which could contribute to future industry programs.	Noted. See comments to Submission 4 regarding marketing and trade issues.

Submission	Summary of issues raised	Comment
	Given the time, consultation and agreements required to develop and implement such a program, suggests a transition period of at least one growing season before placing dealings with MON-ØØØ73-7 on the Register. Claims that the organisation's experience and expertise will be crucial to developing and ensuring adoption of such a program by industry. Provides a summary of current critical stewardship activities implemented.	
7	Notes that MON-ØØØ73-7 canola has a history of successful commercial cultivation in Australia and that now GM canola accounts for approximately one quarter of the total area planted to canola. Outlines the industry history of effectively managing both the growth of GM canola and segregation of GM and non-GM canola within the supply chain required by the market. Considered the implications of addition of MON-ØØØ73-7 canola onto the GMO Register for both the domestic and international market. Offers to undertake to communicate to the market to allay any concerns of misinterpretation and avoid risks that the market may see this as 'complete deregulation' of GM canola in Australia and loss of segregation.	Noted.
	Notes that there would be no stewardship activities after a 'handover' period. Understands that no conditions can be applied by the OGTR if MON-ØØØ73-7 canola is placed on the Register. Emphasises the critical importance of stewardship in successful expansion of GM canola in Australia and will consult with other industry bodies to assess how best to address this issue. Does not object to the inclusion of MON-ØØØ73-7 canola on the GMO Register, views this as a natural progression in the acceptance of GM technology.	Noted. For dealings with a GMO to be placed on the GMO Register, the dealings must pose minimal risks to human health and safety or the environment. The commercial dealings with the GMO are placed on the GMO Register without imposing any conditions. Section 79(2c) of the Act provides that conditions can be imposed. However, in this case the Regulator does not impose conditions as risks are minimal and there is no risk that would require management. If risks to human health and safety, or risks to the environment arise from dealings with a GMO on the GMO Register, under Section 80 of the *Gene Technology Act 2000*, the Regulator can vary the GMO Register to impose, revoke or vary conditions, or remove the dealings from the GMO Register.
8	Supports access to new technologies including biotechnology in farming systems and supports the inclusion of dealings with MON-ØØØ73-7 canola on the GMO Register.	Noted. See comments to Submission 5 regarding stewardship and trade.

Submission	Summary of issues raised	Comment
	Notes the Australian industry has historically been able to meet expectations of environment management, markets and regulatory concerns for growing MON-ØØØ73-7 canola in Australia. Is aware of the concern around glyphosate herbicide resistance evolution and management implications for use of glyphosate resistant canola within the production system. Recognises that including MON-ØØØ73-7 canola on the GMO Register leaves a potential regulatory gap regarding future stewardship management of products and potential risks to trade. Refers to the OGTR Genetically Modified Organism Herbicide Tolerance Trait Review.	
9	Notes a history of safe use in Australian commercial cultivation of MON-ØØØ73-7 canola and effective segregation of GM canola from non-GM canola in the supply chain to ensure retaining market choice. Supports including dealings with MON-ØØØ73-7 on the GMO Register, but is concerned, as are other key industry organisations, that there is a gap in the policy settings regarding the critical ongoing stewardship of products on the GMO Register. Believes that an ongoing stewardship program for this, or any other GM grain crops, is essential. Believes that broadening the responsibility for stewardship of a product beyond that of the original licence holder requires further consideration, particularly the potential impact on trade. Encourages work with the relevant government departments, peak industry bodies and grower groups to ensure that the trade-related implications of placing agricultural commodities on the GMO Register are fully understood and consider notifying key trading partners of the proposed regulatory changes before making them public.	Noted. See comments to Submission 5 regarding stewardship and trade.
10	Supports the OGTR's science-based approach for regulating commercial transactions with GMOs. Discusses organisation's role in development of industry code of practice. Notes the history of safe use of MON-ØØØ73-7 canola in Australia and the licence holder's oversight of critical stewardship activities for reducing the risk of adverse effects to the environment under the existing OGTR licence. Has concerns about the ongoing stewardship of MON-ØØØ73-7 after it is placed on the GMO Register and suggests that further dialogue and discussion is required by Government and industry participants to ensure its ongoing safe use and to address trade and market access risks.	Noted. See comments to Submission 5 regarding stewardship and trade.

Submission	Summary of issues raised	Comment
	May propose actions and activity to ensure there is ongoing critical stewardship activities for MON-ØØØ73-7 and future products listed on the GMO Register.	