



Australian Government

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

March 2025

Risk Assessment and Risk Management Plan for

DIR 209

Limited and controlled release of sorghum
genetically modified for altered reproduction
from sexual to asexual

Applicant: The University of Queensland

Summary of the Risk Assessment and Risk Management Plan for Licence Application No. DIR 209

Introduction

The Gene Technology Regulator (the Regulator) has decided to issue a licence for this application for the intentional release of a genetically modified organism (GMO) into the environment. A Risk Assessment and Risk Management Plan (RARMP) for this application has been prepared by the Regulator in accordance with the *Gene Technology Act 2000* (the Act) and corresponding state and territory legislation, and finalised following consultation with a wide range of experts, agencies and authorities, and the public. The RARMP concluded that the proposed field trial poses low risk to human health and safety and the environment and that any risks posed by the dealings can be managed by imposing conditions on the release.

The application

Project Title	Limited and controlled release of sorghum genetically modified for altered reproduction from sexual to asexual
Applicant	The University of Queensland
Parent organism	Sorghum (<i>Sorghum bicolor</i>)
Genetic modifications	
Introduced genes ¹ and modified traits	<p>Introduced genes conferring altered reproduction from sexual to asexual:</p> <ul style="list-style-type: none"> • A parthenogenesis gene from a grass species • A gene-editing <i>cas9</i> gene with guide RNAs that knock out 4 endogenous sorghum genes and cause mitosis instead of meiosis <p>Two marker genes</p>
Genetic modification method	<i>Agrobacterium</i> -mediated transformation
Number of lines	Up to 10 lines
Principal purpose	To assess agronomic and genetic characteristics of the genetically modified (GM) sorghum plants under field conditions
Proposed limits	
Proposed use of GM plants	No use in human food or animal feed
Proposed location/s	One trial site at the University of Queensland's Gatton Campus
Proposed release size	Up to 1 hectare per year
Proposed period of release	From March 2025 to March 2028

¹ Confidential Commercial Information (CCI): Details about the introduced genetic elements have been declared as CCI under section 185 of the Act. This information is provided to the prescribed experts and agencies that are consulted on this application. CCI is not available to the public.

Risk assessment

The risk assessment process considers how the genetic modification and proposed activities conducted with the GMOs might lead to harm to people or the environment. Risks are characterised in relation to both the seriousness and likelihood of harm, taking into account current scientific/technical knowledge, information in the application (including proposed limits and controls) and relevant previous approvals. Both short- and long-term risks are considered.

Credible pathways to potential harm that were considered included exposure of people or animals to the GM plant material, potential for persistence or dispersal of the GMOs, and transfer of the introduced genetic material to non-GM sorghum or related weeds. Potential harms associated with these pathways included toxicity or allergenicity to people, toxicity to desirable animals, and environmental harms due to weediness.

The risk assessment concludes that the proposed dealings pose negligible risks to the health and safety of people and low risks to the environment. The identified low risks involve transfer of introduced genetic material from the GM sorghum to related weeds, leading to environmental harms relating to increased weediness.

Risk management plan

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

The risk management plan concludes that the identified low risks to the environment can be managed by risk treatment measures that minimise the dispersal of GM pollen from the trial sites. The licence also includes limits on the size, location and duration of the release, as well as controls to prohibit the use of GM plant material in human food and animal feed, to minimise dispersal of the GMOs from the trial sites, to transport GMOs in accordance with the Regulator's guidelines, to destroy the GMOs at the end of the trial and to conduct post-harvest monitoring at the trial sites to ensure the GMOs are destroyed.

Table of contents

Summary of the Risk Assessment and Risk Management Plan	I
Introduction	I
The application	I
Risk assessment	II
Risk management plan	II
Table of contents	III
Abbreviations.....	V
Chapter 1 Risk assessment context.....	1
Section 1 Background.....	1
1.1 Interface with other regulatory schemes	2
Section 2 The proposed dealings	2
2.1 The proposed limits of the trial (duration, size, location and people)	2
2.2 The proposed controls to restrict the spread and persistence of the GMOs	2
Section 3 The parent organism	3
Section 4 The GMOs, nature and effect of the genetic modifications.....	3
4.1 Introduction to the GMOs.....	3
4.2 Method of genetic modification	4
4.3 The introduced genetic elements	4
4.4 Toxicity/allergenicity of the proteins associated with the introduced genes.....	5
4.5 Characterisation of the GMOs	5
Section 5 The receiving environment.....	5
5.1 Relevant abiotic factors	5
5.2 Relevant biotic factors	5
5.3 Relevant agricultural practices.....	6
5.4 Presence of related plants in the receiving environment.....	6
5.5 Presence of similar genes and encoded proteins in the environment	6
Section 6 Relevant Australian and international approvals	7
6.1 Australian approvals.....	7
6.2 International approvals.....	7
Chapter 2 Risk assessment	8
Section 1 Introduction.....	8
Section 2 Risk identification	9
2.1 Risk source	9
2.2 Causal pathway	10
2.3 Potential harm	11

2.4	Postulated risk scenarios.....	11
2.5	Risk scenario 1.....	13
2.6	Risk scenario 2.....	14
2.7	Risk scenario 3.....	17
2.8	Risk scenario 4.....	19
Section 3	Risk characterisation	19
3.1	Risk scenario 4.....	19
3.2	Likelihood assessment	20
3.3	Consequence assessment	22
3.4	Risk estimate	22
Section 4	Uncertainty.....	23
Section 5	Risk evaluation.....	23
Chapter 3	Risk management plan	25
Section 1	Background.....	25
Section 2	Risk treatment measures for substantive risks	25
Section 3	General risk management	26
3.1	Limits and controls on the release.....	26
3.2	Other risk management considerations	28
Section 4	Issues to be addressed for future releases.....	29
Section 5	Conclusions of the RARMP	29
References		30
Appendix A: Summary of submissions from prescribed experts, agencies and authorities on the consultation RARMP.....		34
Appendix B: Summary of submissions from the public on the consultation RARMP.....		36

Abbreviations

Cas9	CRISPR associated protein 9
CCI	Confidential Commercial Information
CRISPR	clustered regularly interspaced short palindromic repeats
DIR	Dealings involving Intentional Release
DNA	deoxyribonucleic acid
GM	genetically modified
GMO	genetically modified organism
gRNA	guide RNA
ha	hectare
HGT	horizontal gene transfer
m	metre
mm	millimetre
NHEJ	non-homologous end joining
OGTR	Office of the Gene Technology Regulator
qPCR	quantitative polymerase chain reaction
RARMP	Risk Assessment and Risk Management Plan
Regulations	Gene Technology Regulations 2001
Regulator	Gene Technology Regulator
RNA	ribonucleic acid
the Act	<i>Gene Technology Act 2000</i>

Chapter 1 Risk assessment context

Section 1 Background

1. An application has been made under the *Gene Technology Act 2000* (the Act) for Dealings involving the Intentional Release (DIR) of genetically modified organisms (GMOs) into the Australian environment.
2. The Act and the Gene Technology Regulations 2001 (the Regulations), together with corresponding State and Territory legislation, comprise Australia’s national regulatory system for gene technology. Its objective is to protect the health and safety of people, and to protect the environment, by identifying risks posed by or as a result of gene technology, and by managing those risks through regulating certain dealings with GMOs.
3. Section 50 of the Act requires that the Gene Technology Regulator (the Regulator) must prepare a Risk Assessment and Risk Management Plan (RARMP) in response to an application for release of GMOs into the Australian environment. Sections 50, 50A and 51 of the Act and Sections 9 and 10 of the Regulations outline the matters which the Regulator must take into account and who must be consulted when preparing the RARMP.
4. The *Risk Analysis Framework* (OGTR, 2013) explains the Regulator’s approach to the preparation of RARMPs in accordance with the Act and the Regulations. The Regulator has also developed operational policies and guidelines that are relevant to DIR licences. These documents are available from the Office of the Gene Technology Regulator (OGTR) [website](#).
5. Figure 1 shows the information that is considered, within the regulatory framework above, in establishing the risk assessment context. This information is specific for each application. Risks to the health and safety of people or the environment posed by the proposed release are assessed within this context. Chapter 1 provides the specific information for establishing the risk assessment context for this application.

RISK ASSESSMENT CONTEXT	
<p>The GMO Modified genes Novel traits</p> <p>Parent organism (comparator) Origin and taxonomy Cultivation and use Biology</p> <p>Receiving environment Environmental conditions: abiotic and biotic factors Production practices Related organisms Similar genes and proteins</p>	<p>Proposed GMO dealings Activities Limits Controls</p> <p>Previous releases Australian approvals International approvals</p>

Figure 1. Summary of parameters used to establish the risk assessment context, within the legislative requirements, operational policies and guidelines of the OGTR and the Risk Analysis Framework.

6. In accordance with Section 50A of the Act, this application is considered to be a limited and controlled release application, as the Regulator was satisfied that it meets the criteria prescribed by the Act. Therefore, the Regulator was not required to consult with prescribed experts, agencies and authorities before preparation of the RARMP.

7. Section 52 of the Act requires the Regulator to seek comment on the RARMP from agencies - the Gene Technology Technical Advisory Committee (GTTAC), State and Territory Governments, Australian Government authorities or agencies prescribed in the Regulations, Australian local councils and the Minister for the Environment - and from the public. The advice from the prescribed experts, agencies and authorities and how it was taken into account is summarised in Appendix A. One public submission was received and its consideration is summarised in Appendix B.

1.1 Interface with other regulatory schemes

8. Gene technology legislation operates in conjunction with other regulatory schemes in Australia. The GMOs and any proposed dealings may also be subject to regulation by other Australian government agencies that regulate GMOs or GM products, including Food Standards Australia New Zealand, the Australian Pesticides and Veterinary Medicines Authority, the Therapeutic Goods Administration, the Australian Industrial Chemicals Introduction Scheme and the Department of Agriculture, Fisheries and Forestry. These dealings may also be subject to the operation of State legislation recognising an area as designated for the purpose of preserving the identity of GM crops, non-GM crops, or both GM crops and non-GM crops, for marketing purposes.

9. To avoid duplication of regulatory oversight, risks that have been considered by other regulatory agencies will not be re-assessed by the Regulator.

Section 2 The proposed dealings

10. The University of Queensland (the applicant) proposes to release up to 10 GM sorghum lines into the environment under limited and controlled conditions. The GM plants have been genetically modified for altered reproduction from sexual to asexual.

11. The purpose of the proposed field trial is to assess agronomic and genetic characteristics of the GM sorghum plants under field conditions.

12. The dealings involved in the proposed release are to:

- conduct experiments with the GMOs
- propagate the GMOs
- grow the GMOs
- transport the GMOs
- dispose of the GMOs

and possess, supply or use the GMOs in the course of any of these dealings.

2.1 The proposed limits of the trial (duration, size, location and people)

13. The field trial is proposed to take place between March 2025 and March 2028 at one site at the University of Queensland's Gatton Campus (Lockyer Valley Region in Queensland). Up to one hectare of GM sorghum would be grown per season.

14. Only trained and authorised persons would be permitted to deal with the GM sorghum.

2.2 The proposed controls to restrict the spread and persistence of the GMOs

15. The applicant has proposed a number of controls to restrict the spread and persistence of the GM sorghum and the introduced genetic material in the environment. These include:

- locating the trial site at least 100 m away from the nearest natural waterway
- locating the planting area inside a lockable bird-proof enclosure (hail guard netting) that would exclude birds and larger animals
- baiting to control rodents in the trial site
- bagging GM sorghum panicles during flowering to limit pollen spread

- surrounding the planting area with a 100 m monitoring zone that is inspected while the GM sorghum is flowering to destroy any sorghum or sexually compatible plants
- cleaning equipment used with the GMOs prior to use for any other purpose
- destroying all harvested GM seed that is not required for analysis or future planting
- post-harvest monitoring of the trial site, with inspections every 35 days, to identify and destroy any volunteer sorghum, until no volunteers are detected for 6 consecutive months
- post-harvest irrigation of the trial site if there is insufficient rainfall to germinate sorghum
- transporting and storing GMOs in accordance with the current Regulator's [Guidelines for the Transport, Storage and Disposal of GMOs](#)
- not allowing the GMOs or GM products to be used for human food or animal feed.

16. The proposed limits and controls are taken into account in the risk assessment (Chapter 2) and their suitability for containing the release will be evaluated in the risk management plan (Chapter 3).

Section 3 The parent organism

17. The parent organism of the GMOs is cultivated grain sorghum (*Sorghum bicolor* subsp. *bicolor*), which is referred to as sorghum in this document. Sorghum is not native to Australia.

18. Detailed information about the parent organism is contained in the reference document produced to inform the risk analysis process for licence applications involving GM sorghum: The Biology of *Sorghum bicolor* (L.) Moench subsp. *bicolor* (Sorghum) (OGTR, 2024). This biology document is available from the [Resources page](#) on the OGTR website. Baseline information from the biology document will be used and referred to throughout the RARMP.

19. Grain sorghum is the main summer crop in Queensland and northern New South Wales, with an average of 630,000 hectares per year grown over the last 3 growing seasons (ABARES, 2024; GRDC, 2023). Within Australia, sorghum is used predominantly as livestock feed, but also for production of biofuel and in gluten-free food products. Grain is exported for both animal and human consumption (Grain Growers, 2021; GRDC, 2023).

20. Sorghum is not a weed of national significance or a declared weed in any state or territory of Australia ([Weeds Australia website](#), accessed 9 October 2024). A weed risk assessment for sorghum by the OGTR found that sorghum possesses few weedy attributes (OGTR, 2024). Similarly, a weed risk assessment of sorghum by the Western Australia government placed sorghum in the lowest weed risk ranking category (DPIRD, 2022).

21. Sorghum foliage accumulates the toxins dhurrin and nitrates, particularly under drought stress. This limits its use as a livestock forage crop under dry conditions in Australia (Cowan et al., 2020).

22. People with grass pollen allergies may be sensitive to sorghum pollen (OGTR, 2024).

Section 4 The GMOs, nature and effect of the genetic modifications

4.1 Introduction to the GMOs

23. The applicant proposes to release up to 10 GM sorghum lines that have been genetically modified to enable asexual reproduction.

24. The GM sorghum contains an introduced gene that confers the trait of parthenogenesis, which is the spontaneous development of embryos from unfertilised egg cells. This gene originates from a grass species which naturally forms embryos without fertilisation.

25. In addition, the GM sorghum has been gene edited by a CRISPR/Cas9 system to knock out 4 endogenous sorghum genes. The 4 targeted sorghum genes are involved in the process of meiosis, which is the mixing and halving of genetic material to form haploid male and female reproductive

cells. The knockout of all copies of these 4 genes confers the trait of mitosis instead of meiosis. This means that the pollen and egg cells contain diploid genomes identical to the genome of the parent GM sorghum plant.

26. Due to the combination of the mitosis instead of meiosis trait and the parthenogenesis trait, the GM sorghum will produce clonal seed that grows into diploid offspring genetically identical to the parent plant.

27. Australian sorghum crops are generally grown from hybrid seed (GRDC, 2017), as crosses between 2 inbred sorghum lines possess agronomically desirable hybrid vigour. However, hybrid vigour is not retained in the offspring of hybrids due to genetic segregation during sexual reproduction. GM sorghum hybrids with asexual reproduction through seeds may be useful in agriculture as they are hypothesised to maintain hybrid vigour from generation to generation.

28. The GM sorghum also contains a selectable marker gene that confers herbicide tolerance and a visual marker gene. These markers were used during development of the GM sorghum lines and have no intended function in the field.

4.2 Method of genetic modification

29. The GM sorghum is generated by *Agrobacterium*-mediated transformation. Information about this method can be found in the document [Methods of plant genetic modification](#), available from the OGTR Risk Assessment References page.

30. GM sorghum hybrid lines are produced by transforming one inbred sorghum line with a construct containing the parthenogenesis gene, a second inbred sorghum line with a construct containing the *cas9* gene and the 2 marker genes, and a third inbred sorghum line with a construct encoding 4 guide RNAs (gRNAs) for gene editing. The 3 GM inbred sorghum lines are sequentially crossed to produce GM sorghum hybrids containing all 3 transformation events.

31. The GM sorghum events are tested using qPCR to confirm that the introduced constructs are present, that unwanted plasmid components are absent, and to determine the copy number of the inserts. Only GM sorghum events with single copies of the gene inserts are used for production of the GM sorghum hybrid lines for release in the proposed field trial.

32. Gene editing to knock out the 4 targeted endogenous sorghum genes occurs in the GM sorghum hybrid lines after crossing between the parent containing the introduced *cas9* gene and the parent containing a construct encoding the 4 gRNAs. The expressed Cas9 protein forms a complex with each gRNA, designed to create a double-stranded break in the targeted DNA sequence. Imperfect natural repair of these breaks often leads to short insertions or deletions (mostly single base-pair changes) in the target plant DNA sequence, although it can sometimes produce larger deletions (Soyars et al., 2018). The result of this imperfect repair is usually gene knockout as the targeted gene is no longer functional. The applicant does not have exact data regarding the efficiency of their multiplex gene editing system, but estimates that less than 5% of GM hybrids that contain the full gene editing system result in homozygous knockouts of all 4 endogenous sorghum genes, i.e. knockouts of all 8 targeted alleles in the diploid sorghum genome. Only GM sorghum lines containing successful homozygous knockouts of the targeted sorghum genes will be released in the proposed field trial.

4.3 The introduced genetic elements

33. The exact identity of the introduced genes, their promoters and the endogenous sorghum genes knocked out by gene editing has been declared as Confidential Commercial Information (CCI) under section 185 of the Act. This information is provided in a CCI Attachment to the RARMP, which is available to the prescribed experts and agencies that are consulted on the RARMP.

4.4 Toxicity/allergenicity of the proteins associated with the introduced genes

34. The exact identity of the introduced genes has been declared CCI. Information about the potential toxicity or allergenicity of the proteins encoded by these genes is provided in a CCI Attachment to the RARMP, which is available to the prescribed experts and agencies that are consulted on the RARMP.

35. Overall, a search of the scientific literature yielded no information to suggest that the proteins encoded by the introduced genes were toxic or allergenic to people or toxic to animals.

4.5 Characterisation of the GMOs

36. International collaborators of the applicant have conducted limited glasshouse testing of some of the GM sorghum lines proposed for release. The GM sorghum was reported to have no changes to seed size or panicle shattering compared to non-GM sorghum. The applicant intends to conduct further glasshouse testing of the GM sorghum prior to beginning the proposed field trial in the 2025-26 growing season.

37. Under licence [DIR 189](#), the applicant conducted a single-season field trial of another GM sorghum containing only the introduced parthenogenesis gene. The applicant did not observe any differences in agronomic phenotype between that GM sorghum and non-GM sorghum.

Section 5 The receiving environment

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

39. Detailed information about non-GM sorghum in the Australian environment is presented in the document: *The Biology of Sorghum bicolor* (L.) Moench subsp. *bicolor* (Sorghum) (OGTR, 2024).

5.1 Relevant abiotic factors

40. The proposed trial site is located at the University of Queensland's Gatton Campus. During the winter months, the mean maximum temperature at Gatton is 21.5°C and the mean minimum temperature is 6.9°C ([Bureau of Meteorology website](#), accessed 10 October 2024). Sorghum germinates poorly at soil temperatures lower than 16°C (GRDC, 2017), so would not be expected to grow well during winter in the Gatton area.

41. Sorghum crops are generally planted in spring or early summer and harvested 3-4 months later. Sorghum needs approximately 400 mm of soil moisture or in-crop rainfall to provide good yields (GRDC, 2017). The average annual rainfall in Gatton is 759 mm, with a summer-dominant rainfall pattern ([Bureau of Meteorology website](#), accessed 10 October 2024). The Gatton Campus field trial site is also equipped for overhead spray irrigation if this is needed.

42. The Gatton Campus field trial site is approximately 300 m from the nearest natural waterway. The applicant states that there has been no recorded flooding of the site. In the widespread south-east Queensland floods in early 2022, areas surrounding the proposed planting area were flooded, but the planting area itself was not flooded.

5.2 Relevant biotic factors

43. The major insect pests of sorghum in Australia are cotton bollworm (*Helicoverpa armigera*) and sorghum midge (*Stenodiplosis sorghicola*) (GRDC, 2017). The applicant proposes to use insecticides to control insect pests during the field trial as per industry standard practices.

44. The major disease of sorghum in Australia is ergot, caused by the fungus *Claviceps africana* infecting florets. In southern Queensland, ergot disease risk can be managed by planting from mid-October to mid-January, so that flowering occurs during warm summer months when the probability of ergot infection is lower (GRDC, 2017). The applicant proposes to avoid late planting (i.e. post-January) of the field trial and may apply a fungicide if cool weather is forecast during flowering.

45. A range of native Australian and introduced bird species are known to feed on sorghum grain. Rodents feed on sorghum and also collect and disperse viable grain (OGTR, 2024).

5.3 Relevant agricultural practices

46. The controls proposed for the field trial are outlined in Section 2.2 of this Chapter. Aside from implementing these controls, it is proposed that the GM sorghum would be maintained in a similar fashion to commercial sorghum crops.

47. Herbicides may be applied to control weeds or over the crop at maturity, in accordance with label instructions. The applicant indicates that glyphosate (mode-of-action group 9), carfentrazone-ethyl (group 14), fluroxypyr (group 4) and halosulfuron (group 2) herbicides may be used on the trial site.

5.4 Presence of related plants in the receiving environment

48. As discussed in Section 3, grain sorghum (*S. bicolor* subsp. *bicolor*) is widely cultivated in southern Queensland. Forage sorghum (*S. bicolor*) is also grown in southern Queensland (GRDC, 2017). All plants from species *S. bicolor* are diploids (OGTR, 2024).

49. Johnson grass (*S. halepense*), Columbus grass (*S. x alnum*; a cross between *S. bicolor* and *S. halepense*) and Silk forage sorghum (*S. hybrid* cv. Silk; a cross between *S. bicolor* and *S. halepense*) are noxious weeds that are naturalised in southern Queensland ([Weeds Australia website](#), accessed 21 October 2024). Populations of Johnson grass have been reported at the Gatton Campus trial site during previous field trials. Johnson grass, Columbus grass and Silk forage sorghum are all tetraploids but are able to cross with grain sorghum and forage sorghum via wind pollination (OGTR, 2024).

50. Johnson grass is an invasive perennial grass that is a serious weed in most parts of the world. It grows rapidly, is highly competitive with other plants and can be toxic to grazing animals. It reproduces both sexually, via prolific production of seeds that survive for at least 6 years under field conditions, and asexually via rhizomes. Due to regrowth from rhizomes, established Johnson grass populations are not effectively controlled by single tillage events, pre-emergent herbicides or contact herbicides. The only herbicide classes widely recommended for control of Johnson grass are Group 1, Group 2 and Group 9 herbicides (DiTomaso et al., 2013; Peerzada et al., 2017; Travlos et al., 2019) ([Weeds Australia website](#), accessed 21 October 2024).

51. There are 17 other species from the *Sorghum* genus native to Australia. However, none of these species are able to naturally hybridise with cultivated sorghum (Myrans et al., 2020). They are not members of the *Eusorghum* subgenus that contains cultivated sorghum, where all species in the subgenus are able to interbreed (OGTR, 2024).

5.5 Presence of similar genes and encoded proteins in the environment

52. The source organisms of the introduced genes have been declared as CCI. Information regarding the presence of these source organisms, or similar genes and encoded proteins, in the Australian environment is provided in a CCI Attachment to the RARMP available to the prescribed experts and agencies that are consulted on the RARMP.

Section 6 Relevant Australian and international approvals

6.1 Australian approvals

53. The Regulator has not previously assessed or approved the GM sorghum in this application.

54. The Regulator has previously approved 2 field trial licences for GM sorghum. Licence DIR 189 was for sorghum genetically modified for asexual seed formation, with the same introduced parthenogenesis gene as the GM sorghum in this application. Licence DIR 153 was for sorghum genetically modified for grain quality traits. Information on these GM sorghum field trial licences is available from the [OGTR GMO Record](#). There have been no reports of adverse effects on human health or the environment resulting from these releases.

55. The Regulator has not approved commercial release of any GM sorghum in Australia.

6.2 International approvals

56. The GM sorghum in this application has not been approved for field trials in other countries.

57. There have been no international approvals of any GM sorghum for food, feed or commercial cultivation ([ISAAA website](#); accessed 10 October 2024; [BioTrack Product database](#); accessed 10 October 2024). In the United States, the Department of Agriculture has ruled that four types of GM sorghum are not subject to regulation ([USDA regulated article inquiry website](#); [USDA exemption confirmation letters website](#); accessed 10 October 2024). These types of GM sorghum are modified for herbicide tolerance, altered starch content or altered sugar content.

Chapter 2 Risk assessment

Section 1 Introduction

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

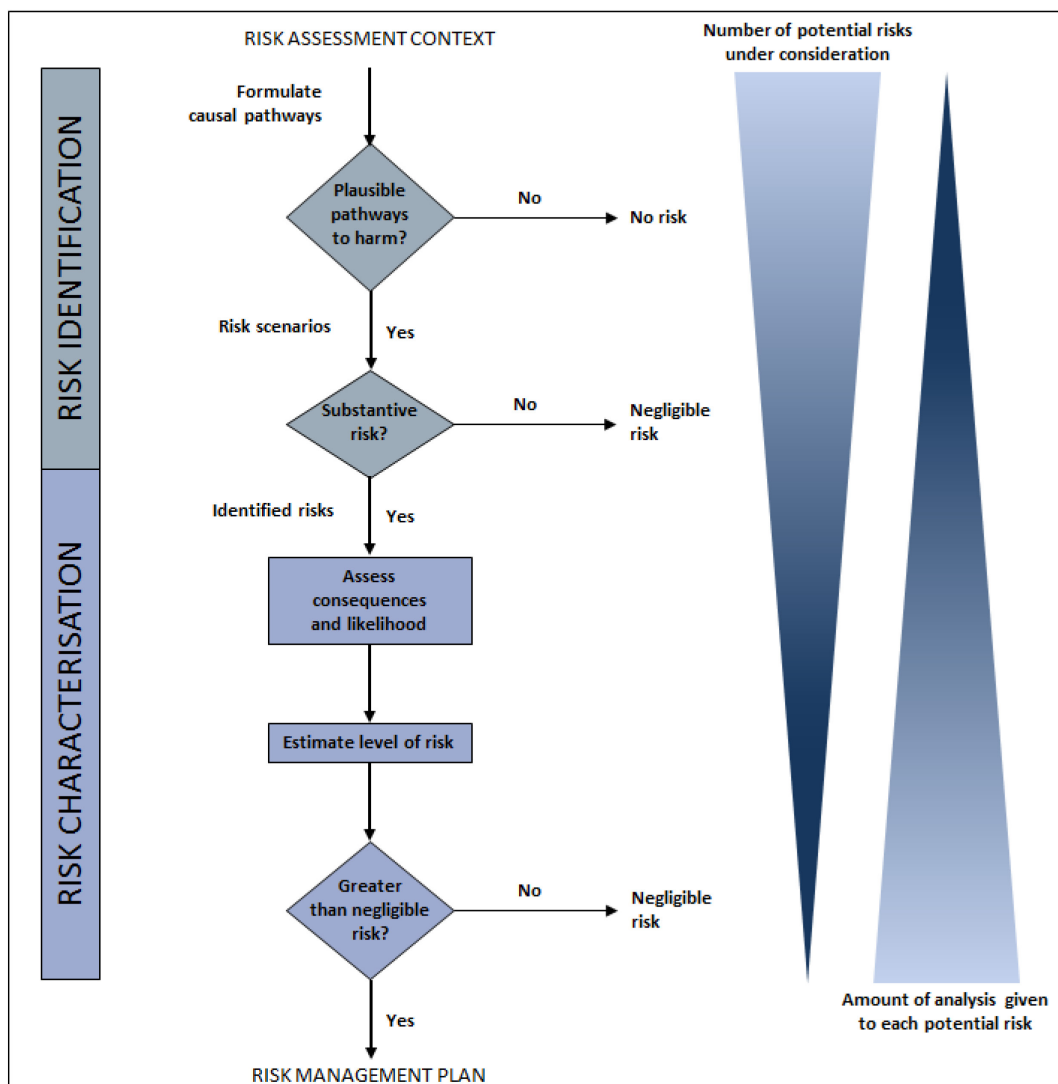


Figure 2. The risk assessment process

59. The Regulator uses a number of techniques to identify risks, including checklists, brainstorming, previous agency experience, reported international experience and consultation (OGTR, 2013).

60. Risk identification first considers a wide range of circumstances in which the GMO, or the introduced genetic material, could come into contact with people or the environment. This leads to postulating causal pathways that may give rise to harm for people or the environment from dealings with a GMO. These are called risk scenarios.

61. Risk scenarios are screened to identify substantive risks, which are risk scenarios that are considered to have some reasonable chance of causing harm. Risk scenarios that could not plausibly

occur, or do not lead to harm in the short and long term, do not advance in the risk assessment process (Figure 2), i.e. the risk is considered to be no greater than negligible.

62. Risk scenarios identified as substantive risks are further characterised in terms of the potential seriousness of harm (consequence assessment) and the likelihood of harm (likelihood assessment). The consequence and likelihood assessments are combined to estimate the level of risk and determine whether risk treatment measures are required. The potential for interactions between risks is also considered.

63. A weed risk assessment approach is used to identify traits that may contribute to risks from GM plants, as this approach addresses the full range of potential adverse outcomes associated with plants. In particular, novel traits that may increase the potential of the GMO to spread and persist in the environment or increase the level of potential harm compared with the parental plant(s) are considered in postulating risk scenarios (Keese et al., 2014). Risk scenarios postulated in previous RARMPs prepared for licence applications for the same or similar GMOs are also considered.

Section 2 Risk identification

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

- i. the source of potential harm (risk source)
- ii. a plausible causal linkage to potential harm (causal pathway)
- iii. potential harm to people or the environment.

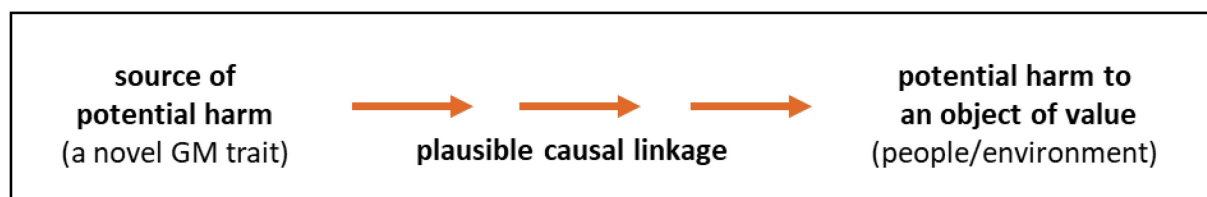


Figure 3. Components of a risk scenario

65. When postulating relevant risk scenarios, the risk context is taken into account, including the following factors detailed in Chapter 1:

- the proposed dealings,
- the proposed limits including the extent and scale of the proposed dealings,
- the proposed controls to limit the spread and persistence of the GMO, and
- the characteristics of the parent organism(s).

2.1 Risk source

66. The sources of potential harms can be intended novel GM traits associated with one or more introduced genetic elements, or unintended effects/traits arising from the use of gene technology.

67. As discussed in Chapter 1, Section 4, the GM sorghum has been modified by introduction of a gene conferring parthenogenesis, a gene-editing *Cas9* gene with associated gRNAs, a herbicide tolerance selectable marker gene and a visual marker gene. All of these introduced genes will be further considered as sources of potential harm.

68. The introduced genes are controlled by introduced regulatory sequences. Regulatory sequences, such as promoters, enhancer sequences and terminators, are naturally present in all plants and the introduced sequences are expected to operate in similar ways to endogenous sequences. The regulatory sequences are DNA that is not expressed as a protein, so exposure is to the DNA only and dietary DNA has no toxicity (Delaney et al., 2018). Hence, potential for harm from the regulatory elements will not be considered further.

69. The genetic modifications could cause unintended effects in several ways including altered expression of endogenous genes by random insertion of introduced DNA in the genome, increased metabolic burden due to expression of the introduced proteins, novel traits arising out of interactions with non-target proteins and secondary effects arising from altered substrate or product levels in biochemical pathways. However, these types of effects also occur spontaneously in plants generated by conventional breeding. Accepted conventional breeding techniques such as hybridisation, mutagenesis and somaclonal variation can have a much larger impact on the plant genome than genetic engineering (Anderson et al., 2016; Schnell et al., 2015). Plants generated by conventional breeding have a long history of safe use, and there are no documented cases where conventional breeding has resulted in the production of a novel toxin or allergen in a crop (Steiner et al., 2013). Therefore, unintended effects resulting from the process of genetic modification will not be considered further.

70. The genetic modifications involving knockout of genes by CRISPR/Cas9 have the potential to cause two classes of unintended effects. The first class of unintended effects are significant genomic deletions or rearrangements at the intended site of gene editing (Hahn and Nekrasov, 2019), leading to altered expression of endogenous genes. The applicant will use CRISPR/Cas9 to generate double-stranded breaks in DNA sequences that will be randomly repaired by non-homologous end joining (NHEJ). The conventional plant breeding technique of mutagenesis also generates double-strand breaks repaired by NHEJ and can also produce significant genomic deletions or rearrangements (Shirley et al., 1992). As discussed in the previous paragraph, conventional breeding using mutagenesis has a long history of safe use. The second class of unintended effects is off-target gene editing, leading to inadvertent knockout of additional genes with sequences that closely match the intended site of gene editing. Several studies have found that most plants edited by CRISPR/Cas9 have no off-target gene editing. Even in plants where off-target gene editing occurs, the frequency of off-target mutations caused by gene editing is far lower than the frequency of random mutations caused by somaclonal variation (Li et al., 2019; Tang et al., 2018; Wang et al., 2021). As discussed in the previous paragraph, conventional breeding using somaclonal variation has a long history of safe use. Therefore, unintended effects arising from genome editing will not be further assessed for this application.

2.2 Causal pathway

71. The following factors are considered when postulating plausible causal pathways to potential harm:

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

72. Although all of these factors are taken into account, some are not included in the risk scenarios because they have been considered in previous RARMPs and are not expected to give rise to substantive risks.

73. The potential for horizontal gene transfer (HGT) and any possible adverse outcomes has been reviewed in the literature (Keese, 2008; Philips et al., 2022) and assessed in previous RARMPs. No risk greater than negligible was identified, due to the rarity of HGT events and because the gene sequences are already present in the environment and available for transfer via demonstrated natural mechanisms. Therefore, HGT will not be assessed further.

74. Previous RARMPs have considered the potential for unauthorised activities to lead to an adverse outcome. The Act provides for substantial penalties for non-compliance and unauthorised dealings with GMOs. The Act also requires the Regulator to have regard to the suitability of the applicant to hold a licence prior to the issuing of a licence. These legislative provisions are considered sufficient to minimise risks from unauthorised activities, and no risk greater than negligible was identified in previous RARMPs. Therefore, unauthorised activities will not be considered further.

2.3 Potential harm

75. Potential harms from GM plants are based on those used to assess the risk from weeds (Keese et al., 2014; Virtue, 2008) including:

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

76. Judgements of what is considered a harm depend on the management objectives of the land where the GM plant may be present. For example, a plant species may have a different weed risk potential in different land uses such as dryland cropping or nature conservation.

2.4 Postulated risk scenarios

77. Four risk scenarios were postulated and screened to identify any substantive risks. These scenarios are summarised in Table 1 and examined in detail in Sections 2.5 - 2.8 (this Chapter).

78. In the context of the activities proposed by the applicant and considering both the short and long term, only Risk Scenario 4 gave rise to a substantive risk which warranted further assessment (characterised in Section 3).

Table 1. Summary of risk scenarios from the proposed dealings

Risk scenario	Risk source	Causal pathway	Potential harm	Substantive risk?	Reason
1	All introduced genes	GM sorghum grows at the field trial site ↓ Expression of the introduced genes in the GM sorghum ↓ Exposure of people or animals to GM plant material	Increased toxicity or allergenicity to people OR Increased toxicity to desirable animals	No	<ul style="list-style-type: none"> • GM sorghum would not be used for human food or animal feed • The small size, short duration and proposed controls for the field trial would restrict exposure of people or animals to the GM sorghum • The proteins encoded by the introduced genes are

Risk scenario	Risk source	Causal pathway	Potential harm	Substantive risk?	Reason
		containing the gene products			not known to be toxic or allergenic
2	All introduced genes	GM sorghum grows at the field trial site ↓ Persistence of GM sorghum at the trial site or dispersal of GM sorghum seed outside the trial site ↓ Establishment of populations of volunteer GM sorghum in the environment	Increased toxicity or allergenicity to people OR Increased toxicity to desirable animals OR Reduced establishment or yield of desirable plants OR Increased reservoir for pathogens or pests	No	<ul style="list-style-type: none"> The proposed controls would minimise persistence of GM sorghum at the trial site The proposed controls would minimise dispersal of GM sorghum seed outside the trial site Sorghum has limited ability to establish ongoing volunteer populations in the environment The proteins encoded by the introduced genes are not known to be toxic or allergenic
3	All introduced genes	GM sorghum grows at the field trial site ↓ Pollen flow from the GM sorghum to non-GM sorghum plants outside the trial site ↓ Production of GM sorghum seeds expressing the introduced genes outside the field trial	Increased toxicity or allergenicity to people OR Increased toxicity to desirable animals OR Reduced yield of desirable plants	No	<ul style="list-style-type: none"> Sorghum is primarily self-pollinated The proposed limits and controls would minimise pollen flow from the GM sorghum to non-GM sorghum outside the trial sites The proteins encoded by the introduced genes are not known to be toxic or allergenic
4	All introduced genes	GM sorghum grows at the field trial site ↓ Pollen flow from the GM sorghum to tetraploid related weeds such as Johnson grass ↓ Establishment of hybrids between GM sorghum and related weeds in the environment	Increased allergenicity to people OR Increased toxicity to desirable animals OR Reduced establishment or yield of desirable plants	Yes	<ul style="list-style-type: none"> Johnson grass is present in the vicinity of the trial site The GM sorghum has increased potential to outcross with tetraploid weeds The introduced herbicide tolerance gene could confer increased persistence to weeds

Risk scenario	Risk source	Causal pathway	Potential harm	Substantive risk?	Reason
		<p style="text-align: center;">↓</p> <p>a) Spread and persistence of the hybrids expressing introduced genes in the environment, or</p> <p>b) introgression of introduced genes into the weed population</p>	<p>OR</p> <p>Increased reservoir for pathogens or pests</p> <p>OR</p> <p>Reduced biodiversity</p>		

2.5 Risk scenario 1

<i>Risk Source</i>	All introduced genes
<i>Causal Pathway</i>	<p style="text-align: center;">GM sorghum grows at the field trial site</p> <p style="text-align: center;">↓</p> <p style="text-align: center;">Expression of the introduced genes in the GM sorghum</p> <p style="text-align: center;">↓</p> <p style="text-align: center;">Exposure of people or animals to GM plant material containing the gene products</p>
<i>Potential Harm</i>	<p style="text-align: center;">Increased toxicity or allergenicity to people</p> <p style="text-align: center;">OR</p> <p style="text-align: center;">Increased toxicity to desirable animals</p>

Risk source

79. The source of potential harm for this postulated risk scenario is the introduced genes in the GM sorghum.

Causal Pathway

80. The GM sorghum would be grown at the field trial site. The 4 introduced genes would be expressed in the GM sorghum. Information regarding the expression of the introduced genes in different plant tissues is provided in a CCI Attachment to the RARMP, which is available to the prescribed experts and agencies that are consulted on the RARMP.

Exposure of people to the GM sorghum

81. The applicant proposes that the GM sorghum would not be used as human food. Therefore, people would not be exposed to the GM plant material through consumption.

82. People conducting the proposed dealings with the GM sorghum could be exposed to GM plant material containing introduced gene products via skin contact during cultivation or analysis.

83. The applicant proposes that while the GM sorghum is flowering, the panicles will be bagged to limit pollen spread. This would minimise inhalation of wind-borne GM sorghum pollen by people in the vicinity of the trial site. After flowering, when the pollination bags are removed from the GM sorghum, it is likely that a small proportion of the pollen would spill from the bags. Although this pollen is not expected to be viable, it would still contain gene products from the introduced genes. Therefore, people removing pollination bags could be exposed to GM plant material containing introduced gene products via inhalation of pollen.

84. Due to the small size and short duration of the proposed field trial, few people would engage in dealings with the GM sorghum. Therefore, few people would be exposed to the GM plant material via skin contact or inhalation of pollen.

Exposure of desirable animals to the GM sorghum

85. The applicant proposes that GM sorghum grown in the trial would not be used as animal feed. Therefore, agricultural livestock would not be exposed to the GM plant material.

86. The proposed trial site would be enclosed in bird-proof netting intended to exclude birds and larger animals from the trial site. This would minimise exposure of birds and larger animals to the GM plant material. Smaller animals and insects could live inside the trial site enclosure, or could potentially pass under or through the netting to feed on the GM sorghum. However, the small size and short duration of the proposed field trial would restrict the number of small animals or insects that could be exposed to the GM plant material.

Potential harm

87. The postulated potential harms for this risk scenario are increased toxicity or allergenicity to people, or increased toxicity to desirable animals.

88. As discussed in Chapter 1, Section 4.4, a search of the scientific literature found no information to suggest that the proteins encoded by the introduced genes are toxic or allergenic to people or toxic to animals. However, there is limited data available for some of the introduced genes, so this is an area of uncertainty.

89. As discussed in Chapter 1, Section 3, non-GM sorghum naturally produces the toxins dhurrin and nitrates in foliage, and sorghum pollen can be allergenic. There is no reason to expect that the introduced parthenogenesis gene, the introduced *Cas9* gene for targeted gene editing, or either of the 2 introduced marker genes would affect the levels of endogenous sorghum toxins or allergens.

Conclusion

90. Risk scenario 1 is not identified as a substantive risk because GM sorghum would not be used for human food or animal feed, the small size, short duration and proposed controls for the field trial would restrict exposure of people or animals to the GM sorghum, and the proteins encoded by the introduced genes are not known to be toxic or allergenic. Therefore, this risk could not be greater than negligible and does not warrant further detailed assessment.

2.6 Risk scenario 2

<i>Risk Source</i>	All introduced genes
<i>Causal Pathway</i>	<p style="text-align: center;">GM sorghum grows at the field trial site</p> <p style="text-align: center;">↓</p> <p style="text-align: center;">Persistence of GM sorghum at the trial site or dispersal of GM sorghum seed outside the trial site</p> <p style="text-align: center;">↓</p> <p style="text-align: center;">Establishment of populations of volunteer GM sorghum in the environment</p>
<i>Potential Harm</i>	<p style="text-align: center;">Increased toxicity or allergenicity to people</p> <p style="text-align: center;">OR</p> <p style="text-align: center;">Increased toxicity to desirable animals</p> <p style="text-align: center;">OR</p> <p style="text-align: center;">Reduced establishment or yield of desirable plants</p> <p style="text-align: center;">OR</p> <p style="text-align: center;">Increased reservoir for pathogens or pests</p>

Risk source

91. The source of potential harm for this postulated risk scenario is the introduced genes in the GM sorghum.

Causal Pathway

92. The GM sorghum would be grown at the field trial site. Due to the genetic modifications conferring asexual reproduction (discussed in Chapter 1, Section 4.1), the GM sorghum is expected to produce clonal GM seed. In addition, any non-GM sorghum grown as part of the trial may be pollinated by the GM sorghum and may produce GM seeds.

93. The applicant reports that GM sorghum grown in the glasshouse had no changes to seed size or panicle shattering compared to non-GM sorghum (Chapter 1, Section 4.5). It is not known whether there are any other phenotypic differences between the GM sorghum and non-GM sorghum.

Persistence of GM sorghum at the trial site

94. Grain sorghum is often grown in cultivation as a single-stemmed plant, but there are tillers at the base of the plants that can develop into additional stems. In irrigated cropping in Queensland, if sorghum is planted early, farmers can harvest the sown sorghum crop and grow a second ratoon sorghum crop from tillers (Eyre et al., 2019). However, after harvesting the field trial, the applicant proposes to destroy the GM sorghum plants. The applicant would also destroy any harvested GM sorghum seeds that are not required for analysis or future planting.

95. Some GM sorghum seeds would remain on or in the soil of the trial site after harvesting, for instance, due to seed losses during harvest. These seeds could germinate and grow into volunteer GM sorghum plants.

96. The applicant proposes to deplete the GM sorghum seedbank on the trial site by undertaking post-harvest monitoring every 35 days to identify and destroy any volunteer sorghum plants. Sorghum has very low seed dormancy, although seeds will not germinate if soil is too dry or soil temperatures are too low (OGTR, 2024). The applicant proposes post-harvest irrigation of the trial site if there is insufficient rainfall to germinate sorghum. The applicant also proposes to continue post-harvest monitoring until no volunteers are detected for a period of at least 6 months, which would include some months when soil temperatures are suitable for sorghum germination (Chapter 1, Section 5.1). These measures, which are discussed further in Chapter 3, Section 3.1, are expected to minimise persistence of viable GM sorghum seed at the trial site.

Dispersal of GM sorghum seeds outside the trial sites

97. Dispersal of GM sorghum seeds outside the trial site could potentially occur through transport by wind or water, activity of animals or activity of people. Viable GM sorghum seed would be present at the trial site and available for dispersal during the period of sowing and after grain has matured.

98. Sorghum seeds are not usually spread by wind as cultivated sorghum has non-shattering seed heads and the seeds lack specialised structures to aid windborne dispersal (OGTR, 2024). It is possible that GM sorghum seeds could be dispersed by high winds if a severe storm occurred while mature seed was present.

99. Sorghum seeds on the soil surface could be transported by water during heavy runoff or flooding. The applicant reports that the Gatton trial site is approximately 300 m from the nearest waterway, which would minimise the potential for seed dispersal via flooding.

100. The applicant proposes that GM sorghum grown in the trial would not be used as animal feed, so agricultural livestock would not enter the trial site. The proposed trial site would also be enclosed in bird-proof netting intended to exclude birds and larger animals. This would minimise the potential for birds and larger animals to disperse GM sorghum seed.

101. Mice feeding on GM sorghum grain are likely to consume seeds on site, but they can also collect seeds to hoard, and transport the seeds over distances estimated as up to 50 m (Andersson and de Vicente, 2010). Ants may transport seeds to nest sites over distances that average 2 m over all ant genera, but up to 10 m for some genera (Gómez and Espadaler, 2013). The applicant proposes to control rodents in the vicinity of the trial site by baiting. Also, if GM sorghum seeds are dispersed up to 10 m from the parent plant by animal activity, or by human activity such as harvesting, the seeds are expected to remain within the area subject to proposed post-harvest monitoring to manage seed persistence (see Chapter 3, Section 3.1).

102. The proposed field trial would occur at a research station, and only people involved in the field trial would enter the site. The applicant proposes that all equipment used with the GMOs would be cleaned prior to removal from the trial site or use for other purposes. Transport of GM sorghum seeds to and from the trial site would be conducted in accordance with the Regulator's Guidelines for the Transport, Storage and Disposal of GMOs. These controls would minimise dispersal of GM sorghum seed outside the trial site by human activity.

Ability of GM sorghum to establish populations in the environment

103. In Australia, volunteer non-GM sorghum plants grow in disturbed sites, such as agricultural areas and roadsides (Groves et al., 2003; Richardson et al., 2011), but volunteer sorghum is not considered a major problem warranting control (Groves et al., 2003). In a survey of weed species at farms in the northern grain region of Australia (including south-east Queensland), sorghum was grown as a rotation crop in 74% of paddocks sampled, providing excellent opportunity for creation of a sorghum seedbank. However, volunteer sorghum plants were only observed in 54% of paddocks, and comprised less than 2% of total weed populations (Rew et al., 2005), indicating that only a small proportion of the sorghum seedbank successfully grew into volunteer plants. This suggests that non-GM cultivated sorghum has limited ability to establish ongoing volunteer populations in the environment.

104. The GM sorghum lines for release will be hybrids that produce clonal seeds. The applicant hypothesises that clonal offspring of the GM sorghum will retain hybrid vigour (see Chapter 1, Section 4.1). Most sorghum volunteers in the environment would be sexual offspring of commercial sorghum hybrids and would not retain hybrid vigour. Therefore, GM sorghum volunteers could have a fitness advantage over non-GM sorghum volunteers. However, GM sorghum volunteers are still unlikely to establish ongoing populations in the environment due to plant characteristics common to hybrid and non-hybrid grain sorghum, including lack of seed shattering, very low seed dormancy (OGTR, 2024), and slow growth during the first month after seedling emergence (Contreras et al., 2022). Lack of seed shattering restricts the ability of sorghum to spread in the environment and establish additional volunteer populations. Very low seed dormancy restricts the persistence of sorghum volunteer populations, as sorghum seeds in a seedbank tend to emerge simultaneously, and can then be killed by weed management or unfavourable environmental conditions, eliminating the entire volunteer population. Slow growth after seedling emergence means that young sorghum volunteers have poor ability to compete with other plants.

105. The introduced selectable marker gene that confers a herbicide tolerance trait could potentially lead to increased persistence of GM sorghum volunteers in the environment. A discussion of this trait is provided in a CCI Attachment to the RARMP, which is available to the prescribed experts and agencies that are consulted on the RARMP. The discussion finds that the trait would not have an important effect on the ability of GM sorghum volunteers to establish populations in the environment.

Potential harm

106. The postulated potential harms for this risk scenario are increased toxicity or allergenicity to people, increased toxicity to desirable animals, reduced establishment or yield of desirable plants, or an increased reservoir for pathogens or pests.

107. If GM sorghum volunteers grew as weeds in the environment, people would not consume plant material, but they could be exposed to pollen through inhalation. GM sorghum volunteers could be eaten by desirable animals, including livestock, native mammals and birds, and insect pollinators. However, as discussed in Risk Scenario 1, the proteins encoded by the introduced genes are not known to be toxic or allergenic. There is no reason to expect that GM sorghum volunteers would be more toxic or allergenic than non-GM sorghum volunteers.

108. Although sorghum is not considered weedy (Chapter 1, Section 3), unmanaged volunteer sorghum could compete with and reduce establishment or yield of desirable plants, such as agricultural crops in farms or native plants in nature reserves. Alternatively, volunteer sorghum surviving in agricultural regions during the off-season could provide a reservoir for insect pests or diseases that could transfer to a following sorghum crop. As discussed above, GM sorghum volunteers may have a small fitness advantage over non-GM sorghum volunteers, so could have slightly increased ability to compete with desirable plants or to survive and provide a reservoir for pests or diseases.

Conclusion

109. Risk scenario 2 is not identified as a substantive risk because the proposed controls would minimise persistence of GM sorghum at the trial site or dispersal of GM sorghum seed outside the trial site, sorghum has limited ability to establish ongoing volunteer populations in the environment, and the proteins encoded by the introduced genes are not known to be toxic or allergenic. Therefore, this risk could not be greater than negligible and does not warrant further detailed assessment.

2.7 Risk scenario 3

<i>Risk Source</i>	All introduced genes
<i>Causal Pathway</i>	<p>GM sorghum grows at the field trial site</p> <p style="text-align: center;">↓</p> <p>Pollen flow from the GM sorghum to non-GM sorghum plants outside the trial site</p> <p style="text-align: center;">↓</p> <p>Production of GM sorghum seeds expressing the introduced genes outside the field trial</p>
<i>Potential Harm</i>	<p>Increased toxicity or allergenicity to people</p> <p style="text-align: center;">OR</p> <p>Increased toxicity to desirable animals</p> <p style="text-align: center;">OR</p> <p>Reduced yield of desirable plants</p>

Risk source

110. The source of potential harm for this postulated risk scenario is the introduced genes in the GM sorghum.

Causal Pathway

111. The GM sorghum would be grown at the field trial site and would produce pollen. If the pollen is carried by wind outside the trial site, and non-GM sorghum plants are flowering at the same time in the vicinity of the trial site, the GM sorghum could pollinate non-GM sorghum plants outside the trial site.

112. The proposed trial site is in a sorghum growing area (Chapter 1, Section 5.4). Non-GM grain sorghum crops, forage sorghum crops or volunteer sorghum plants could grow in the vicinity of the trial site. Forage sorghum grown for grazing is usually grazed prior to flowering, but forage sorghum grown for hay or silage is often allowed to flower before harvest (Cameron, 2006). Grain sorghum crops and unmanaged sorghum volunteers will also flower. Non-GM sorghum growing in the vicinity of the trial site may or may not flower at the same time as the GM sorghum, as the planting window for

sorghum in Queensland ranges between September and January (GRDC, 2017), and flowering periods vary accordingly.

113. Cultivated sorghum is primarily self-pollinating. Outcrossing rates in the field depend on the cultivar and are reported to range between 2% and 26% for 10 cultivars (Djè et al., 2004; Pedersen et al., 1998). To the extent that outcrossing occurs, sorghum is adapted for wind pollination rather than insect pollination (OGTR, 2024).

114. Two studies of wind-mediated outcrossing in grain sorghum (*S. bicolor* spp. *bicolor*) measured outcrossing between a pollen donor field and male-sterile pollen recipients, with one study finding <1% outcrossing at distances of 26 m or greater (Schmidt and Bothma, 2006) and the other study finding <1% outcrossing at distances of 20 m or greater (Rabbi et al., 2011). Another study measured pollen flow from grain sorghum to fully fertile shattercane (a non-domesticated form of *S. bicolor*) in the direction of the prevailing winds, and found that the average percentage of hybrid seeds produced by the recipient shattercane plants was 0.53% at 100 m (Schmidt et al., 2013). Shattercane has a more open panicle structure than grain sorghum and generally has higher rates of outcrossing, so this model would represent an upper limit on the rate of outcrossing between GM sorghum and non-GM sorghum outside the trial site.

115. The small size of the proposed trial would limit the amount of pollen produced by the GM sorghum, in comparison to the amount of pollen produced by commercial non-GM sorghum crops that may be present in the environment and compete with the GM pollen. The applicant proposes to bag the GM sorghum plants during flowering. Pollination bags are expected to contain most of the pollen produced by the GM sorghum until it loses viability. The applicant also proposes to surround the planting area with a 100 m monitoring zone that is inspected while the GM sorghum is flowering to destroy any sorghum plants. The combination of these limits and controls would minimise the potential for pollen flow from the GM sorghum to non-GM sorghum outside the trial sites.

116. The introduced gene editing system in the GM sorghum confers a trait of mitosis instead of meiosis. Therefore, the GM sorghum is expected to produce diploid pollen (Chapter 1, Section 4.1). If the diploid GM sorghum pollen fertilises non-GM sorghum (which has haploid reproductive cells), the resultant GM seed is expected to be triploid. Studies report that in a parallel situation, when Johnson grass pollen (which is diploid) fertilises sorghum, there is a post-fertilisation “triploid block” to seed development (Hodnett et al., 2019; Sias et al., 2023). Approximately 99% of developing seeds undergo endosperm failure and die prior to maturity (Hodnett et al., 2019). In maize, which is closely related to the *Sorghum* genus, a similar seed abortion effect occurs in triploid seed resulting from crosses between tetraploid and diploid maize lines (Pennington et al., 2008). Therefore, it is likely that most triploid seeds resulting from the GM sorghum pollinating non-GM sorghum will abort prior to seed maturity. However, seed development of these crosses has not been directly tested and is an area of uncertainty.

Potential harm

117. The postulated potential harms for this risk scenario are increased toxicity or allergenicity to people, increased toxicity to desirable animals, or reduced yield of desirable plants.

118. If GM sorghum pollinates any non-GM sorghum outside the trial site, the resultant GM seed (normal or aborted) could be eaten by desirable animals, including livestock, native mammals and birds. It is unlikely that harvested GM seed would be eaten by people, given that little of the Australian sorghum crop is used for food production. As discussed in Risk Scenario 1, the proteins encoded by the introduced genes are not known to be toxic or allergenic. There is no reason to expect that GM sorghum seed would be more toxic or allergenic than non-GM sorghum seed.

119. If GM sorghum pollinates a non-GM grain sorghum crop outside the trial site, and most of the resultant GM seeds abort, this could reduce the yield of the grain sorghum crop. However, given the proposed controls to restrict pollen flow from the GM sorghum, and that sorghum is primarily self-

pollinated, only a tiny proportion of the seeds in the grain sorghum crop could be GM, and the effect on yield would be negligible.

Conclusion

120. Risk scenario 3 is not identified as a substantive risk because sorghum is primarily self-pollinated, the proposed limits and controls would minimise pollen flow from the GM sorghum to non-GM sorghum outside the trial sites, and the proteins encoded by the introduced genes are not known to be toxic or allergenic. Therefore, this risk could not be considered greater than negligible and does not warrant further detailed assessment.

2.8 Risk scenario 4

121. Risk Scenario 4 considers the potential for pollen flow from GM sorghum to related weeds such as Johnson grass, leading to harms relating to increased weediness. As Risk Scenario 4 is considered to be a substantive risk, a risk characterisation was conducted as detailed in Section 3.

Section 3 Risk characterisation

122. Four risk scenarios were postulated and evaluated, as summarised in Table 1. The fourth risk scenario was identified as posing a substantive risk which warrants further assessment. This section provides detail on the characterisation of this risk.

123. Risk characterisation involves a likelihood assessment, a consequence assessment, a risk estimate, and a decision on whether risk treatment is required. See the Risk Analysis Framework (OGTR, 2013) for further information about the OGTR’s approach to conducting risk analysis.

3.1 Risk scenario 4

<i>Risk Source</i>	All introduced genes
<i>Causal Pathway</i>	<p style="text-align: center;">GM sorghum grows at the field trial site</p> <p style="text-align: center;">↓</p> <p style="text-align: center;">Pollen flow from the GM sorghum to tetraploid related weeds such as Johnson grass</p> <p style="text-align: center;">↓</p> <p style="text-align: center;">Hybrids between GM sorghum and related weeds establish in the environment</p> <p style="text-align: center;">↓</p> <p style="text-align: center;">a) Spread and persistence of the hybrids expressing introduced genes in the environment</p> <p style="text-align: center;">OR</p> <p style="text-align: center;">b) introgression of introduced genes into the weed population</p>
<i>Potential Harm</i>	<p style="text-align: center;">Increased allergenicity to people</p> <p style="text-align: center;">OR</p> <p style="text-align: center;">Increased toxicity to desirable animals</p> <p style="text-align: center;">OR</p> <p style="text-align: center;">Reduced establishment or yield of desirable plants</p> <p style="text-align: center;">OR</p> <p style="text-align: center;">Increased reservoir for pathogens or pests</p> <p style="text-align: center;">OR</p> <p style="text-align: center;">Reduced biodiversity</p>

Risk source

124. The source of potential harm for this postulated risk scenario is the introduced genes in the GM sorghum.

3.2 Likelihood assessment

125. A likelihood assessment determines the chance that harm may occur, ranging from highly unlikely to highly likely. The likelihood assessment for the causal pathway for Risk Scenario 4 is presented below.

126. The GM sorghum would grow at the trial site and would produce pollen. Windborne pollen could pollinate related weeds that are present in the vicinity of the trial site and flowering at the same time as the GM sorghum. As the related weed Johnson grass is known to be present in the vicinity of the trial site, this risk scenario will focus on pollen flow to Johnson grass. However, similar risks would be posed by pollen flow to the related weeds Columbus grass or Silk forage sorghum, which are hybrids of Johnson grass and are also naturalised in southern Queensland (Chapter 1, Section 5.4).

127. In a previous field trial in 2022-23 at the proposed trial site (DIR 189), the planting area and a 100 m monitoring zone were inspected for Johnson grass during the flowering period of sorghum. The licence holder found and destroyed 43 pre-flowering Johnson grass plants in the planting area or monitoring zone, despite weed management measures in these areas, such as regular mowing of the monitoring zone. It is highly likely that there will be a population of Johnson grass in the vicinity of the trial site during the proposed field trial.

128. Johnson grass plants develop multiple stems and flower throughout summer and autumn (Ohadi et al., 2018)([Weeds Australia website](#), accessed 21 October 2024). Therefore, Johnson grass in the vicinity of the proposed trial site is expected to flower at the same time as the GM sorghum, unless the Johnson grass plants are killed before flowering.

129. Hybridisation between grain sorghum (male parent) and Johnson grass (female parent) occurs under field conditions. In a field study, outcrossing between grain sorghum pollen donor fields and Johnson grass plants occurred at an average rate of 1% at 100 m, which was the maximum distance tested (Arriola and Ellstrand, 1996).

130. There is a partial ploidy barrier to hybridisation between grain sorghum, which is diploid, and Johnson grass, which is tetraploid. Comparing two field studies, outcrossing between grain sorghum pollen donor plots and Johnson grass pollen recipients occurred at an average rate of 5.6% at 5 m distance (Arriola and Ellstrand, 1996), while outcrossing between Johnson grass pollen donor plots and Johnson grass pollen recipients occurred at an average rate of 13.4% at 5 m distance, despite a much smaller donor plot size (Maity et al., 2022). This suggests that hybridisation rates are more than 2-fold higher in the absence of a ploidy barrier. Crosses between tetraploid sorghum lines (male parent) and Johnson grass (female parent) have no ploidy barrier and are reported to be highly crossable (Sangduen and Hanna, 1984). The introduced gene editing system in the GM sorghum confers a trait of mitosis instead of meiosis and the GM sorghum is expected to produce diploid pollen (Chapter 1, Section 4.1). There would be no ploidy barrier to GM sorghum diploid pollen fertilising Johnson grass diploid egg cells. Therefore, in comparison with non-GM sorghum, the GM sorghum is expected to have increased ability to outcross with Johnson grass. As outcrossing between non-GM sorghum and Johnson grass is reported to occur at an average rate of 1% at 100 m distance (Arriola and Ellstrand, 1996), outcrossing between GM sorghum and Johnson grass could occur at a rate of over 2% at 100 m distance. Outcrossing rates between the GM sorghum and Johnson grass have not been directly measured so are an area of uncertainty.

131. The applicant proposes to surround the planting area with a 100 m monitoring zone that is inspected while the GM sorghum is flowering to destroy any sexually compatible plants. However, as discussed in the previous paragraph, the GM sorghum is probably capable of substantive levels of outcrossing with Johnson grass plants further than 100 m from the planting area. The proposed monitoring zone by itself would not be an effective measure to manage pollen flow from the GM sorghum to Johnson grass. The applicant also proposes to bag GM sorghum plants during flowering. This measure is intended to contain pollen produced by the GM sorghum until it loses viability, but the containment would not be completely effective. For example, a small proportion of pollen may leak from the bottom of pollination bags due to a poor seal, particularly if it is windy. GM sorghum heads

could flower at unexpected times, for example on flowering tillers, and not be bagged. Pollination bags could be dislodged by high winds or damaged by heavy rain or vigorously growing sorghum heads. Therefore, despite the proposed controls, it is considered likely that the GM sorghum could outcross with Johnson grass plants in the vicinity of the trial site and produce some viable hybrid seeds.

132. Weeds typically produce many seeds, but only a small proportion of viable seeds successfully grow into established weeds. Reasons for seed or seedling loss include predation, land management activities and competition with other plants (including the perennial parent plant, in the case of Johnson grass). Therefore, it is considered unlikely that hybrids between the GM sorghum and Johnson grass would establish in the environment.

133. In most cases, hybrids between crop plants and weeds have lower fitness than the weedy parent. However, several studies have reported that hybrids between sorghum and Johnson grass have similar fitness to the weedy parent (Arriola and Ellstrand, 1997) or slightly increased fitness attributed to interspecific hybrid vigour (Magomere et al., 2015; Sangduen and Hanna, 1984). Hybrids between tetraploid sorghum (male parent) and Johnson grass (female parent) have 2 sorghum genomes and 2 Johnson grass genomes, so are a good model for hybrids between GM sorghum and Johnson grass. These hybrids are reported to resemble the weedy parent in perennial growth habit (due to rhizomes) and seed shattering, to be more leafy and vigorous than either parent, and to be both male and female fertile (Sangduen and Hanna, 1984). Therefore, hybrids between GM sorghum and Johnson grass may be as weedy as Johnson grass.

134. As the GM sorghum pollen contains an exact copy of the parental genome, it carries the introduced marker genes. In hybrids between GM sorghum and Johnson grass, the introduced selectable marker gene that confers a herbicide tolerance trait could potentially lead to increased persistence in the environment. A discussion of this trait is provided in a CCI Attachment to the RARMP, which is available to the prescribed experts and agencies that are consulted on the RARMP. The discussion finds that the trait is likely to provide a selective advantage to GM Johnson grass or Johnson grass hybrids, as there are a limited number of ways of effectively controlling Johnson grass. Therefore, the trait could increase the ability of GM Johnson grass or Johnson grass hybrids to persist as weeds in the environment, in areas where the relevant herbicides are used.

135. The GM sorghum pollen would also carry the introduced parthenogenesis gene and introduced gene editing system intended to confer the meiosis to mitosis trait. In hybrids between GM sorghum and Johnson grass, the gene editing system would act on target sites in the genomes inherited from the Johnson grass parent. The possible outcomes are:

- a) Complete gene editing causing homozygous knockout of all 4 endogenous genes involved in meiosis. The hybrid would reproduce by asexual seeds and asexual rhizomes.
- b) Partial gene editing causing homozygous knockout of some of the endogenous genes involved in meiosis. Based on information supplied by the applicant, a hybrid of this type would probably be male and female infertile, but could reproduce by asexual rhizomes.
- c) Partial, non-homozygous gene editing. The hybrid could reproduce sexually via pollen and seed, and asexually via rhizomes.

136. If hybrids between GM sorghum and Johnson grass established in the environment and reproduced asexually, the progeny would retain both hybrid vigour and the selective advantage conferred by the herbicide tolerance gene. It is plausible that the GM hybrids could spread and persist in the environment.

137. If hybrids between GM sorghum and Johnson grass established in the environment and reproduced sexually, they could backcross with other Johnson grass plants. The herbicide tolerance gene that confers a selective advantage could be inherited by progeny. The gene cassette containing the herbicide tolerance gene also contains a *Cas9* gene (without gRNAs) and the visual marker gene (Chapter 1, Section 4.2), but these linked genes are not expected to have a deleterious effect. It is

plausible that this introduced gene cassette could introgress and spread in the Johnson grass population in the environment.

138. In order for a risk scenario to lead to harm, all of the individual steps in the causal pathway must occur. The least likely of the steps in the causal pathway, establishment of GM hybrids in the environment, was considered unlikely to occur. Therefore, the overall likelihood of the risk scenario is assessed as **unlikely**.

3.3 Consequence assessment

139. A consequence assessment determines the degree of seriousness of harm to people or the environment, ranging from marginal to major. The potential harms for this risk scenario relate to an introduced herbicide tolerance gene increasing the ability of GM Johnson grass or Johnson grass hybrids to persist in the environment. This could lead to a small increase to population levels of Johnson grass or Johnson grass-like hybrids in the environment and cause Johnson grass to do more of the same harms that it currently does as a noxious weed.

140. Johnson grass pollen has been shown to elicit allergenic sensitivity in people with grass pollen allergies in Brisbane (Davies et al., 2012), so an increase to Johnson grass populations in the environment could increase the amount of pollen in the air and may increase the likelihood or severity of allergenic reactions in people. However, Johnson grass is not an important allergenic species in Australia and this harm is assessed as a marginal harm to people.

141. Young Johnson grass plants produce high levels of dhurrin toxin, and can cause poisoning in grazing ruminants in Australia (Peerzada et al., 2017)([Weeds Australia website](#), accessed 21 October 2024; [Queensland Government website](#), accessed 19 November 2024). A small increase to Johnson grass populations in pastures could cause increased toxicity to desirable animals. As livestock farmers are expected to be aware of the risks from grazing animals on Johnson grass, this harm is assessed as a minor harm to the environment.

142. Johnson grass that establishes in agricultural fields seriously reduces crop yield due to direct competition and allelopathic action (Peerzada et al., 2017; Travlos et al., 2019)([Weeds Australia website](#), accessed 21 October 2024). A small increase to Johnson grass populations could cause further reduced establishment or yield of desirable crop plants. This harm is assessed as a minor harm to the environment.

143. Perennial Johnson grass is a host for insect pests, including sorghum midge, and a reservoir for viral and fungal pathogens between crop seasons (Peerzada et al., 2017)([Weeds Australia website](#), accessed 21 October 2024). A small increase to Johnson grass populations in agricultural areas could provide an increased reservoir for pathogens or pests of crops. This harm is assessed as a minor harm to the environment.

144. Johnson grass is primarily an agricultural weed, but it can also invade native vegetation (Groves et al., 2003; Peerzada et al., 2017)([Weeds Australia website](#), accessed 21 October 2024). A small increase to Johnson grass populations in natural areas could reduce biodiversity. However, the introduced herbicide tolerance gene is unlikely to provide a selective advantage to Johnson grass in natural areas, as herbicides are rarely used in natural areas. This harm is assessed as a marginal harm to the environment.

145. As the most serious harms under this risk scenario are assessed as minor harms to the environment, the overall consequence assessment for the risk scenario is **minor**.

3.4 Risk estimate

146. The risk estimate is based on a combination of the likelihood and consequence assessments, using the Risk Estimate Matrix, as described in the Regulator's Risk Analysis Framework (OGTR, 2013).

147. As the likelihood assessment is **unlikely** and the consequence assessment is **minor**, the overall risk is estimated as **low**.

Section 4 Uncertainty

148. Uncertainty is an intrinsic part of risk and is present in all aspects of risk analysis. This is discussed in detail in the Regulator’s [Risk Analysis Framework](#) document.

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

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

151. For DIR 209, uncertainty is noted particularly in relation to:

- potential for increased toxicity or allergenicity of the GM sorghum
- potential for differences in agronomic phenotype between the GM sorghum and non-GM sorghum
- in comparison with non-GM sorghum, potential changes to the ability of the GM sorghum to pollinate diploid sorghum plants and tetraploid Johnson grass plants and produce viable seed.

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

153. Chapter 3, Section 4, discusses information that may be required for future releases.

Section 5 Risk evaluation

154. Risk is evaluated against the objective of protecting the health and safety of people and the environment to determine the level of concern and, subsequently, the need for controls to mitigate or reduce risk. Risk evaluation may also aid consideration of whether the proposed dealings should be authorised, need further assessment, or require collection of additional information.

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

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

156. Four risk scenarios were postulated whereby the proposed dealings might give rise to harm to people or the environment. In the context of the limits and controls proposed by the applicant, and considering both the short and long term, three of these scenarios were considered to pose negligible risks. The principal reasons for these conclusions are summarised in Table 1 and include:

- GM sorghum would not be used for human food or animal feed
- limits on the size and duration of the proposed release
- controls proposed by the applicant to restrict the spread and persistence of the GM sorghum plants and their genetic material
- sorghum is primarily self-pollinated

- sorghum has limited ability to establish ongoing volunteer populations in the environment
- the proteins encoded by the introduced genes are not known to be toxic or allergenic.

157. Risk Scenario 4 describes a pathway where the GM sorghum pollinates Johnson grass or other related weeds, the introduced genetic material provides an advantage to the weeds, and there are increased harms related to weediness. Following risk characterisation, the risk described in Risk Scenario 4 was estimated to pose a **low** risk to the environment.

158. The Risk Analysis Framework (OGTR, 2013) describes low risk as a risk of minimal concern that may invoke actions for mitigation beyond standard practices. Measures to mitigate the identified risk are proposed in Chapter 3, Section 2.

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

Chapter 3 Risk management plan

Section 1 Background

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

161. Under Section 56 of the Act, the Regulator must not issue a licence unless satisfied that any risks posed by the dealings proposed to be authorised by the licence are able to be managed in a way that protects the health and safety of people and the environment.

162. All licences are subject to 3 conditions prescribed in the Act. Section 63 of the Act requires that each licence holder inform relevant people of their obligations under the licence. The other statutory conditions allow the Regulator to maintain oversight of licensed dealings: Section 64 requires the licence holder to provide access to premises to OGTR inspectors and Section 65 requires the licence holder to report any information about risks or unintended effects of the dealings to the Regulator on becoming aware of them. Matters related to the ongoing suitability of the licence holder must also be reported to the Regulator.

163. The licence is also subject to any conditions imposed by the Regulator. Examples of the matters to which conditions may relate are listed in Section 62 of the Act. Licence conditions can be imposed to limit and control the scope of the dealings and to manage risk to people or the environment. In addition, the Regulator has extensive powers to monitor compliance with licence conditions under Section 152 of the Act.

Section 2 Risk treatment measures for substantive risks

164. The risk characterisation of Risk scenario 4 in Chapter 2 concluded that there is a low risk to the environment from the proposed field trial of the GM sorghum. The risk scenario involves the GM sorghum pollinating Johnson grass or other related weeds, the introduced genetic material providing an advantage to the weeds, and increased harms related to weediness.

165. This risk could be managed by a risk treatment measure that reduces the likelihood of pollen flow from the GM sorghum to Johnson grass or other related weeds. The applicant proposed to manage pollen flow by enclosing GM sorghum panicles in pollination bags during flowering, and by surrounding the planting area with a 100 m monitoring zone. The monitoring zone would be inspected while the GMOs are flowering to destroy any sorghum or related species. An additional risk treatment measure to reduce pollen flow is to increase the size of the monitoring zone from 100 m to 200 m.

166. The OECD Scheme for certification of seed from *Sorghum x almum* (a tetraploid hybrid between sorghum and Johnson grass) specifies that crops for production of certified seed must be located at least 200 m from any source of contaminating pollen to achieve internationally acceptable varietal purity (OECD, 2024). In addition, a study measuring pollen flow from grain sorghum to shattercane (a non-domesticated form of *S. bicolor*) found that the average outcrossing rate at a distance of 200 m was 2.5-fold lower than the average outcrossing rate at a distance of 100 m (Schmidt et al., 2013). Therefore, increasing the size of the monitoring zone from 100 m to 200 m is expected to substantially reduce pollen flow from GM sorghum to Johnson grass.

167. The licence conditions imposed to restrict pollen flow are to enclose GM sorghum panicles in pollination bags during flowering and to surround the planting area with a 200 m monitoring zone. These conditions are considered sufficient to manage the risks associated with Risk scenario 4.

168. The risk assessment of the other risk scenarios listed in Chapter 2 concluded that they pose negligible risks to people and the environment. These risk scenarios were considered in the context of the scale of the proposed release (Chapter 1, Section 2.1), the proposed controls (Chapter 1, Section 2.2), and the receiving

environment (Chapter 1, Section 5), and considering both the short and the long term. The risk evaluation concluded that no specific risk treatment measures are required to treat these negligible risks. Limits and controls proposed by the applicant and other general risk management measures are discussed below.

Section 3 General risk management

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

3.1 Limits and controls on the release

170. Sections 2.1 and 2.2 in Chapter 1 list the limits and controls proposed by the applicant. Many of these are discussed in the 4 risk scenarios considered in Chapter 2. The controls to restrict pollen flow are further discussed in Section 2 of this chapter. The appropriateness of the remaining limits and controls is considered further in the following section.

3.1.1 Consideration of limits and controls proposed by the applicant

171. The applicant proposes to limit the field trial to a duration of 3 years at a single site with an area of up to 1 ha per year. The small size and short duration of the trial would restrict the exposure of people and desirable animals to the GMOs (Risk scenario 1). These limits are included in the licence.

172. The applicant proposes that the GM sorghum and its products would not be used for human food or animal feed. This measure would restrict the exposure of people and livestock to the GMOs (Risk scenario 1) and minimise dispersal of the GMOs by livestock (Risk scenario 2). A licence condition prohibits the use of GM plant material in human food or animal feed.

173. The applicant does not specify whether non-GM sorghum plants will be grown as part of the field trial. If non-GM sorghum plants are grown, they could be pollinated by GM sorghum and bear GM seeds. It is also possible that GM sorghum plants could grow in non-GM plots due to seed dispersal during planting. Therefore, a licence condition requires that any non-GM sorghum plants grown in the trial planting area must be treated as if they are GMOs.

174. The applicant proposes to enclose the planting area in netting that would exclude birds and larger animals. This measure would restrict the exposure of desirable animals to the GMOs (Risk scenario 1) and restrict dispersal of the GMOs by animals (Risk scenario 2). Licence conditions require that each planting area is enclosed in netting capable of excluding birds, livestock and other large animals, and that the netting is inspected regularly for damage and repaired or replaced as necessary.

175. After harvest of the trial site, the applicant proposes to destroy GM sorghum plants and to destroy harvested GM seed that is not required for analysis or future planting. These measures would restrict persistence of GM sorghum (Risk scenario 2). Licence conditions require that trial sites must be cleaned (which would destroy any surviving GM plants) within 14 days after harvest, and that harvested GM seed not required for experimentation or future planting must be destroyed as soon as practicable. In addition, to deal with the case of failed crops that may not be harvested, a licence condition requires that GM sorghum must be harvested or destroyed within 8 months after planting.

176. The applicant proposes post-harvest monitoring of the trial site to identify and destroy any volunteer sorghum. Inspections would occur every 35 days and continue until no volunteers are detected for 6 consecutive months. The applicant would irrigate the trial site post-harvest if there is insufficient rainfall to germinate sorghum. These proposed measures would manage the persistence of GM sorghum (Risk scenario 2), and are further discussed below.

177. The applicant has not specified which parts of the trial site would be inspected for volunteer sorghum after harvest. GM sorghum seed lost during harvest and threshing activities could fall a short

distance outside the planting area unobserved, as sorghum seeds are small and inconspicuous. There is also potential for short-distance dispersal of GM sorghum seeds by ants or rodents (Risk scenario 2). Therefore, the licence requires post-harvest inspections of at least the planting area and a 10 m buffer zone surrounding the outer edge of the planting area.

178. In Australia, the time from planting to 50% flowering of sorghum crops varies from 55 to 80 days, depending both on cultivar and on temperatures (GRDC, 2017). Sorghum plants can also grow from tillers, and ratoon plants growing from tillers mature more quickly than plants growing from seeds (Doggett, 1988). Therefore, the proposed frequency of post-harvest monitoring, every 35 days, is considered suitable to detect emerging sorghum volunteers before flowering and is included in the licence.

179. The applicant did not specify the total period of post-harvest inspections. A study of the longevity of grain sorghum seeds in a temperate location found that no seeds remained viable after 8 months buried in soil (Jacques et al., 1974). A similar study in a tropical location, where seeds are not killed by winter cold, found that 0.3% of grain sorghum seeds remained viable after 12 months burial and no seeds remained viable after 18 months burial (Adugna, 2013). The licence requires post-harvest inspections for a period of at least 12 months and until no sorghum volunteers have been detected in the area for at least the final 6 months of inspections.

180. The applicant did not specify when the trial site would need to receive rainfall or be irrigated to promote germination of sorghum volunteers. Generally, sorghum crops in southern Queensland are planted in October or later to avoid cold conditions (GRDC, 2017). The licence requires a watering event between October and February in the growing season following harvest of the GMOs. The licence also requires light tillage prior to the watering event, to further promote seed germination.

181. The applicant proposes to locate each planting area at least 100 m away from the nearest natural waterway. This measure would restrict the potential for GM sorghum seeds to be dispersed by flooding (Risk scenario 2), and is included in the licence. In addition, licence conditions require that planting areas must not be located in flood prone areas, and that the licence holder must immediately notify the Regulator of any extreme weather event affecting a planting area, to allow assessment and management of any risks.

182. The applicant proposes that rodents in the trial site would be controlled by baiting. This would restrict dispersal of GM seed by rodents (Risk scenario 2). The licence requires implementation of measures to control rodents, such as baits or traps, at the trial sites while the GMOs are grown. The licence also requires the innermost 10 m of the monitoring zone to be maintained in a manner that does not attract or harbour rodents while the GMOs are grown at a planting area, to deter rodents from travelling into or out of the planting area.

183. The applicant proposes to clean equipment used with the GMOs prior to use for any other purpose. The applicant also proposes to transport and store GMOs in accordance with the Regulator's current [Guidelines for the Transport, Storage and Disposal of GMOs](#). These measures would minimise dispersal of GM sorghum seed outside the trial sites by human activity (Risk scenario 2) and are included in the licence.

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

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

- limit the duration of the release to between March 2025 and March 2028
- limit the size of the release to one site per year, with a maximum planting area of 1 ha
- not allow GM plant material to be used for human food or animal feed
- enclose the planting area in netting capable of excluding birds and large animals
- destroy all harvested GM seed not required for further analysis or future planting
- monitor each post-harvest trial site at least every 35 days for a period of at least 12 months, and destroy any sorghum plants that may grow, until no volunteers have been detected for a period of 6 consecutive months
- till and irrigate the post-harvest trial sites to promote germination of sorghum seed

- locate the planting areas at least 100 m away from waterways
- implement measures to control rodents within the planting areas
- clean equipment after use with the GMOs
- transport and store GMOs in accordance with the Regulator’s guidelines
- enclose GM sorghum panicles in pollination bags during flowering
- surround the planting area with a 200 m monitoring zone which is inspected while the GMOs are flowering to destroy any sorghum or related species.

3.2 Other risk management considerations

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

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

3.2.1 Applicant suitability

186. In making a decision whether or not to issue a licence, the Regulator must have regard to the suitability of the applicant to hold a licence. Under section 58 of the Act, matters that the Regulator must take into account include:

- any relevant convictions of the applicant
- any revocation or suspension of a relevant licence or permit held by the applicant under a law of the Commonwealth, a State or a foreign country and
- the capacity of the applicant to meet the conditions of the licence.

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

188. In addition, the applicant organisation must have access to an Institutional Biosafety Committee (IBC) and be an accredited organisation under the Act.

3.2.2 Contingency plan

189. The University of Queensland is required to submit a contingency plan to the Regulator before planting the GMOs. This plan will detail measures to be undertaken in the event of any unintended presence of the GM sorghum outside permitted areas.

190. Before planting the GMOs, the University of Queensland is also required to provide the Regulator with a method to reliably detect the GMOs or the presence of the genetic modifications in a recipient organism.

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

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

3.2.4 Reporting requirements

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

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

- any unintended effects of the field trial.

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

- expected and actual dates of planting
- details of areas planted with the GMOs
- expected dates of flowering
- expected and actual dates of harvest and cleaning after harvest and
- details of inspection activities.

3.2.5 Monitoring for compliance

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

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

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

Section 4 Issues to be addressed for future releases

197. Additional information has been identified that may be required to assess an application for a commercial release of the GM sorghum or to justify a reduction in limits and controls. This includes:

- additional molecular or biochemical characterisation of the GM sorghum plants with respect to potential for increased toxicity or allergenicity
- additional phenotypic characterisation of the GM sorghum in comparison to non-GM sorghum
- additional data regarding the capacity of the GM sorghum to pollinate diploid sorghum plants and tetraploid Johnson grass plants and produce viable seed, in comparison to the capacity of non-GM sorghum.

Section 5 Conclusions of the RARMP

198. The risk assessment concludes that the proposed limited and controlled release of GM sorghum poses negligible risks to the health and safety of people and a low risk to the environment as a result of gene technology. The risk to the environment warrants specific risk treatment measures.

199. The risk management plan concludes that the identified low risk to the environment can be managed by risk treatment measures that restrict pollen flow from the GM sorghum to related weeds. Licence conditions are also imposed to limit the trial to the proposed scale and to enact the proposed controls to restrict the spread and persistence of the GMO in the environment, as these were important considerations in establishing the context for assessing the risks.

References

- ABARES (2024). Australian Crop Report: June quarter 2024. (Canberra: Australian Bureau of Agricultural and Resource Economics and Sciences).
- Adugna, A. (2013). Ecotypic variation for seed dormancy, longevity and germination requirements in wild/weedy *Sorghum bicolor* in Ethiopia: implications for seed mediated transgene dispersal and persistence. *SpringerPlus* 2, 248.
- Anderson, J.E., Michno, J.-M., Kono, T.J.Y., Stec, A.O., Campbell, B.W., Curtin, S.J., and Stupar, R.M. (2016). Genomic variation and DNA repair associated with soybean transgenesis: a comparison to cultivars and mutagenized plants. *BMC Biotechnology* 16, 41.
- Andersson, M.S., and de Vicente, M.C. (2010). Sorghum. In *Gene Flow between Crops and Their Wild Relatives* (The Johns Hopkins University Press), pp. 443-462.
- Arriola, P.E., and Ellstrand, N.C. (1996). Crop-to-weed gene flow in the genus *Sorghum* (Poaceae): Spontaneous interspecific hybridization between Johnsongrass, *Sorghum halepense*, and crop sorghum, *S. bicolor*. *American Journal of Botany* 83, 1153-1160.
- Arriola, P.E., and Ellstrand, N.C. (1997). Fitness of interspecific hybrids in the genus *Sorghum*: Persistence of crop genes in wild populations. *Ecological Applications* 7, 512-518.
- Cameron, A.G. (2006). Forage Sorghum. (Northern Territory Government).
- Contreras, D., Leon, R.G., Post, A.R., and Everman, W.J. (2022). Critical period of grass weed control in ALS-tolerant grain sorghum (*Sorghum bicolor*) is affected by planting date and environment. *Frontiers in Agronomy* 4.
- Cowan, M.F., Blomstedt, C.K., Norton, S.L., Henry, R.J., Møller, B.L., and Gleadow, R. (2020). Crop wild relatives as a genetic resource for generating low-cyanide, drought-tolerant *Sorghum*. *Environmental and Experimental Botany* 169, 103884.
- Davies, J.M., Li, H., Green, M., Towers, M., and Upham, J.W. (2012). Subtropical grass pollen allergens are important for allergic respiratory diseases in subtropical regions. *Clinical and Translational Allergy* 2, 4.
- Delaney, B., Goodman, R.E., and Ladics, G.S. (2018). Food and feed safety of genetically engineered food crops. *Toxicological Sciences* 162, 361-371.
- DiTomaso, J.M., Kyser, G.B., Oneto, S.R., Wilson, R.G., Orloff, S.B., Anderson, L.W., Wright, S.D., *et al.* (2013). *Weed Control in Natural Areas in the Western United States* (Weed Research and Information Centre, University of California).
- Djè, Y., Heuertz, M., Ater, M., Lefèbvre, C., and Vekemans, X. (2004). In situ estimation of outcrossing rate in sorghum landraces using microsatellite markers. *Euphytica* 138, 205-212.
- Doggett, H. (1988). *Sorghum*, 2nd edn (Essex, UK: Longman Scientific and Technical).
- DPIRD (2022). *Sorghum bicolor* - environmental weed risk assessment 2022. (Perth: Department of Primary Industries and Regional Development, Western Australia).
- Eyre, J., Wilkus, E., Rodriguez, D., Serafin, L., Hellyer, M., Bishop, A., Broad, I., *et al.* (2019). Dryland and irrigated winter-sown sorghum. (Grains Research and Development Corporation).

- Gómez, C., and Espadaler, X. (2013). An update of the world survey of myrmecochorous dispersal distances. *Ecography* 36, 1193-1201.
- Grain Growers (2021). State of the Australian grains industry 2021. (Sydney: Grain Growers Limited).
- GRDC (2017). GRDC Grownotes: Sorghum. (Canberra: Grains Research and Development Corporation).
- GRDC (2023). 2023 NVT Sorghum Harvest Report. (Canberra: Grains Research and Development Corporation).
- Groves, R.H., Hosking, J.R., Batianoff, G.N., Cooke, D.A., Cowie, I.D., Johnson, R.W., Keighery, G.J., *et al.* (2003). Weed categories for natural and agricultural ecosystem management (Bureau of Rural Sciences, Canberra).
- Hahn, F., and Nekrasov, V. (2019). CRISPR/Cas precision: do we need to worry about off-targeting in plants? *Plant Cell Reports* 38, 437-441.
- Hodnett, G.L., Ohadi, S., Pugh, N.A., Bagavathiannan, M.V., and Rooney, W.L. (2019). *Sorghum bicolor* x *S. halepense* interspecific hybridization is influenced by the frequency of 2n gametes in *S. bicolor*. *Scientific Reports* 9, 17901.
- Jacques, G.L., Vesecky, J.F., Feltner, K.C., and Vanderlip, R.L. (1974). Effects of depth and duration of burial on shattercane seed. *Crop Science* 14, 787-789.
- Keese, P. (2008). Risks from GMOs due to horizontal gene transfer. *Environmental Biosafety Research* 7, 123-149.
- Keese, P.K., Robold, A.V., Myers, R.C., Weisman, S., and Smith, J. (2014). Applying a weed risk assessment approach to GM crops. *Transgenic Research* 23, 957-969.
- Li, J., Manghwar, H., Sun, L., Wang, P., Wang, G., Sheng, H., Zhang, J., *et al.* (2019). Whole genome sequencing reveals rare off-target mutations and considerable inherent genetic or/and somaclonal variations in CRISPR/Cas9-edited cotton plants. *Plant Biotechnology Journal* 17, 858-868.
- Magomere, T.O., Obukosia, S.D., Shibairo, S.I., Ngugi, E.K., and Mutitu, E. (2015). Evaluation of relative competitive ability and fitness of *Sorghum bicolor* x *Sorghum halepense* and *Sorghum bicolor* x *Sorghum sudanense* F1 hybrids. *Journal of Biological Sciences* 15, 1-15.
- Maity, A., Young, B., Subramanian, N., and Bagavathiannan, M. (2022). Pollen-mediated transfer of herbicide resistance between johnsongrass (*Sorghum halepense*) biotypes. *Scientific Reports* 12, 7663.
- Myrans, H., Diaz, M.V., Khoury, C.K., Carver, D., Henry, R.J., and Gleadow, R. (2020). Modelled distributions and conservation priorities of wild sorghums (*Sorghum* Moench). *Diversity and Distributions* 26, 1727-1740.
- OECD (2024). OECD Seed Schemes: Rules and Regulations. (Organisation for Economic Co-operation and Development).
- OGTR (2013). Risk Analysis Framework 2013, 4th edn (Canberra: Office of the Gene Technology Regulator).
- OGTR (2024). The Biology of *Sorghum bicolor* (L.) Moench subsp. *bicolor* (Sorghum) (Canberra: Office of the Gene Technology Regulator).
- Ohadi, S., Hodnett, G., Rooney, W., and Bagavathiannan, M. (2018). Gene flow and its consequences in *Sorghum* spp. *Critical Reviews in Plant Sciences* 36, 367-385.

- Pedersen, J.F., Toy, J.J., and Johnson, B. (1998). Natural outcrossing of sorghum and sudangrass in the central grass plains. *Crop Science* 38, 937-939.
- Peerzada, A.M., Ali, H.H., Hanif, Z., Bajwa, A.A., Kebaso, L., Frimpong, D., Iqbal, N., *et al.* (2017). Eco-biology, impact, and management of *Sorghum halepense* (L.) Pers. *Biological Invasions* 25, 955-973.
- Pennington, P.D., Costa, L.M., Gutierrez-Marcos, J.F., Greenland, A.J., and Dickinson, H.G. (2008). When genomes collide: aberrant seed development following maize interploidy crosses. *Annals of Botany* 101, 833-843.
- Philips, J.G., Martin-Avila, E., and Robold, A.V. (2022). Horizontal gene transfer from genetically modified plants - Regulatory considerations. *Frontiers in Bioengineering and Biotechnology* 10.
- Rabbi, I.Y., Parzies, H.K., Kiambi, D., Haussmann, B.I., Folkertsma, R., and Geiger, H.H. (2011). Experimental studies on pollen-mediated gene flow in *Sorghum bicolor* (L.) Moench using male-sterile bait plants. *Plant Breeding* 130, 217-224.
- Rew, L.J., Medd, R.W., Van de Ven, R., Gavin, J.J., Robinson, G.R., Tuitee, M., Barnes, J., *et al.* (2005). Weed species richness, density and relative abundance on farms in the subtropical grain region of Australia. *Australian Journal of Experimental Agriculture* 45, 711-723.
- Richardson, F.J., Richardson, R.G., and Shepherd, R.C.H. (2011). *Weeds of the South-East: an identification guide for Australia*, 2nd edn (Meredith, Victoria, Australia: R.G. and F.J. Richardson).
- Sangduen, N., and Hanna, W. (1984). Chromosome and fertility studies on reciprocal crosses between two species of autotetraploid sorghum: *Sorghum bicolor* (L.) Moench and *S. halepense* (L.) Pers. *Journal of Heredity* 75, 293-296.
- Schmidt, J.J., Pedersen, J.F., Bernards, M.L., and Lindquist, J.L. (2013). Rate of shattercane x sorghum hybridization in situ. *Crop Science* 53, 1677-1685.
- Schmidt, M., and Bothma, G. (2006). Risk assessment for transgenic sorghum in Africa: Crop-to-crop gene flow in *Sorghum bicolor* (L.) Moench. *Crop Science* 46, 790-798.
- Schnell, J., Steele, M., Bean, J., Neuspiel, M., Girard, C., Dormann, N., Pearson, C., *et al.* (2015). A comparative analysis of insertional effects in genetically engineered plants: considerations for pre-market assessments. *Transgenic Research* 24, 1-17.
- Shirley, B.W., Hanley, S., and Goodman, H.M. (1992). Effects of ionizing radiation on a plant genome: analysis of two *Arabidopsis transparent testa* mutations. *Plant Cell* 4, 333-347.
- Sias, C., Subramanian, N., Hodnett, G., Rooney, W., and Bagavathiannan, M. (2023). Rate of crop-weed hybridization in *Sorghum bicolor* x *Sorghum halepense* is influenced by genetic background, pollen load, and the environment. *Evolutionary Applications* 16, 781-796.
- Soyars, C.L., Peterson, B.A., Burr, C.A., and Nimchuk, Z.L. (2018). Cutting edge genetics: CRISPR/Cas9 editing of plant genomes. *Plant & Cell Physiology* 59, 1608-1620.
- Steiner, H.Y., Halpin, C., Jez, J.M., Kough, J., Parrott, W., Underhill, L., Weber, N., *et al.* (2013). Evaluating the potential for adverse interactions within genetically engineered breeding stacks. *Plant Physiology* 161, 1587-1594.
- Tang, X., Liu, G., Zhou, J., Ren, Q., You, Q., Tian, L., Xin, X., *et al.* (2018). A large-scale whole-genome sequencing analysis reveals highly specific genome editing by both Cas9 and Cpf1 (Cas12a) nucleases in rice. *Genome Biology* 19, 84.

Travlos, I.S., Montull, J.M., Kukorelli, G., Malidza, G., Dogan, M.N., Cheimona, N., Antonopoulos, N., *et al.* (2019). Key aspects on the biology, ecology and impacts of Johnsongrass [*Sorghum halepense* (L.) Pers] and the role of glyphosate and non-chemical alternative practices for the management of this weed in Europe. *Agronomy* 9.

Virtue, J.G. (2008). SA weed risk management guide. (Adelaide: Government of South Australia: Department of Water, Land and Biodiversity Conservation).

Wang, X., Tu, M., Wang, Y., Yin, W., Zhang, Y., Wu, H., Gu, Y., *et al.* (2021). Whole-genome sequencing reveals rare off-target mutations in CRISPR/Cas9-edited grapevine. *Horticultural Research* 8, 114.

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

The Regulator received several submissions from prescribed experts, agencies and authorities² on the consultation RARMP. All issues raised in submissions relating to risks to the health and safety of people and the environment were considered in the context of the currently available scientific evidence and were used in finalising the RARMP that formed the basis of the Regulator’s decision to issue the licence. Advice received is summarised below.

Submission	Summary of issues raised	Comment
1	<p>Agrees that the risk assessment identifies all plausible risk scenarios by which the proposed dealings could potentially give rise to risks relating to the health and safety of people or the environment.</p> <p>Agrees that the proposed risk treatment measures to restrict pollen flow are appropriate to manage the identified risk.</p> <p>Agrees that the other limits and controls are appropriate for the field trial.</p> <p>Agrees with the overall conclusion of the RARMP.</p>	Noted.
2	Notes that the licence will prohibit the use of GM plant material in human food or animal feed. Does not have any further comments on the licence application at this stage.	Noted.
3	Does not have any advice or comments on the RARMP for DIR 209.	Noted.
4	Accepts that, overall, the University of Queensland’s application has negligible risks to the health and safety of people and the environment. Satisfied that the measures taken to manage the short- and long-term risks from the proposal are adequate.	Noted.
5	There is a risk of GM pollen crossing with compatible weeds, like Johnson grass, which may become weedier as a result. The trial takes precautions to prevent this, including collecting pollen-bearing flower heads. This should be carried out thoroughly as the wind-borne pollen can carry large distances.	<p>The risks from GM sorghum crossing with compatible weeds, such as Johnson grass, are discussed in Risk Scenario 4 in Chapter 2 of the RARMP.</p> <p>Measures to restrict pollen flow from the GM sorghum to compatible weeds are discussed in Section 2 of Chapter 3 of the RARMP. The controls imposed are to enclose pollen-bearing flower heads in pollen-proof bags during flowering, and to surround the GM sorghum planting area with a 200 m monitoring zone that contains no compatible weeds. These controls are considered sufficient to manage any risks from GM pollen fertilising compatible weeds.</p>

² Prescribed experts, agencies and authorities include GTTAC, State and Territory Governments, Australian Government agencies and the Minister for the Environment.

Submission	Summary of issues raised	Comment
	<p>Taking into consideration the risks included in the RARMP and the limits and controls in the draft licence, one member advised that the licence could be issued.</p> <p>Any risks to possible food chain contamination have been addressed.</p>	Noted.
6	<p>Agrees that the proposed field trial poses negligible risk to human health and safety and a low risk to the environment, and that the potential risks can be managed through risk treatment measures.</p> <p>The limits and controls outlined in the RARMP for this field trial are appropriate.</p>	Noted.

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

The Regulator received one submission from a member of the public on the consultation RARMP. The issues raised in the submission are summarised in the table below. All issues that related to risks to the health and safety of people and the environment were considered in the context of currently available scientific evidence in finalising the RARMP that formed the basis of the Regulator’s decision to issue the licence.

Submission	Summary of issues raised	Comment
1	<p>Application DIR 209 must include detailed results of DIR 189 trials of sorghum genetically modified for asexual seed formation, with the same introduced parthenogenesis gene as the GM sorghum in application DIR 209. Not providing this data and its analysis for public consideration makes the DIR 209 application incomplete.</p> <p>The RARMP indicates that “a search of the scientific literature found no information to suggest that the proteins encoded by the introduced genes are toxic or allergenic to people or toxic to animals. However, there is limited data available for some of the introduced genes, so this is an area of uncertainty.” These unknowns are of major importance, so the DIR 209 application should not proceed further until compelling evidence of no harm is found.</p>	<p>The outcome of the field trial of GM sorghum under licence DIR 189 is described in general terms in the RARMP. The applicant did not observe any differences in agronomic phenotype between the GM sorghum and non-GM sorghum (Chapter 1, Section 4.5). There were no reports of adverse effects on human health or the environment resulting from the DIR 189 release (Chapter 1, Section 6.1).</p> <p>The Regulator did not ask the applicant to supply detailed data from the DIR 189 field trial. The effect of the single gene introduced in the GMO in DIR 189 is very different from the effects of the combination of genetic modifications in the GMO in DIR 209. Therefore, detailed data from the DIR 189 field trial would have little value in predicting the characteristics of the GMO in DIR 209.</p> <p>Licence application DIR 209 is for a small-scale field trial. As discussed in Section 4 of Chapter 2 of the RARMP, field trials are part of the process of gathering data about a GMO. Therefore, at the point when a field trial application is assessed, generally the applicant does not have complete data about the GMO. Field trials are permitted under stringent limits and controls that restrict exposure to the GMO.</p> <p>The potential for GM sorghum grown in the field trial to be toxic or allergenic to people or toxic to animals is considered in Risk Scenario 1 in Chapter 2 of the RARMP. The discussion notes partial data regarding toxicity or allergenicity of some of the introduced genes, however, the uncertainty does not affect the level of risk. The risk scenario concludes that the limits and controls effectively restrict exposure of people or animals to the GMO and the risk is negligible. The controls include that the GM sorghum must not be used for human food or animal feed, and that the field trial site must be enclosed in netting that excludes birds, livestock and other large animals.</p> <p>If the applicant submits a future licence application for commercial release of GM sorghum, the Regulator will require further information regarding potential toxicity or allergenicity of the GMO, as any risk would not be managed by limits and controls.</p>

Submission	Summary of issues raised	Comment
	<p>The RARMP indicates that “it is likely that most triploid seeds resulting from the GM sorghum pollinating non-GM sorghum will abort prior to seed maturity. However, seed development of these crosses has not been directly tested and is an area of uncertainty.” These are further grounds for stopping the clock on DIR 209 until substantial data is produced and assessed.</p>	<p>Risk Scenario 3 in Chapter 2 of the RARMP considers the potential for GM sorghum to pollinate non-GM sorghum. The discussion notes uncertainty regarding whether crosses between GM sorghum and non-GM sorghum will produce viable seed, however, the uncertainty does not affect the level of risk. The risk scenario concludes that the limits and controls minimise pollen flow from the GM sorghum to non-GM sorghum outside the trial site and the risk is negligible.</p>
	<p>Three species from the <i>Sorghum</i> genus are declared noxious in NSW. Gene flow between cultivated sorghum and related invasive weed species may affect their weediness and make them more invasive. <i>S. halepense</i> (Johnson grass) is an invasive and aggressive weed. According to the RARMP, hybridisation between grain sorghum and Johnson grass occurs under field conditions. Yet “outcrossing rates between the GM sorghum and Johnson grass have not been directly measured so are an area of uncertainty”. This evidence gap is a major regulatory failure. Potential outcrossing is an environmental hazard that must be quantified, assessed and minimised. Any outcrossing from GM sorghum to Johnson grass, with genes that may enhance its fitness, must be prevented.</p>	<p>Risk Scenario 4 in Chapter 2 of the RARMP considers the potential for GM sorghum to outcross with related weeds. This risk scenario addresses uncertainty about the rate of outcrossing between the GM sorghum and Johnson grass by making the conservative assumption that the GM sorghum is highly crossable with Johnson grass, and outcrossing could occur at a rate as high as crossing between Johnson grass plants. Risk scenario 4 is identified as a substantive risk. Detailed risk characterisation for this risk scenario found a low risk to the environment.</p> <p>Risk treatment measures to manage the risks associated with Risk Scenario 4 are discussed in Section 2 of Chapter 3 of the RARMP, and are imposed in the licence.</p>
	<p>According to the OGTR’s document: The Biology of Sorghum, high levels of outcrossing can occur. Recommended isolation distances for basic sorghum seed are 400 m. Yet the licence applicant was allowed to conduct DIR 189 and seeks to conduct DIR 209 trials with only a 100 m separation from Johnson grass, a very invasive weed. The RARMP does not adequately justify the small buffer zone of the trial plot from open environments.</p>	<p>In both DIR 189 and DIR 209 field trials, the primary control to prevent outcrossing is to use pollination bags, i.e. to enclose the flowering heads of GM sorghum in pollen-proof bags during flowering. A monitoring zone (isolation distance) is imposed as a secondary control, in case a small amount of GM pollen escapes the pollination bags. The DIR 189 field trial required a monitoring zone of 100 m. For DIR 209, the applicant proposed a monitoring zone of 100 m, but the RARMP found that this was insufficient due to the characteristics of the GM sorghum in DIR 209 (Risk Scenario 4, Chapter 2), and a monitoring zone of 200 m has been imposed (Section 2, Chapter 3). The combination of using pollination bags and a 200 m monitoring zone is considered sufficient to manage any risks associated with pollen flow from the GM sorghum to Johnson grass.</p>
	<p>According to the OGTR’s document: The Biology of Sorghum, there is uncertainty regarding the potential of sorghum seeds to be dispersed by birds or animals. This evidence gap must be filled with comprehensive and independent scientific evidence.</p>	<p>Risk Scenario 2 in Chapter 2 of the RARMP considers the potential for birds or animals to disperse GM sorghum seeds. The risk scenario makes the conservative assumption that birds and animals are able to disperse sorghum seeds. The risk scenario concludes that the controls would minimise dispersal of GM sorghum seed outside the trial site and the risk is negligible.</p>

Submission	Summary of issues raised	Comment
	<p>According to the OGTR’s document: The Biology of Sorghum, sorghum volunteers are commonly found in cropping areas, and in other areas due to human transport. Sorghum contains several anti-nutritional compounds and volunteers can act as a reservoir for a range of pests and pathogens. This weediness poses impediments to DIR 209 and any subsequent applications being approved.</p>	<p>The Gene Technology Act requires the Regulator to identify and manage risks to human health and safety and the environment posed by gene technology.</p> <p>The listed traits of sorghum are natural characteristics of non-GM sorghum. They are not risks posed by gene technology. The Regulator cannot decide whether or not to issue a licence based on traits that are not caused by gene technology.</p>
	<p>The DIR 209 RARMP focusses on agricultural contexts. The RARMP should consider more fully the negative impacts on natural environments of both this trial and any future commercial release.</p>	<p>The DIR 209 licence application is for a small-scale field trial in an agricultural area. Due to the limits and controls on the trial and the fact that volunteer sorghum plants are found in disturbed sites, such as agricultural areas and roadsides, there is limited ability for GM sorghum to be dispersed to natural areas and persist. Therefore, the RARMP gives greater consideration to the effects of GM sorghum on the areas at and around the trial site. Risk Scenario 4 in Chapter 2 of the RARMP considers the potential for Johnson grass carrying introduced genes from the GM sorghum to spread in the environment and cause harm to natural areas.</p> <p>If the applicant submits a future licence application for commercial release of GM sorghum, the RARMP prepared for that application will thoroughly consider any risks to natural areas.</p>
	<p>DIR 209 should be assessed under the EPBC Act before it can progress any further.</p>	<p>As part of the consultation process for licence application DIR 209, the RARMP was sent to the Minister of the Environment for comment. The Minister’s response did not indicate that any separate assessment was required.</p>
	<p>The DIR 209 RARMP should assess the economic costs of GM sorghum.</p>	<p>The Gene Technology Act requires the Regulator to identify and manage risks to human health and safety and the environment posed by gene technology. The Regulator cannot consider economic costs or benefits when deciding whether to issue a licence.</p>