Australian Government
Department of Health
Office of the Gene Technology Regulator

May 2017

Risk Assessment and Risk Management Plan
(consultation version)
for

DIR 153

Limited and controlled release of sorghum genetically modified for grain quality traits

Applicant - University of Queensland

This RARMP is open for consultation until 26 June 2017.

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

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

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

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

for

Licence Application No. DIR 153

Introduction

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

The application

Application number	DIR 153
Applicant	The University of Queensland (UQ)
Project title	Limited and controlled release of sorghum genetically modified for grain quality traits
Parent organism	Sorghum (*Sorghum bicolor*)
Introduced genes and modified traits	• modified kafirin gene[1] from sorghum for altered seed protein content and digestibility • fragment of a foldase enzyme gene[1] from sorghum for altered seed size, protein content and digestibility • fragments of three membrane protein genes[1] from sorghum for altered seed size or number of seeds • *nptII* selectable marker gene from *Escherichia coli*
Proposed location	One site in the first year and up to four sites in the second and third years in south-east Queensland
Proposed release size	Up to 1 ha in the first year and up to 5 ha in the second and third years
Proposed release dates	October 2017 – June 2020
Primary purpose	To assess agronomic characteristics, yield and grain quality of the GM sorghum plants

Risk assessment

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

[1] Specific gene names are not provided as they have been declared Confidential Commercial Information.

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

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 other sorghum plants 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 principal reasons for the conclusion of negligible risks are that the GM plant material will not be used for human food or animal feed except in an experimental poultry feeding trial, the proposed limits and controls effectively contain the GMOs and their genetic material and minimise exposure, and the GM sorghum has limited ability to establish populations outside cultivation.

Risk management plan

The risk management plan describes measures to protect the health and safety of people and to protect the environment by controlling or mitigating risk. The risk management plan is given effect through licence conditions. Draft licence conditions are detailed in Chapter 4 of the RARMP.

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

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Abbreviations

Act	*Gene Technology Act 2000*
CCI	Confidential Commercial Information
cm	centimetres
DIR	Dealings involving Intentional Release
DNA	deoxyribonucleic acid
FSANZ	Food Standards Australia New Zealand
GM	genetically modified
GMO	genetically modified organism
ha	hectare
HGT	horizontal gene transfer
m	metres
NLRD	Notifiable Low Risk Dealing
nptII	neomycin phosphotransferase type II
NSW	New South Wales
OGTR	Office of the Gene Technology Regulator
PC2	Physical Containment level 2
RARMP	Risk Assessment and Risk Management Plan
Regulations	Gene Technology Regulations 2001
Regulator	Gene Technology Regulator
siRNA	short interfering ribonucleic acid
subsp.	subspecies
UQ	the University of Queensland

Chapter 1 Risk assessment context

Section 1 Background

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

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

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

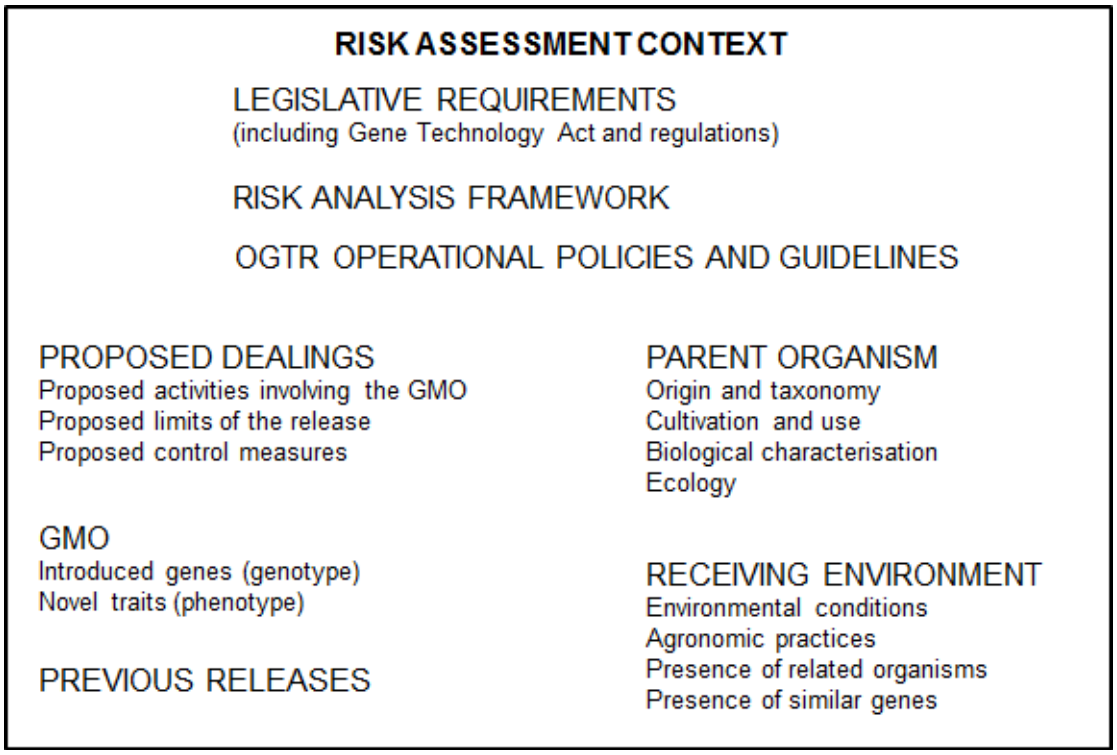

Figure 1. Summary of parameters used to establish the risk assessment context

Section 2 Regulatory framework

4. Sections 50, 50A and 51 of the Act outline the matters which the Gene Technology Regulator (the Regulator) must take into account, and who must be consulted, when preparing the Risk Assessment and Risk Management Plans (RARMPs) that inform the decisions on licence applications. In addition, the Regulations outline further matters the Regulator must consider when preparing a RARMP.

5. In accordance with section 50A of the Act, this application is considered to be a limited and controlled release application, as its principal purpose is to enable the applicant to conduct experiments and the applicant has proposed limits on the size, location and duration of the release, as well as controls to restrict the spread and persistence of the GMOs and their genetic material in the

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

6. Section 52 of the Act requires the Regulator to seek comment on the RARMP from the States and Territories, the Gene Technology Technical Advisory Committee, Commonwealth authorities or agencies prescribed in the Regulations, the Minister for the Environment, relevant local council(s), and the public.

7. The *Risk Analysis Framework* (OGTR 2013) explains the Regulator's approach to the preparation of RARMPs in accordance with the legislative requirements. Additionally, there are a number of operational policies and guidelines developed by the Office of the Gene Technology Regulator (OGTR) that are relevant to DIR licences. These documents are available from the OGTR website.

8. Any dealings conducted under a licence issued by the Regulator may also be subject to regulation by other Australian government agencies that regulate GMOs or GM products, including Food Standards Australia New Zealand (FSANZ), the Australian Pesticides and Veterinary Medicines Authority, the Therapeutic Goods Administration and the Department of Agriculture and Water Resources. These dealings may also be subject to the operation of State legislation declaring areas to be GM, GM free, or both, for marketing purposes.

Section 3 The proposed dealings

9. The University of Queensland (UQ) proposes to release up to 42 lines of sorghum genetically modified for grain quality traits into the environment under limited and controlled conditions. The purpose of the release is to assess agronomic characteristics, yield and grain quality of the GM sorghum plants under field conditions.

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

- conducting experiments with the GMOs
- breeding the GMOs
- propagating the GMOs
- using the GMOs in the course of manufacture of a thing that is not a GMO
- growing the GMOs
- transporting the GMOs
- disposing of the GMOs

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

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

11. The release is proposed to take place over three years, between October 2017 and June 2020. In the first year the GM sorghum would be grown on one trial site with an area of up to 1 ha, and in each of the second and third years the GMOs would be grown on up to four sites with combined areas of up to 5 ha. The local government areas where trial sites may be located are Brisbane City, Goondiwindi, Lockyer Valley, Redland City, Somerset, Southern Downs, South Burnett and Toowoomba, all in south-east Queensland.

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

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

13. 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 field trial sites at least 100 m from any natural waterway
- restricting pollen flow from the GM sorghum by (option A):
    - surrounding each trial site with a 7.5 m pollen trap of non-GM sorghum
    - surrounding each pollen trap with a 200 m monitoring zone which will be inspected while the GM sorghum is flowering to destroy any plants that are sexually compatible with sorghum
    - manipulating the planting date of the GM sorghum in such a way that it will not flower synchronously with any sorghum crops planted within 100 m of the monitoring zone
- or by (option B):
    - bagging the GM sorghum panicles during flowering
    - surrounding the trial site with a 100 m monitoring zone which will be inspected while the GM sorghum is flowering to destroy any plants that are sexually compatible with sorghum
- controlling rodents in the trial sites by baiting
- cleaning equipment used with the GMOs before use for other purposes or removal from a trial site
- destroying all GM seed that is not required for analysis or future planting
- treating non-GM sorghum grown in the trial sites or pollen traps the same as GM plants
- cultivating and irrigating the post-harvest trial sites to promote germination of volunteers
- monitoring the post-harvest trial sites at least every 30 days during the summer months and at least every 60 days at other times, and destroying any sorghum volunteers prior to flowering
- continuing monitoring of the post-harvest trial sites for at least 12 months and until the sites are free of sorghum volunteers for at least 6 months
- transporting and storing GM plant materials in accordance with the current Regulator's *Guidelines for the Transport, Storage and Disposal of GMOs*
- not allowing GM plant material to be used for human food or animal feed, with the exception of a poultry feeding trial if approved by an Animal Ethics Committee.

Section 4 The parent organism

14. The parent organism is grain sorghum (*Sorghum bicolor* (L.) Moench subsp. *bicolor*) which is exotic to Australia. Grain sorghum is an important summer crop in Queensland and NSW, with an average of over 600,000 ha/year planted in recent years (ABARES 2016). Within Australia sorghum is used predominantly as livestock feed but also for production of ethanol fuel. Grain is exported for both animal and human consumption (Gordon 2016).

15. Detailed information about the parent organism is contained in the reference document *The Biology of* Sorghum bicolor *(L.) Moench subsp.* bicolor *(Sorghum)* (OGTR 2017) which was produced to inform the risk assessment process for licence applications involving GM sorghum. Baseline information from this document will be used and referred to throughout the RARMP.

16. The GM sorghum lines were generated in cultivar RTx430, an American inbred cultivar that is commonly used as a male parent in sorghum hybrid breeding worldwide. During the trial the GM sorghum lines may be crossed with non-GM inbred female parents to produce hybrid seed. The average height of RTx430 sorghum plants is 102-107 cm, and the average time from planting to 50% flowering is 78 days in field trials (Peterson et al. 2009; Rooney et al. 2011).

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

5.1 Introduction to the GMOs

17. The applicant proposes to release up to 42 lines of GM sorghum. The lines are classified into four categories (Table 1). Each line contains a single introduced gene or gene fragment intended to alter grain quality traits and an introduced selectable marker gene. All of the introduced genes or gene fragments conferring altered grain quality are derived from cultivated grain sorghum (*S. bicolor* subsp. *bicolor*).

Table 1 Categories of GM sorghum

Category	Introduced genetic element conferring altered grain quality	Number of lines
1	Modified kafirin gene	Up to 6
2	Gene silencing construct containing fragment of foldase enzyme gene	Up to 6
3	Gene silencing construct containing fragment of GP1, GP2 or GP3 membrane protein genes	Up to 15
4	Truncated version of GP1, GP2 or GP3 membrane protein genes	Up to 15

18. The exact names of the sorghum genes or gene fragments in Table 1 have been declared Confidential Commercial Information (CCI). The names are listed in a CCI Attachment to the RARMP which is available to the prescribed experts and agencies that are consulted on the RARMP.

19. All GM sorghum lines contain the selectable marker gene *nptII* derived from the bacterium *Escherichia coli*. This gene confers antibiotic resistance on GM plant cells and was used during initial development of the GM plants in the laboratory to select plant cells containing the introduced genes.

20. Short regulatory sequences that control gene expression are also present in the GM sorghum lines. The introduced sorghum kafirin gene (Category 1, Table 1) is controlled by its native promoter and signal peptide for specific expression in developing endosperm. All other introduced genes or gene fragments are controlled by the *ubiquitin 1* (*ubi1*) constitutive promoter from maize (*Zea mays*). The terminator used for all categories is *nos* derived from the common soil bacterium *Agrobacterium tumefaciens*.

21. The GM sorghum lines were produced using biolistic transformation (particle bombardment). Information about this transformation method can be found in the document *Methods of plant genetic modification* available from the OGTR Risk Assessment References page.

22. During the course of the proposed field trial, different GM sorghum lines may be crossed using conventional breeding, producing GMOs containing up to two introduced genes or gene fragments conferring altered grain quality.

5.2 The introduced genes, encoded proteins and their associated effects

5.2.1 The modified kafirin gene

23. The kafirin gene family encodes the major storage proteins in sorghum grain. Kafirin proteins make up approximately 70% of total protein in whole grain and are packaged into protein bodies located in the endosperm (Belton et al. 2006; Duodu et al. 2003). Sorghum grain has low protein digestibility compared to other cereals such as wheat or maize. This is attributed to a combination of factors including high hydrophobicity of kafirin proteins and protein crosslinking between kafirins (Duodu et al. 2003).

24. The synthetic kafirin gene introduced into some lines of the GM sorghum (Category 1) is based on a native sorghum kafirin gene with the sequence modified to add ten proteolytic sites. Proteolytic sites are parts of a protein sequence where digestive enzymes can react with the protein and cleave it into smaller fragments (Page 1981). The modified kafirin gene is controlled by an endosperm-specific promoter so is expected to be expressed in the sorghum grain. The introduced gene confers increased grain protein content and improved grain protein digestibility.

25. Further information on the modified kafirin gene is present in the CCI Attachment to the RARMP which is available to the prescribed experts and agencies that are consulted on the RARMP.

5.2.2 The foldase enzyme gene

26. Some lines of the GM sorghum (Category 2) contain a gene silencing construct that suppresses expression of a native sorghum "foldase" enzyme gene. The targeted foldase gene is expressed preferentially in the endosperm and encodes an enzyme involved in folding seed storage proteins. The introduced foldase silencing construct confers increased sorghum grain size, increased grain protein content and improved grain protein digestibility.

27. Gene silencing constructs are a widely-used technique designed to suppress or reduce expression of target genes. Suppression of the target genes is mediated by a natural regulatory mechanism in plants known as ribonucleic acid interference (RNAi) or gene silencing (Baykal & Zhang 2010). Using the RNAi pathway, an introduced silencing construct containing a fragment of the target gene is transcribed into double-stranded RNA, which is processed by endogenous cellular machinery into short interfering RNAs (siRNAs). The siRNAs direct the degradation of messenger RNA (mRNA) molecules with matching sequence after the mRNAs are transcribed from genes and before they are translated into proteins. The efficiency of gene silencing is generally determined by the extent of homology between the silencing construct and the target gene (usually > 95% homology is required) and the length of the homologous region. In plants, introduced silencing constructs have been shown to effectively suppress expression of the target genes, but can also give rise to silencing of non-target genes with closely matching sequences.

28. Further information on the targeted foldase gene is present in the CCI Attachment to the RARMP which is available to the prescribed experts and agencies that are consulted on the RARMP.

5.2.3 The membrane protein genes

29. Some lines of the GM sorghum are designed to alter the function of one of three related membrane protein genes, which are given the identifiers GP1, GP2 and GP3 for the purposes of this application. Category 3 lines each contain a gene silencing construct that suppresses expression of one of the membrane protein genes. Category 4 lines each overexpress a truncated version of one of the membrane protein genes. These changes confer either increased sorghum grain size (GP1 and GP2 lines) or increased grain number per panicle (GP3 lines).

30. Further information on the membrane protein genes is present in the CCI Attachment to the RARMP which is available to the prescribed experts and agencies that are consulted on the RARMP.

5.2.4 The nptII gene

31. The *nptII* gene was isolated from the common gut bacterium *E. coli* and encodes the enzyme neomycin phosphotransferase type II (NPTII), which inactivates aminoglycoside antibiotics such as kanamycin and neomycin. The *nptII* gene is used extensively as a selectable marker in the production of GM plants. Regulatory agencies in Australia and in other countries have assessed the use of the *nptII* gene in GM plants as not posing a risk to human health and safety or to the environment. Further information about this gene can be found in the document *Marker genes in GM plants* available from the Risk Assessment References page on the OGTR website.

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

32. The introduced grain quality genes are based on sorghum genes that are expressed in cultivated sorghum grain. Sorghum grain is a staple food in many countries in Africa and Asia, and is grown for livestock feed in Australia and other developed countries (OGTR 2017). The proteins in sorghum grain are regularly consumed by humans and livestock without adverse effects.

33. In Category 1 lines the introduced kafirin protein is modified to increase digestibility, and in Category 4 lines the introduced membrane proteins are truncated. No toxicity or allergenicity studies have been conducted on the modified or truncated versions of these proteins, as the proposed trial is at preliminary research stage.

34. In Category 2 and Category 3 lines, the introduced genetic elements conferring grain quality traits are gene silencing constructs. The function of gene silencing constructs is to suppress expression of a gene. They do not encode a protein that could potentially be toxic or allergenic.

35. All of the GM sorghum lines contain the *nptII* selectable marker gene. Regulatory agencies in Australia and other countries have found no evidence that the NPTII protein is toxic or allergenic (EFSA 2009; FSANZ 2010).

36. All of the GM sorghum lines have been grown by the applicant in glasshouse trials. Staff handling the GM plants in the glasshouse have not reported any adverse effects.

5.4 Characterisation of the GMOs

37. All GM sorghum lines proposed for release have been grown in the glasshouse for at least two generations. Phenotypic changes observed in glasshouse trials for each category of GM sorghum (Table 1) are detailed below.

38. Category 1 GM sorghum lines produced seed which had 40-70% higher protein content and increased *in vitro* protein digestibility compared to the non-GM parent cultivar.

39. Category 2 GM sorghum lines produced seed which had 15-30% heavier seed weight, 0-30% higher protein content, and increased *in vitro* protein digestibility compared to the non-GM parent cultivar.

40. Category 3 and Category 4 GM sorghum lines caused similar changes to phenotype. Lines which either suppressed expression or expressed truncated versions of GP1 or GP2 membrane protein genes had on average 7% heavier seed weight than the non-GM parent cultivar. Lines which either suppressed expression or expressed a truncated version of the GP3 membrane protein gene had no change in seed weight, but had up to 18% more seeds per plant.

41. All GM sorghum lines proposed for release had normal phenotypes when grown in the greenhouse. The GM lines were not distinguishable from the RTx430 parent cultivar except in the targeted grain quality traits described above.

Section 6 The receiving environment

42. 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).

43. Information relevant to the growth and distribution of commercial sorghum in Australia is discussed in *The Biology of* Sorghum bicolor *(L.) Moench subsp.* bicolor *(Sorghum)* (OGTR 2017).

6.1 Relevant abiotic factors

44. The release is proposed to take place at the University of Queensland Gatton Campus research facility in all years of the field trial, and at up to six other sites in south-east Queensland during the second and third years. The average temperatures in Gatton range between 19 – 31°C in summer and 7 – 21°C in winter (Bureau of Meteorology website). The GM sorghum cultivar that would be genetically modified, RTx430, is photoperiod insensitive (Cuevas et al. 2016) so in principle could grow throughout the year. However, RTx430 has low cold tolerance and seeds germinate poorly at soil temperatures lower than 16°C (Franks et al. 2006), so the GM sorghum would not be expected to grow well during winter in south-east Queensland. Sorghum is most sensitive to heat stress during flowering, as high daily temperatures (e.g. 26 – 36°C or 21 – 38°C) during this period will reduce seed set (Nguyen et al. 2013). These temperatures are higher than the average summer temperatures in south-east Queensland, but the GM sorghum could suffer from heat stress if a heat wave coincided with flowering.

45. Sorghum is a water-efficient crop with high drought tolerance (GRDC 2014; OECD 2016a). It is estimated that over 90% of sorghum in Australia is grown as a dryland crop (Philp et al. 2010). The applicant proposes that the GM sorghum would be grown either on irrigated or dryland trial sites.

6.2 Relevant biotic factors

46. The major insect pests of sorghum in Queensland are *Helicoverpa armigera* and sorghum midge, which both feed on developing seed (QDAF Insect pest management in sorghum). The applicant may spray insecticide on the GM sorghum to control sorghum midge post-flowering. Agricultural chemicals would be used according to the label instructions, in the same way as on non-GM sorghum.

47. The major disease of sorghum in Australia is ergot, caused by the fungus *Claviceps africana*, which generates alkaloids that are toxic to livestock (GRDC 2014). Ergot infection occurs during cool and humid weather at flowering (QDAF Disease management for sorghum). The applicant proposes to avoid late planting so that flowering occurs during the warmer summer months. If cool weather is forecast during flowering, the applicant may apply a prophylactic fungicide. If there are heavy rainfall events during grain maturity, the applicant may apply fungicide to prevent grain mould.

48. Birds will feed on developing or ripe sorghum grain (Doggett 1988). Cockatoos and corellas, in particular, are known pests of sorghum in Queensland (ABC Rural news). The proposed Gatton trial site is enclosed in bird-proof netting, but other proposed trial sites are not. Mice also feed on sorghum, particularly grain, and during plagues have been recorded at populations of up to 3000 mice/ha in sorghum crops (GRDC 2011). The applicant proposes to control rodents by baiting.

6.3 Relevant agricultural practices

49. The applicant proposes to plant GM sorghum seed by hand or with precision planters, in rows of 75 cm spacing, with approximately 100,000 plants/ha on irrigated sites and 50,000 plants/ha on dryland sites. Bags may be used to cover flowers on some plants to facilitate controlled crossing. The sorghum may be sprayed with glyphosate as a desiccant prior to harvest. This is a common practice of commercial sorghum growers in Queensland which is intended to prevent tiller growth once main heads are mature and to conserve soil moisture for the next crop (GRDC 2014). The applicant proposes that the GM sorghum would be threshed and cleaned on site. Trial sites would be left fallow during the off-season and could be re-planted to the GM sorghum in the following growing season.

6.4 Presence of related plants in the receiving environment

50. As discussed in Section 4, grain sorghum (*Sorghum bicolor* subsp. *bicolor*) is widely cultivated in south-east Queensland. Forage sorghum (*S. bicolor* subsp. *bicolor*), Sudan grass (*S. bicolor* subsp. *drummondii*) or sorghum x Sudan grass hybrids may also be cultivated in the receiving environment (Pacific Seeds summer forage). The wild progenitor of cultivated sorghum, *S. bicolor* subsp.

arundinaceum, is naturalised in Australia, including south-east Queensland (Atlas of Living Australia). All plants from species *S. bicolor* are diploids that hybridise freely with grain sorghum (OGTR 2017).

51. Johnson grass (*S. halepense*), Colombus grass (*S. x almum*) and perennial sorghum (*S. spp.* hybrid cv. Silk) are noxious weeds that are naturalised in southern Queensland (National weeds list). The impacts of these weeds are discussed in Chapter 2, Section 2.4.6. These tetraploid species can cross with cultivated sorghum despite ploidy level differences, but hybrid offspring typically have reduced fertility (OGTR 2017).

52. Other *Sorghum* species present in Australia are not members of the *Eusorghum* section that includes cultivated sorghum. Cultivated sorghum cannot naturally hybridise with species outside *Eusorghum*, due to pollen-pistil incompatibilities and other obstacles (Hodnett et al. 2005).

6.5 Presence of similar genes and encoded proteins in the environment

53. All except one of the introduced genes or gene fragments in the GM sorghum are derived from sorghum. As discussed in Section 4, grain sorghum is widely cultivated in south-east Queensland.

54. The *nptII* gene is derived from *E. coli*, which is a common gut bacterium.

Section 7 Relevant Australian and international approvals

7.1 Australian approvals

7.1.1 Approvals by the Regulator

55. None of the GM sorghum lines included in this application have previously been approved for release in Australia.

56. The Regulator has not received any previous applications for release of GM sorghum.

7.1.2 Approvals by other government agencies

57. There are no approvals of GM sorghum, or applications for GM sorghum under consideration, from other Australian authorities.

7.2 International approvals

58. None of the GM sorghum lines covered in this application have been approved for release in any other country.

59. Different sorghum lines genetically modified for altered grain quality have been approved for field trials in the United States (Information Systems for Biotechnology). In some of the lines trialled, suppression of native kafirin genes increased sorghum grain protein digestibility (da Silva et al. 2011).

60. No GM sorghum has been approved for commercial release in any country. In the United States, the Department of Agriculture has recently ruled that two types of GM sorghum are not subject to regulation, as they are not plant pests and do not pose an increased noxious weed risk (USDA letter re TRSBG101S transgenic sorghum, USDA letter re TRSBG101B transgenic sorghum).

Chapter 2 Risk assessment

Section 1 Introduction

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

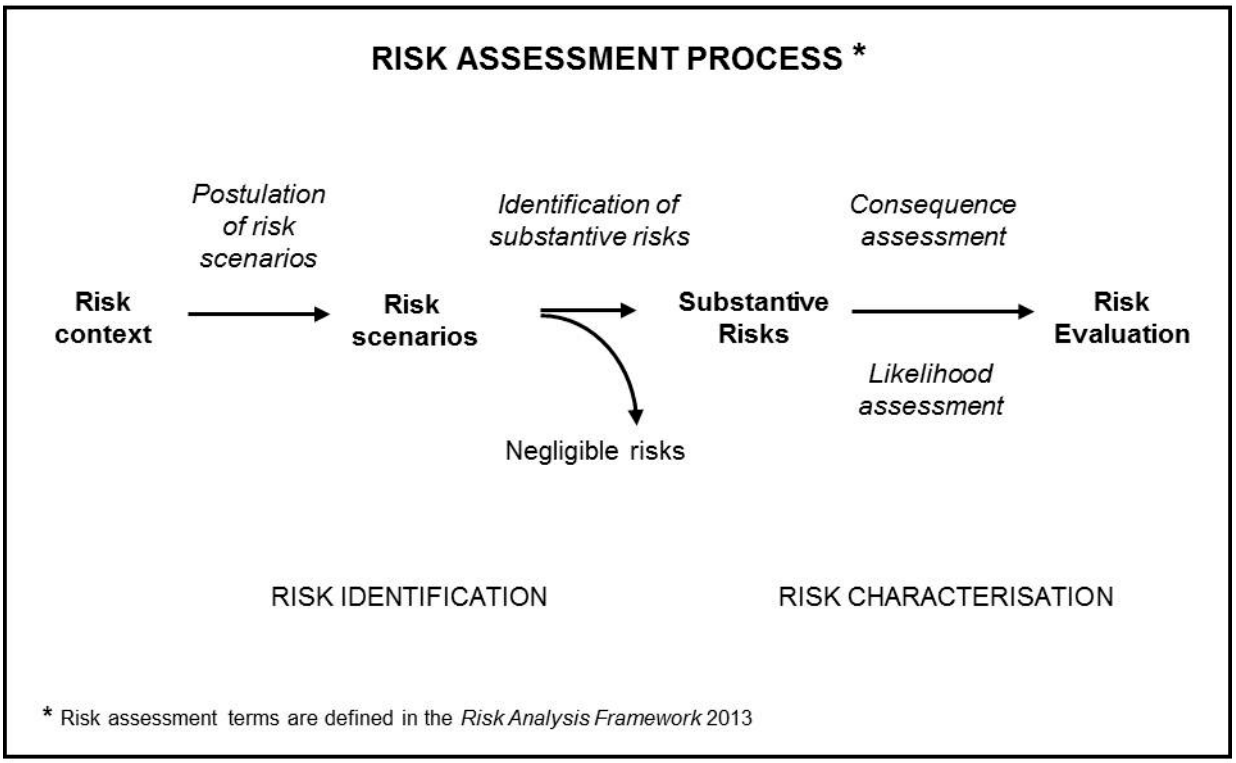

Figure 2. The risk assessment process

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

63. A number of risk identification techniques are used by the Regulator and staff of the OGTR, including checklists, brainstorming, reported international experience and consultation (OGTR 2013). A weed risk assessment approach is used to identify traits that may contribute to risks from GM plants, as this approach addresses the full range of potential adverse outcomes associated with plants. In particular, novel traits that may increase the potential of the GMO to spread and persist in the environment or increase the level of potential harm compared with the parental plant(s) are used to postulate risk scenarios (Keese et al. 2014). Risk scenarios postulated in previous RARMPs prepared for licence applications of the same or similar GMOs are also considered.

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

65. Substantive risks (ie those identified for further assessment) are characterised in terms of the potential seriousness of harm (Consequence assessment) and the likelihood of harm (Likelihood

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

Section 2 Risk identification

66. Postulated risk scenarios are comprised of three components:

i. The source of potential harm (risk source).

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

iii. Potential harm to an object of value, people or the environment.

67. When postulating relevant risk scenarios, the risk context is taken into account, including the following factors:

- the proposed dealings, which may be to conduct experiments, develop, produce, breed, propagate, grow, import, transport or dispose of the GMOs, use the GMOs in the course of manufacture of a thing that is not the GMO, and the possession, supply and use of the GMOs in the course of any of these dealings
- 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

68. 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.

69. As discussed in Chapter 1, the GM sorghum lines have been modified by the introduction of one of eight genetic elements derived from sorghum and designed to alter grain quality traits. These introduced genetic elements are considered further as potential sources of risk.

70. All of the GM sorghum lines also contain the *nptII* gene which confers antibiotic resistance and was used as a selectable marker gene. This gene and its product have already been extensively characterised and assessed as posing negligible risk to human or animal health or to the environment by the Regulator as well as by other regulatory agencies in Australia and overseas. Further information about this gene can be found in the document *Marker genes in GM plants* available from the Risk Assessment References page on the OGTR website. As the gene has not been found to pose a substantive risk to either people or the environment, its potential effects will not be further considered for this application.

71. The introduced genetic elements are controlled by introduced regulatory sequences. These were derived from sorghum, maize and the common soil bacterium *Agrobacterium tumefaciens*. Regulatory sequences are naturally present in 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, and dietary DNA has no toxicity (Society of Toxicology 2003). Hence, potential harms from the regulatory sequences will not be further assessed for this application.

72. The genetic modifications have the potential to cause unintended effects in several ways including altered expression of endogenous genes by random insertion of introduced DNA in the genome or off-target gene silencing of endogenous sorghum genes with highly similar sequences to targeted genes. However, these types of effects also occur spontaneously and in plants generated by conventional breeding. Accepted conventional breeding techniques such as hybridisation, mutagenesis and somaclonal variation can have a much larger impact on the plant genome than genetic engineering (Schnell et al. 2015). Plants generated by conventional breeding have a long

history of 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, the potential for the processes of genetic modification to result in unintended effects will not be considered further.

2.2 Causal pathway

73. The following factors are taken into account when postulating plausible causal pathways to potential harm:

- routes of exposure to the GMOs, the introduced gene(s) 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, (eg reproductive characteristics, dispersal pathways and establishment potential)
- tolerance to abiotic conditions (e.g. climate, soil and rainfall patterns)
- tolerance to biotic stressors (e.g. pest, pathogens and weeds)
- tolerance to cultivation management practices
- gene transfer to sexually compatible organisms
- gene transfer by horizontal gene transfer (HGT)
- unauthorised activities.

74. Although all of these factors are taken into account, some are not included in risk scenarios because they have been considered in previous RARMPs.

75. The potential for horizontal gene transfer (HGT) from GMOs to species that are not sexually compatible, and any possible adverse outcomes, have been reviewed in the literature (Keese 2008) and assessed in many previous RARMPs. HGT was most recently considered in the RARMP for DIR 108. Although the DIR 108 RARMP is for GM canola, the HGT considerations are the same for the current RARMP: HGT events rarely occur and the wild-type gene sequences or homologues are already present in the environment and available for transfer via demonstrated natural mechanisms. Therefore, no substantive risk was identified in previous assessments and HGT will not be further considered for this application.

76. The potential for unauthorised activities to lead to an adverse outcome has been considered in many previous RARMPs, most recently in the RARMP for DIR 117. In previous assessments of unauthorised activities, no substantive risk was identified. The Act provides for substantial penalties for unauthorised dealings with GMOs or non-compliance with licence conditions, and also requires the Regulator to have regard to the suitability of an applicant to hold a licence prior to the issuing of the licence. These legislative provisions are considered sufficient to minimise risks from unauthorised activities. Therefore, unauthorised activities will not be considered further.

2.3 Potential harm

77. Potential harms from GM plants include:

- harm to the health of people or desirable organisms, including toxicity/allergenicity
- reduced biodiversity through harm to other organisms or ecosystems
- reduced establishment or yield of desirable plants
- reduced products or services from the land use
- restricted movement of people, animals, vehicles, machinery and/or water

- reduced quality of the biotic environment (eg providing food or shelter for pests or pathogens) or abiotic environment (eg negative effects on fire regimes, nutrient levels, soil salinity, soil stability or soil water table).

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

2.4 Postulated risk scenarios

79. Six risk scenarios were postulated and screened to identify substantive risk. These scenarios are summarised in Table 2, and examined in detail in Sections 2.4.1 – 2.4.6. Postulation of risk scenarios considers impacts of the GM sorghum or its products on people undertaking the dealings, as well as impacts on people and the environment if the GM plants or genetic material were to spread and/or persist.

80. In the context of the activities proposed by the applicant and considering both the short and long term, none of the six risk scenarios gave rise to any substantive risks.

Table 2 Summary of risk scenarios from the proposed dealings

Risk scenario	Risk source	Causal pathway	Potential harm/s	Substantive risk?	Reasons
1	Introduced genetic elements conferring altered grain quality	Growing GM sorghum plants at the trial sites ⬇ Expression of introduced genetic elements in GM plants ⬇ Exposure of people who deal with the GM plant material or of people in the vicinity of the trial sites	Toxicity or allergenicity to people	No	• GM plant material would not be used as human food. • The proposed limits and controls would restrict exposure of people to the GM plant material through skin contact or inhalation of pollen. • There were no adverse health effects on people handling the GM plants in glasshouse trials.
2	Introduced genetic elements conferring altered grain quality	Growing GM sorghum plants at the trial sites ⬇ Expression of introduced genetic elements in GM plants ⬇ Exposure of animals eating GM plant material	Toxicity to desirable animals	No	• GM plant material would not be used as livestock feed. • The small size and short duration of the proposed trial would minimise exposure of native animals, birds or desirable insects to the GM plant material.

Risk scenario	Risk source	Causal pathway	Potential harm/s	Substantive risk?	Reasons
3	Introduced genetic elements conferring altered grain quality	Growing GM sorghum plants at the trial sites ⬇ Persistence of GM plants after completion of the trial ⬇ Establishment of volunteer GM plants in the environment ⬇ Expression of introduced genetic elements in the volunteer plants	Toxicity or allergenicity to people OR Toxicity to desirable animals OR Reduced establishment or yield of desirable plants OR Increased levels of pests or pathogens	No	• The proposed controls would minimise persistence of GMOs after completion of the trial. • Sorghum has limited ability to establish ongoing volunteer populations in the environment.
4	Introduced genetic elements conferring altered grain quality	Growing GM sorghum plants at the trial sites ⬇ Dispersal of GM sorghum seeds outside the trial sites ⬇ Establishment of volunteer GM plants in the environment ⬇ Expression of introduced genetic elements in the volunteer plants	Toxicity or allergenicity to people OR Toxicity to desirable animals OR Reduced establishment or yield of desirable plants OR Increased levels of pests or pathogens	No	• The proposed controls, if applied to all trial sites, would minimise dispersal of GM seed. • Sorghum has limited ability to establish ongoing volunteer populations in the environment.
5	Introduced genetic elements conferring altered grain quality	Growing GM sorghum plants at the trial sites ⬇ Pollen flow to non-GM sorghum crops or volunteers outside the trial site ⬇ Production of hybrid seed with GM traits	Toxicity or allergenicity to people OR Toxicity to desirable animals OR Reduced establishment or yield of desirable plants OR Increased levels of pests or pathogens	No	• The proposed controls, if applied to all trial sites, would minimise pollen flow to non-GM sorghum outside the trial sites. • Sorghum has limited ability to establish ongoing volunteer populations in the environment. • Consumption of sorghum containing low levels of GM grain by people or livestock is not expected to cause adverse health effects.

Risk scenario	Risk source	Causal pathway	Potential harm/s	Substantive risk?	Reasons
6	Introduced genetic elements conferring altered grain quality	Growing GM sorghum plants at the trial sites ⬇ Outcrossing with weeds that are sexually compatible with sorghum ⬇ Introgression of GM traits into populations of weedy species	Toxicity or allergenicity to people OR Toxicity to desirable animals OR Reduced establishment or yield of desirable plants OR Increased levels of pests or pathogens OR Reduced services from the land use	No	• The proposed controls, if applied to all trial sites, would minimise outcrossing with sexually compatible weeds

2.4.1 Risk scenario 1

Risk source	Introduced genetic elements conferring altered grain quality
Causal pathway	⬇ Growing GM sorghum plants at the trial sites ⬇ Expression of introduced genetic elements in GM plants ⬇ Exposure of people who deal with the GM plant material or of people in the vicinity of the trial sites ⬇
Potential harm	Toxicity or allergenicity to people

Risk source

81. The source of potential harm for this postulated risk scenario is the introduced genes and gene silencing constructs for grain quality traits.

Causal pathway

82. GM sorghum expressing the introduced genetic elements would be grown at the trial sites. People could potentially be exposed to the GM plant material through consumption, skin contact or inhalation.

83. The licence application proposes that the GM plant material will not be used for human food. In addition, sorghum is generally not used as food in Australia, so there is little potential for accidental ingestion. Thus, it is not expected that people would be exposed to the GM sorghum by consumption.

84. The licence application proposes that only trained and authorised staff would be permitted to deal with the GM sorghum. Due to the small scale of the proposed trial, only a few people would be expected to handle the GM sorghum. These people could be exposed to plant material through skin contact during cultivation, transportation or analysis of the GM sorghum.

85. As sorghum is a wind-pollinated plant, people could inhale airborne pollen during flowering of the GM sorghum. Pollen shedding from R-lines, such as RTx430 which is the parental cultivar of the GM sorghum, usually lasts for 10-15 days (Singh et al. 1997). Workers entering the proposed trial sites during flowering would be exposed to pollen through inhalation. A study has also reported low levels of sorghum pollen travelling 200 m in the direction of the prevailing wind (Schmidt et al. 2013).

Therefore, people in the close vicinity of the proposed trial sites during flowering, for instance working in the research stations or farms where the trial sites are located, could inhale pollen from the GM sorghum. In the event of high winds during flowering, pollen from the GM sorghum could potentially be transported much further than 200 m. However, the severity of allergic reactions to pollen is correlated with atmospheric pollen concentration. If pollen count is below a threshold level (typically around 30 grains/m^3 for grass pollen), this elicits no or minor symptoms even in people sensitive to the pollen allergens (Kiotseridis et al. 2013). Given the small sizes of all proposed trial sites, it is not expected that concentrations of airborne pollen from GM sorghum could exceed a threshold level for allergenicity in areas outside the close vicinity of the trial sites.

86. For some GM sorghum plants grown in the proposed field trials, flowers may be covered with bags, either to facilitate controlled crossing or as one of two alternative measures to control pollen flow (see Section 3.2 of Chapter 1). Bagging GM sorghum plants would minimise exposure of people to pollen from those plants.

Potential harm

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

88. In GM sorghum Category 2 and Category 3 lines (see Section 5 of Chapter 1) the introduced genetic elements conferring grain quality traits are gene silencing constructs. These do not encode a protein that could potentially be toxic or allergenic, but they are processed into siRNAs that could possibly modulate expression of non-target human or animal genes. The pathway by which exposure to siRNAs could lead to toxicity or allergenicity has been addressed in previous RARMPs, most recently DIR 131, and is considered highly unlikely.

89. In Category 1 and Category 4 GM sorghum lines the introduced genes for grain quality are based on native genes expressed in sorghum grain. As discussed in Section 5.3 of Chapter 1, the proteins in sorghum grain are regularly consumed by humans and livestock without adverse effects, so are not expected to be toxic or allergenic. The sequences of the introduced proteins have been modified from the native sorghum protein sequences, so there is some uncertainty regarding whether the modified proteins could increase toxicity or allergenicity.

90. Non-GM sorghum plants naturally produce the toxins dhurrin (which is metabolised to cyanide) and nitrates (which are metabolised to nitrites) (OGTR 2017). Dhurrin mostly occurs in leaves and is not present in grain, and dhurrin levels are higher in young growth or plants grown under drought conditions (Doggett 1988). Nitrates accumulate in stems, leaves and roots rather than flowers or grain, and nitrate levels are higher in young plants or plants grown under unfavourable weather conditions (Sidhu et al. 2011). Sorghum with high levels of dhurrin or nitrates can be toxic to livestock grazing the crop or fed on the hay (QDAF Cyanide and nitrate in sorghum crops). No evidence was found in the literature suggesting that sorghum plants could be toxic to humans through skin contact or inhalation of pollen, regardless of the levels of native toxins present.

91. Pollen from cultivated non-GM sorghum has been reported to elicit allergic sensitivity in people in India (Davies 2014). Also, a study of grass pollen allergies in Brisbane has identified allergic sensitivity to the pollen of Johnson grass (*S. halepense*) (Davies et al. 2012), which is closely related to cultivated sorghum (*S. bicolor*), so immunological cross-reactivity is likely to exist.

92. Pollen allergies are due to protein allergens present in pollen (Radauer & Breiteneder 2006). In Category 2 GM sorghum lines, a foldase enzyme gene is silenced, which confers increased protein content and possibly altered protein folding in the GM sorghum grain. Although the foldase enzyme gene is preferentially expressed in grain, it is also present in other plant parts, and the introduced silencing construct controlled by a constitutive promoter could also silence this gene in pollen. If GM

sorghum pollen has increased protein content and/or altered protein folding, this could increase the quantity or surface exposure of a protein allergen and potentially increase pollen allergenicity.

93. As discussed in Section 5.3 of Chapter 1, the licence applicant has grown all of the GM sorghum lines proposed for release in glasshouse trials. No adverse health effects were reported by people dealing with the GM plants in the glasshouse.

94. ***Conclusion***: Risk scenario 1 is not identified as a substantive risk because the GM plant material would not be used as human food, the proposed limits and controls would restrict exposure of people to the GM plant material through skin contact or inhalation of pollen, and there were no adverse health effects on people handling the GM plants in glasshouse trials. Therefore, this risk could not be greater than negligible and does not warrant further detailed assessment.

2.4.2 Risk scenario 2

Risk source	Introduced genetic elements conferring altered grain quality
Causal pathway	⬇ Growing GM sorghum plants at the trial sites ⬇ Expression of introduced genetic elements in GM plants ⬇ Exposure of animals eating GM plant material ⬇
Potential harm	Toxicity to desirable animals

Risk source

95. The source of potential harm for this postulated risk scenario is the introduced genes and gene silencing constructs for grain quality traits.

Causal pathway

96. GM sorghum expressing the introduced genetic elements would be grown at the trial sites. Animals entering the trial sites could consume GM plant material. Poultry included in the proposed feeding trial would be fed GM plant material.

97. The licence application proposes that the GM plant material will not be used for animal feed, excluding the proposed feeding trial. Thus, agricultural livestock are not expected to be exposed to the GM sorghum.

98. Native animals or birds could enter the trial sites and feed on the GM sorghum plants. One of the proposed trial sites (which may be planted in multiple years) is enclosed in bird-proof netting that is expected to exclude birds and animals, but other proposed sites would not have netting. The small size and short duration of the proposed trial, combined with protection of some sites by netting, would restrict the numbers of native animals or birds that could be exposed to the GM plants.

99. Although non-native pest animals such as rabbits, rodents or feral pigs could be exposed to the GM sorghum through consumption, this will not be considered as a causal pathway leading to harm, as potential toxicity to these pests would not be an environmental harm.

100. Insects, including desirable species such as pollinators, could enter the trial sites and feed on the GM sorghum. The small size and short duration of the proposed trial would restrict the numbers of insects exposed to the GM plants.

101. Although poultry included in a proposed feeding trial would be exposed to the GM sorghum through consumption, this will not be considered as a causal pathway leading to harm, as a main aim of the feeding trial would be to detect any toxicity. The feeding trial would only occur if approved by an Animal Ethics Committee.

Potential harm

102. As discussed in Risk Scenario 1, the introduced proteins conferring grain quality traits are based on proteins present in non-GM sorghum grain. The proteins in sorghum grain are regularly consumed by humans and livestock without adverse effects, so are not expected to be toxic to animals. The sequences of the introduced proteins have been modified from the native sorghum protein sequences, so there is some uncertainty regarding whether the modified proteins could have increased toxicity.

103. As discussed in Risk Scenario 1, non-GM sorghum plants naturally produce the toxins dhurrin and nitrates. GM sorghum lines from categories 2, 3 and 4 are designed to alter the function of a foldase enzyme gene or one of three membrane protein genes. All of these genes are present in many plant parts. The foldase enzyme or one of the membrane proteins could potentially interact with proteins involved in the synthesis of natural toxins in sorghum. Thus, there is some uncertainty regarding whether the genetic modifications could alter the levels of natural toxins in the GM sorghum.

104. Sorghum with high levels of dhurrin or nitrates can be toxic to livestock grazing the crop (QDAF Cyanide and nitrate in sorghum crops). However, both dhurrin and nitrates are less toxic to monogastric animals than to ruminants such as cattle or sheep (Robson 2007a; Robson 2007b). Native Australian mammals that could graze on sorghum are monogastric and may be less affected than livestock by increased levels of natural sorghum toxins. Dhurrin or nitrates do not usually accumulate in sorghum flowers or grain (Doggett 1988; Sidhu et al. 2011). Thus, pollinator insects or seed-feeding birds are unlikely to be affected by increased levels of natural sorghum toxins.

105. ***Conclusion***: Risk scenario 2 is not identified as a substantive risk because the GM plant material would not be used as livestock feed, and the small size and short duration of the proposed trial would minimise exposure of native animals, birds or desirable insects to the GM plant material. Therefore, this risk could not be greater than negligible and does not warrant further detailed assessment.

2.4.3 Risk scenario 3

Risk source	Introduced genetic elements conferring altered grain quality
Causal pathway	⬇ Growing GM sorghum plants at the trial sites ⬇ Persistence of GM plants after completion of the trial ⬇ Establishment of volunteer GM plants in the environment ⬇ Expression of introduced genetic elements in the volunteer plants ⬇
Potential harm	Toxicity or allergenicity to people OR Toxicity to desirable animals OR Reduced establishment or yield of desirable plants OR Increased levels of pests or pathogens

Risk source

106. The source of potential harm for this postulated risk scenario is the introduced genes and gene silencing constructs for grain quality traits.

Causal pathway

107. GM sorghum would be grown at the trial sites and would bear seed. If either live GM plants or viable seed persisted at the trial sites after completion of the trial, this could lead to establishment of volunteer GM sorghum populations in the environment.

108. Grain sorghum is often grown in cultivation as a single-stemmed plant, however, there are tillers at the base of the plants that can develop into additional stems. The extent and timing of tillering depends on both the cultivar and environmental conditions. In some parts of Africa, after harvest of a seeded sorghum crop, a ratoon sorghum crop is grown from the tillers (Doggett 1988). In Australia, it is a common practice for sorghum growers to desiccate the crop with a knockdown herbicide prior to harvest (GRDC 2014), which would be expected to prevent further growth of tillers. The applicant may desiccate the GM sorghum prior to harvest, but if not, viable new GM sorghum stems could potentially grow from tillers after harvest of the trial sites.

109. Some GM sorghum seeds would remain in the soil of the trial sites after harvest due, for instance, to seed losses during harvest and threshing. These seeds could germinate and grow into volunteer GM sorghum plants. Germination would likely occur soon after the harvest as grain sorghum seed has little dormancy. A study of dormancy in a range of grain sorghum cultivars found that by three months after harvest 93% of seeds germinated, and few of the non-germinated seeds were viable (Gritton & Atkins 1963). When grain sorghum seeds were buried in soil, <0.5% of seeds remained viable after four months, and none were viable after eight months (Jacques et al. 1974). The introduced genetic modifications are unlikely to markedly extend seed dormancy, as all lines of the GM sorghum have been grown from seed in glasshouse trials, and the applicant did not observe any changes from normal sorghum phenotype except the targeted traits.

110. The applicant has proposed to monitor the trial sites for sorghum volunteers for at least 12 months after harvest, and until the sites are free of volunteers for at least six consecutive months, and to destroy any volunteers found before they flower. This measure is expected to minimise persistence of GM plants or seeds on the trial sites.

111. 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). A survey of weed species at farms in the Northern Grain Region of Australia (including south-east Queensland) found that sorghum was the major summer crop grown, providing excellent opportunity for creation of a sorghum seedbank, and that volunteer sorghum plants were present in 54% of paddocks. However, in terms of abundance, volunteer sorghum comprised <2% of total weed populations (Rew et al. 2005), indicating that only a tiny 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.

112. The introduced genetic modifications confer some traits that could potentially increase the weediness of the GM sorghum in comparison to non-GM sorghum. Some GM lines have increased seed production, and high seed set is a factor that can contribute to invasiveness of a plant (Keese et al. 2014). Some GM lines have increased seed size, and the greater resources available to seedlings could increase their ability to establish amongst competition from existing vegetation, which is another factor contributing to invasiveness of a plant (Keese et al. 2014). There could also be deliberate or inadvertent crossing between different lines of GM sorghum producing hybrids with traits for both increased seed production and increased seed size.

113. Glasshouse trials of the GM sorghum lines found that the increase in seed production was up to 18%, and the increase in seed size was up to 30% in comparison to the non-GM parent cultivar. A study of the grain traits of 65 sorghum cultivars found that 19/65 cultivars had seed production that was greater than 18% above the average, and 3/65 cultivars had seed size that was greater than 30% above the average (Gambín & Borrás 2011). Thus the increased seed production measured in the GM sorghum is well within the normal range of variation between sorghum cultivars, and the increased

seed size is at the upper limit of normal variation between sorghum cultivars. No cultivars in the grain trait study (Gambín & Borrás 2011) had both seed production >18% above average and seed size >30% above average. If hybrids between GM lines with increased seed production and GM lines with increased seed size inherit both traits in full, these GM hybrids could fall outside the normal range of variation for sorghum cultivars.

114. Given that the genetic modifications confer changes that are within, or marginally outside, the normal range of variation for sorghum cultivars, the GM sorghum is expected to have equivalent or only marginally increased invasiveness compared to non-GM sorghum. Thus the GM sorghum, like non-GM sorghum, would have limited ability to establish ongoing volunteer populations in the environment.

Potential harm

115. One potential harm from volunteer GM sorghum populations would be toxicity or allergenicity to people. People would not be expected to consume wild sorghum plants, but they could be exposed to the GM sorghum through inhalation of pollen. As discussed in Risk Scenario 1, there is uncertainty regarding potential allergenicity of the GM sorghum pollen.

116. Volunteer GM sorghum plants could be eaten by desirable animals, including livestock, native animals, birds and insect pollinators. As discussed in Risk Scenario 2, there is uncertainty regarding potential toxicity of GM sorghum.

117. Volunteer GM sorghum plants could potentially compete with and reduce establishment or yield of desirable plants, such as agricultural crops in farms or native plants in nature reserves. Volunteer non-GM sorghum is considered to be a minor problem as a weed in Australian agricultural environments, and a minor and rare problem as a weed in natural environments (Groves et al. 2003). As discussed above, the GM sorghum is expected to have equivalent or only marginally increased invasiveness compared to non-GM sorghum. Non-GM sorghum volunteers can be effectively controlled by a range of herbicides (Fleming et al. 2012) as well as physical weed management techniques. The GM sorghum with altered grain quality traits is not expected to have increased tolerance to weed management.

118. Volunteer GM sorghum plants could potentially host pests or pathogens, which could subsequently transfer to and damage agricultural crops. Non-GM sorghum volunteers are known to harbour both disease and insects that are agricultural pests (Groves et al. 2003). GM sorghum volunteers with improved grain quality traits could possibly provide a better food source to pests or pathogens that attack grain, and thus carry a higher burden of pests or pathogens than non-GM sorghum volunteers.

Conclusion: Risk scenario 3 is not identified as a substantive risk because the proposed controls would minimise persistence of GMOs after completion of the trial, and sorghum has limited ability to establish ongoing volunteer populations in the environment. Therefore, this risk could not be greater than negligible and does not warrant further detailed assessment.

2.4.4 Risk scenario 4

Risk source	Introduced genetic elements conferring altered grain quality
Causal pathway	⬇ Growing GM sorghum plants at the trial sites ⬇ Dispersal of GM sorghum seeds outside the trial sites ⬇ Establishment of volunteer GM plants in the environment ⬇ Expression of introduced genetic elements in the volunteer plants ⬇
Potential	Toxicity or allergenicity to people

harm	OR Toxicity to desirable animals OR Reduced establishment or yield of desirable plants OR Increased levels of pests or pathogens

Risk source

119. The source of potential harm for this postulated risk scenario is the introduced genes and gene silencing constructs for grain quality traits.

Causal pathway

120. GM sorghum would be grown at the trial sites and would bear seed. GM seeds could potentially be dispersed outside the trial sites by wind or water, by human activity or by animal activity.

121. 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 2017). It is possible that GM sorghum seeds could be dispersed by high winds if a severe storm occurred while mature seed was present on plants or the soil surface. Sorghum seeds on the soil surface could also be transported by water during heavy runoff or flooding. The applicant has proposed that all field trial sites would be located at least 100 m from any natural waterway, which would minimise the potential for seed dispersal through flooding.

122. The proposed field trials would occur on research stations or private land in rural areas, and it is expected that only people conducting dealings would enter the sites. The applicant proposes that all equipment or clothing used in contact with the GMOs would be cleaned before removal from a trial site or use for other purposes. Transport of GM sorghum seeds to and from the trial sites would be conducted in accordance with the Regulator's Guidelines for the Transport, Storage and Disposal of GMOs. These controls would minimise the likelihood of dispersal of GM sorghum seeds from the trial sites by human activity.

123. The applicant has proposed that the GM sorghum will not be used as livestock feed, thus livestock will not be permitted to enter the trial sites. However, wild or pest animals, such as native animals, birds, feral pigs or deer, rabbits, rodents and seed-eating ants could potentially enter the trial sites in order to feed on sorghum seed.

124. Ants may transport seeds to nest sites over distances that are typically between tens of centimetres and a few metres (Gómez & Espadaler 1998). Mice are likely to consume sorghum seed on site but they can also collect and carry seed over distances estimated as up to 50 m (Andersson & de Vicente 2010). The applicant proposes to control rodents in the trial sites by baiting. In addition, any GM seed that is transported a few metres from the parent plant would likely still be located within areas of the trial sites where the applicant proposes to monitor and destroy volunteers (see Chapter 3, Section 3.1.1).

125. The applicant states that the seeds of sorghum cultivars to be grown do not have awns or hooks, and the seeds are not expected to adhere to animal fur or bird plumage. If sorghum seed is on the soil surface and conditions are wet, mud containing seeds could possibly stick to animal or bird feet and be transported outside the trial sites.

126. Birds, including cockatoos and corellas (ABC Rural news), and animals, including feral pigs (Rural Weekly), are known to feed on grain sorghum seed in Queensland. If a proportion of sorghum seed can survive digestion without losing viability, this seed could be dispersed in excreta. When pigs eat whole grain, some of the grain passes through undigested and appears as whole grains in manure (Morgan 2013). Whole sorghum grain may well remain viable after passage through animal digestive tracts as germination of sorghum seeds from deer faeces has been reported (Myers et al. 2004).

However, chickens efficiently digest whole sorghum seeds, partially because feed does not leave the chicken gizzard until it has been broken down into small particles (Rodgers et al. 2005). Based on the limited evidence available, it seems that endozoochory mediated by animals is a plausible pathway for dispersal of sorghum seeds, while endozoochory mediated by birds is less likely.

127. A few Northern Hemisphere bird species hoard or cache seeds (Cummings et al. 2008). It is not known whether any Australian birds carry seeds away for later consumption.

128. Several of the genetic modifications for grain quality traits could potentially increase the palatability of the GM sorghum, which may increase the likelihood of animal or bird ingestion. Conversely, lines with increased grain protein digestibility could have poorer seed survival in digestive tracts. Increased seed size is also correlated with reduced ability to germinate after gut passage (Pakeman et al. 2002).

129. One of the proposed trial sites (which may be planted in multiple years) is enclosed in bird-proof netting that is expected to exclude birds and animals, but other proposed sites would not have netting. If netting or equally effective control measures (see Chapter 3, Section 3.1.1) are extended to all trial sites, this would minimise the potential for seed dispersal by animal activity.

130. As discussed in Risk Scenario 3, the GM sorghum is expected to have equivalent or only marginally increased invasiveness compared to non-GM sorghum. The GM sorghum would have limited ability to establish ongoing volunteer populations in the environment.

Potential harm

131. The potential harms from Risk Scenario 4 are the same as for Risk Scenario 3, which considered harms that may be caused by volunteer GM sorghum populations in the environment.

Conclusion: Risk scenario 4 is not identified as a substantive risk because the proposed controls, if applied to all trial sites, would minimise dispersal of GM seed, and sorghum has limited ability to establish ongoing volunteer populations in the environment. Therefore, this risk could not be greater than negligible and does not warrant further detailed assessment.

2.4.5 Risk scenario 5

Risk source	Introduced genetic elements conferring altered grain quality
Causal pathway	⬇ Growing GM sorghum plants at the trial sites ⬇ Pollen flow to non-GM sorghum crops or volunteers outside the trial sites ⬇ Production of hybrid seed with GM traits ⬇
Potential harms	Toxicity or allergenicity to people OR Toxicity to desirable animals OR Reduced establishment or yield of desirable plants OR Increased levels of pests or pathogens

Risk source

132. The source of potential harm for this postulated risk scenario is the introduced genes and gene silencing constructs for grain quality traits.

Causal Pathway

133. GM sorghum would be grown at the trial sites and would produce pollen. If the GM pollen fertilised non-GM cultivated sorghum plants that flowered simultaneously, either crops or volunteers, the non-GM plants would produce hybrid GM seed. The seed could enter animal feed or human food supply chains, or grow into volunteer GM sorghum plants in the environment.

134. Cultivated sorghum is primarily self-pollinating. Outcrossing rates in the field depend on the cultivar and may be up to 30% (Djè et al. 2004; Pedersen et al. 1998). Outcrossing is known to occur by wind pollination. There is no direct evidence of insect-mediated pollination. A South African study reported bees visiting sorghum flowers and pollen adhering to the insects (Schmidt & Bothma 2005). However, it is noted that sorghum flowers do not produce nectar to attract pollinators, sorghum flowers often bloom at night (Herde et al. 2005; Stephens & Quinby 1934), and that most sorghum pollen loses viability within an hour (Lansac et al. 1994; Stephens & Quinby 1934). These factors suggest that sorghum is poorly adapted for bee pollination.

135. Two studies of wind-mediated outcrossing in grain sorghum (*S. bicolor* spp. *bicolor*) found that outcrossing between a pollen donor field and pollen recipients occurred at low levels at the maximum distances tested, with one study finding 0.06% outcrossing at 153 m (Schmidt & Bothma 2006) and the other study finding 0.04% outcrossing at 100 m (Rabbi et al. 2011). It is noted that both of these studies used male-sterile recipient plants, which were not capable of self-fertilisation, whereas commercial grain sorghum crops are male-fertile. Therefore, outcrossing rates between commercial grain sorghum plants are expected to be substantially lower than measured in these studies.

136. Another study measured pollen flow from grain sorghum to weedy shattercane (*S. bicolor* spp. *drummondii*) in the direction of the prevailing winds. Shattercane, although it is self-fertile, has a more open panicle structure than grain sorghum and generally has higher rates of outcrossing. The study found that the average percentage of hybrid seeds produced by the recipient shattercane plants was 0.53% at 100 m and 0.22% at 200 m (Schmidt et al. 2013). Shattercane belongs to the same subspecies and has similar panicle morphology to Sudan grass, and Sudan grass or Sudan grass hybrids are cultivated as forage sorghum in Australia (see Chapter 1, Section 6.4). Therefore, this study provides a model for expected outcrossing rates from grain sorghum to some types of forage sorghum.

137. The applicant has proposed two options to manage pollen flow (Chapter 1, Section 3.1). In Option A, a GM sorghum planting area would be surrounded by a 7.5 m pollen trap of non-GM sorghum, then a 200 m monitoring zone which would be inspected while the GM sorghum is flowering to destroy any sexually compatible plants, then a 100 m zone where no sorghum crops would flower simultaneously with the GM sorghum. Based on the outcrossing information summarised above, it is expected that this option would minimise pollen flow from the GMOs to grain sorghum volunteers or crops, but might not fully control pollen flow to forage sorghum volunteers or crops.

138. In Option B, the GM sorghum plants would be bagged during flowering to prevent pollen release, and in addition, the planting area would be surrounded by a 100 m monitoring zone which would be inspected while the GM sorghum is flowering to destroy any sexually compatible plants. This option would minimise pollen flow from the GMOs to either grain or forage sorghum. If Option B or equally effective control measures (see Chapter 3, Section 3.1.1) are applied to all trial sites, this would minimise the potential for pollen flow to non-GM sorghum outside the trial sites.

139. The characteristics of sorghum seed endosperm depend on both male and female parents of the seed (Murty & Nicodemus 1987). The grain quality traits introduced into the GM sorghum lines primarily affect the seed endosperm. Therefore, if GM sorghum pollen fertilised non-GM sorghum, the first generation seed would possess altered grain quality characteristics as well as carrying altered genetic elements that could be transmitted to future generations.

140. If GM sorghum pollen fertilised non-GM sorghum plants in a commercial crop, the hybrid seed could be used as animal feed or human food. Alternatively, hybrid seed lost during harvest or spilt

during transport could grow as volunteer GM sorghum in the environment. If GM sorghum pollen fertilised non-GM sorghum volunteers, the hybrid seed could grow as volunteer GM sorghum.

141. As discussed in Risk Scenario 3, the GM sorghum is expected to have equivalent or only marginally increased invasiveness compared to non-GM sorghum. The GM sorghum would have limited ability to establish ongoing volunteer populations in the environment.

Potential harm

142. If a non-GM sorghum crop produced hybrid GM seeds, there is uncertainty about whether the introduced proteins in the grain could be toxic or allergenic to people, as discussed in Risk Scenario 1. Some of the Australian grain sorghum crop is exported for human consumption, particularly for production of baijiu, a traditional Chinese distilled liquor (Gordon 2016). Sorghum flour is also occasionally used in gluten-free food products in Australia (GRDC GroundCover 2017). However, hybrid GM seeds could only be a very small proportion of the seed of a non-GM sorghum crop due to competition from self-pollination or pollen flow from neighbouring plants. In commercial food production, where large quantities of seed are pooled and processed, any toxic or allergenic proteins from GM seeds would be present at extremely low concentrations in a final food product, and would be unlikely to elicit symptoms in people.

143. If a non-GM sorghum crop produced hybrid GM seeds, there is uncertainty about whether the introduced proteins in the grain could be toxic to animals, as discussed in Risk Scenario 2. The non-GM crop would not have increased levels of the natural toxins dhurrin or nitrates due to the GM pollen flow, as dhurrin or nitrates do not accumulate in sorghum grain (Doggett 1988; Sidhu et al. 2011) and the vegetative parts of the crop would not be affected by pollination. Sorghum grain is mainly used in Australia as feed for cattle, pigs and poultry, with some grain going to the pet food industry (GRDC 2014). As hybrid GM seeds could only be a very small proportion of the seed of a non-GM sorghum crop, they would also only form a very small part of the daily diet of livestock. For small pets, where a single sorghum seed might be a substantial portion of a meal, if hybrid GM seed had increased toxicity this could cause adverse health effects.

144. If hybrid GM sorghum seeds grew into volunteer plants in the environment, the potential harms would be the same as discussed in Risk Scenario 3.

Conclusion: Risk scenario 5 is not identified as a substantive risk because the proposed controls (bagging and a monitoring zone), if applied to all trial sites, would minimise pollen flow to non-GM sorghum outside the trial sites, sorghum has limited ability to establish ongoing volunteer populations in the environment, and consumption of sorghum containing low levels of GM grain by people or livestock is not expected to cause adverse health effects. Therefore, this risk could not be greater than negligible and does not warrant further detailed assessment.

2.4.6 Risk scenario 6

Risk source	Introduced genetic elements conferring altered grain quality
Causal pathway	⬇ Growing GM sorghum plants at the trial sites ⬇ Outcrossing with weeds that are sexually compatible with sorghum ⬇ Introgression of GM traits into populations of weedy species ⬇
Potential harms	Toxicity or allergenicity to people OR Toxicity to desirable animals OR Reduced establishment or yield of desirable plants OR

	Increased levels of pests or pathogens OR Reduced services from the land use

Risk source

145. The source of potential harm for this postulated risk scenario is the introduced genes and gene silencing constructs for grain quality traits.

Causal Pathway

146. GM sorghum would be grown at the trial sites and would produce fertile flowers. If the GM sorghum outcrossed with weedy related species that flowered simultaneously, this could produce hybrid GM seed. GM hybrid plants could backcross with the weedy parent leading to introgression of GM traits into the weedy species.

147. As described in Chapter 1, Section 6.4, the weedy species that are sexually compatible with grain sorghum and present in south-east Queensland are wild sorghum (*S. bicolor* subsp. *arundinaceum*), Johnson grass (*S. halepense*), Colombus grass (*S. x almum*) and perennial sorghum (*S. spp.* hybrid cv. Silk). The applicant states that the GM sorghum would be cultivated to flower in the summer months. Johnson grass, Colombus grass and perennial 'Silk' sorghum all flower for extended periods during summer (Parsons & Cuthbertson 2001), so could cross with the GM sorghum. *S. bicolor* subsp. *arundinaceum* flowers between March and May in Queensland (AusGrass2: Sorghum arundinaceum), so is not expected to cross with the GM sorghum, and will not be considered further.

148. Despite ploidy differences, hybridisation occurs between grain sorghum and Johnson grass. 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 & Ellstrand 1996). Some studies of first generation offspring found the hybrids had reduced fertility (reviewed by Warwick & Black 1983), but other studies found that hybrids had comparable vigour and reproductive ability to the weedy parent (Arriola & Ellstrand 1997; Magomere et al. 2015). In the United States, a range of alleles originating from cultivated sorghum were found in Johnson grass populations, including weedy populations with no recent exposure to cultivated sorghum, suggesting occurrence of introgression events followed by dispersal (Morrell et al. 2005).

149. Little information is available in the literature about the likelihood of outcrossing, and subsequent introgression of genes, between grain sorghum and Colombus grass or perennial 'Silk' sorghum. It is noted that neither Colombus grass nor perennial 'Silk' sorghum are separate species, but are genetically intermediate between *S. halepense* and *S. bicolor* (OGTR 2017). If outcrossing rates are also intermediate, they would be lower than the outcrossing rate measured for *S. halepense* (above) and higher than the outcrossing rate measured for *S. bicolor* (Risk Scenario 5).

150. Outcrossing between the GM sorghum and weedy related species could occur either by pollen from the GMOs fertilising weeds within or outside the trial site, or by pollen from weeds fertilising the GMOs. If pollen from the GM sorghum fertilised a weed, hybrid GM seeds growing on the weed could be widely dispersed. For instance, Johnson grass seeds shatter (Tang et al. 2013) and are transported by wind, water, externally on animals and internally through animal digestive tracts (Parsons & Cuthbertson 2001). If pollen from a weed fertilised a GMO, hybrid seeds growing on the GM plant would have fewer dispersal routes, but might not be controlled by the proposed measures to restrict GM seed persistence in the trial sites (Risk Scenario 3) due to high seed dormancy and production of rhizomes that can regrow after an aboveground plant is destroyed (Arriola & Ellstrand 1997; Magomere et al. 2015).

151. The applicant has proposed two options to manage pollen flow to or from weedy related species (Chapter 1, Section 3.1). In Option A, a GM sorghum planting area would be surrounded by a 7.5 m pollen trap of non-GM sorghum, then a 200 m monitoring zone which would be inspected while the GM sorghum is flowering to destroy any sexually compatible plants. Based on the outcrossing

information summarised above, it is unlikely that this option would fully control potential outcrossing of the GMOs with weedy related species.

152. In Option B, the GM sorghum plants would be bagged during flowering to prevent pollen release, and in addition, the planting area would be surrounded by a 100 m monitoring zone which would be inspected while the GM sorghum is flowering to destroy any sexually compatible plants. This option would minimise cross-pollination between the GMOs and weedy related species. If Option B or equally effective control measures (see Chapter 3, Section 3.1.1) are applied to all trial sites, this would minimise the potential for outcrossing with weeds that are sexually compatible with sorghum.

153. As discussed in Risk Scenario 3, the GM traits for increased seed production or increased seed size could potentially marginally increase the invasiveness of the GM sorghum. In the unlikely event that the genetic elements conferring these traits introgressed into related weeds, this could potentially increase the invasiveness of the weeds at a similar level. In a worst case scenario, marginally increased weed invasiveness could have a cumulative effect over generations, causing a build-up of the weed population.

154. It is noted that the traits of increased seed production or increased seed size in the GM sorghum are conferred by either silencing or expressing truncated versions of native sorghum genes. Gene downregulation or truncation can occur by natural mutations, and if these types of mutations conferred substantive fitness advantages, they could have already occurred and spread in sorghum-related weeds.

Potential harms

155. Non-GM Johnson grass, Columbus grass and perennial 'Silk' sorghum are all declared noxious weeds in NSW and Western Australia (National weeds list) and cause a number of harms in the environment. Johnson grass and Columbus grass weeds are difficult to control due to ready regeneration from rhizomes; perennial 'Silk' sorghum has less aggressive rhizomes and is easier to control (Parsons & Cuthbertson 2001).

156. Johnson grass pollen has been shown to elicit allergenic sensitivity in people with grass pollen allergies in Brisbane (Davies et al. 2012). Columbus grass and perennial 'Silk' sorghum are closely related to Johnson grass and may also have allergenic pollen. As discussed in Risk Scenario 1, the genetic modification silencing a foldase gene could possibly increase pollen allergenicity, including if this genetic element was introgressed into a weed. Alternatively, if introgressed GM traits led to marginally increased weed invasiveness and higher weed populations, increased exposure of people to weed pollen could increase the severity of allergy symptoms.

157. Johnson grass, Columbus grass and perennial 'Silk' sorghum are all potentially toxic to livestock, particularly cattle, due to production of dhurrin and nitrates (Parsons & Cuthbertson 2001). As discussed in Risk Scenario 2, there is uncertainty regarding whether the genetic modifications could alter the levels of natural toxins in individual plants. If introgressed GM traits led to marginally increased weed invasiveness and higher weed populations, this could also increase the doses of natural toxins ingested by animals.

158. Johnson grass causes severe crop losses due to direct competition and allelopathic action. Columbus grass is less invasive but can compete with annual crops in high rainfall areas (Parsons & Cuthbertson 2001). Johnson grass is considered a major problem and Columbus grass a minor problem as weeds in natural ecosystems (Groves et al. 2003). If introgressed GM traits led to marginally increased weed invasiveness, particularly in Johnson grass, this could reduce establishment or yield of desirable crops in agricultural areas or desirable native plants in natural ecosystems.

159. Johnson grass, Columbus grass and perennial 'Silk' sorghum all harbour disease and insect pests that can damage sorghum, maize and sugarcane crops (Parsons & Cuthbertson 2001). As discussed in Risk Scenario 3, GM plants with improved grain quality traits could possibly provide a better food source to pests or pathogens that attack grain, and thus carry a higher burden of pests or pathogens. If

introgressed GM traits led to marginally increased weed invasiveness and higher weed populations, this could also increase the levels of pests or pathogens present in the environment.

160. As roadside weeds, Johnson grass, Columbus grass and perennial 'Silk' sorghum can all restrict visibility around curves or corners, and Columbus grass and perennial 'Silk' sorghum are both tall enough to obscure signage (Parsons & Cuthbertson 2001). This makes the roads less usable and can pose a safety hazard to people. If introgressed GM traits led to marginally increased weed invasiveness and higher weed populations, this harm could become more common.

Conclusion: Risk scenario 6 is not identified as a substantive risk because the proposed controls (bagging and a monitoring zone), if applied to all trial sites, would minimise outcrossing with sexually compatible weeds.

Section 3 Uncertainty

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

162. There are several types of uncertainty in risk analysis (Bammer & Smithson 2008; Clark & Brinkley 2001; Hayes 2004). These include:

- uncertainty about facts:
  - knowledge – data gaps, errors, small sample size, use of surrogate data
  - variability – inherent fluctuations or differences over time, space or group, associated with diversity and heterogeneity
- uncertainty about ideas:
  - description – expression of ideas with symbols, language or models can be subject to vagueness, ambiguity, context dependence, indeterminacy or under-specificity
  - perception – processing and interpreting risk is shaped by our mental processes and social/cultural circumstances, which vary between individuals and over time.

163. 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.

164. 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.

165. For DIR 153, uncertainty is noted particularly in relation to:

- Potential for increased toxicity or allergenicity of the GM sorghum
- Potential for the genetic modifications to increase plant invasiveness
- Potential for dispersal of sorghum seeds by birds in Australia

166. 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.

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

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

Section 4 Risk evaluation

168. 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.

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

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

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

- none of the GM plant material would enter human food or animal feed, except in a poultry feeding trial
- no adverse health effects on people handling the GM plants in glasshouse trials
- sorghum has limited ability to establish ongoing volunteer populations in the environment
- limits on the size and duration of the proposed release
- suitability of controls proposed by the applicant to restrict the spread and persistence of the GM sorghum plants and their genetic material.

171. Therefore, risks to the health and safety of people, or the environment, from the proposed release of the GM sorghum plants into the environment are considered to be negligible. The *Risk Analysis Framework* (OGTR 2013), which guides the risk assessment and risk management process, defines negligible risks as risks of no discernible concern with no present need to invoke actions for mitigation. Therefore, no additional controls are required to treat these negligible risks. Hence, the Regulator considers that the dealings involved in this proposed release do not pose a significant risk to either people or the environment[3].

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

Chapter 3 Risk management plan

Section 1 Background

172. 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.

173. 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.

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

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

Section 2 Risk treatment measures for substantive risks

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

Section 3 General risk management

177. The limits and controls proposed in the application were important in establishing the context for the risk assessment and in reaching the conclusion that the risks posed to people and the environment are negligible. Therefore, to maintain the risk context, licence conditions have been drafted to limit the release to the proposed size, locations and duration, and to restrict the spread and persistence of the GMOs and their genetic material in the environment. The conditions are discussed and summarised in this Chapter and listed in detail in Chapter 4 (the draft licence).

3.1 Draft licence conditions to limit and control the release

3.1.1 Consideration of limits and controls proposed by the University of Queensland (UQ)

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

179. The applicant proposes that the duration of the field trial would be limited to three years. In the first year, the trial would be limited to a single site with an area of up to 1 ha. In the second and third years the trial would be limited to up to four sites per year with a combined area of up to 5 ha per year. The small size and short duration of the trial would limit the potential exposure of people and desirable animals to the GMOs (risk scenarios 1 and 2).

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

181. The applicant does not propose that any GM plant material would enter the human food or animal feed supply chain, and the GM sorghum has not been assessed for food use by FSANZ. The applicant does propose to feed a non-viable product (pellets) from the GM sorghum grown in this trial to poultry under experimental conditions, if approved by an Animal Ethics Committee. A draft licence condition prohibits the use of GM plant material in human food or animal feed except as part of a poultry feeding trial. Additionally, animal experiments must have approval from an Animal Ethics Committee operating under The Australian Code for the Care and Use of Animals for Scientific Purposes. These measures would minimise exposure of people or desirable animals to the GM sorghum by consumption (risk scenarios 1 and 2).

182. The applicant proposes that any non-GM sorghum plants grown in the trial sites would be treated as if they were GMOs. This is necessary as the non-GM sorghum plants could be fertilised by GM sorghum pollen and bear GM seed. The applicant also proposes to destroy all GM seed that is not required for analysis or future planting. These standard licence conditions help to minimise persistence or dispersal of GM sorghum seed (risk scenarios 3 and 4).

183. The applicant proposes to monitor the trial sites for sorghum volunteers for at least 12 months after harvest, and until the sites are free of volunteers for at least six consecutive months, and to destroy any volunteers found before they flower. A study found that when grain sorghum seeds were buried in soil, <0.5% of seeds remained viable after four months, and none were viable after eight months (Jacques et al. 1974), so this period of monitoring is considered appropriate to minimise persistence of GM sorghum seed (risk scenario 3).

184. The applicant proposes that the frequency of post-harvest monitoring would be at least every 30 days during the summer months, and at least every 60 days at other times. In Australia, sorghum crops typically begin to flower 60 days after emergence (GRDC 2014). However, times from planting to 50% flowering can vary from 55 to 80 days, depending both on cultivar and on temperatures: hot weather hastens flowering and cold weather delays flowering (Spenceley et al. 2005).A study of the parental cultivar of the GM sorghum, RTx430, measured time from planting to 50% flowering as 78 days (Peterson et al. 2009), indicating that it is not an early maturing cultivar. Thus GM sorghum grown from seed is unlikely to begin flowering earlier than 60 days after emergence except under sustained hot conditions.

185. However, sorghum plants can also grow from tillers, and ratoon plants growing from tillers mature more quickly than plants growing from seeds (Doggett 1988). There is also a possibility that recently emerged small sorghum volunteers could be missed during inspections. Based on these considerations, the proposed post-harvest monitoring frequency of at least every 60 days during non-summer months is not considered sufficiently frequent to detect and destroy all sorghum volunteers before flowering. Conversely, the proposed monitoring frequency of at least every 30 days during summer months is more frequent than necessary. A draft licence condition requires post-harvest inspections to occur at least every 35 days throughout the year.

186. The applicant did not specify which parts of the trial sites would be inspected for sorghum volunteers post-harvest. GM sorghum seed lost during harvest and threshing activities could potentially fall a short distance outside the planting areas unobserved, as sorghum seeds are small and inconspicuous. There is also potential for short-distance dispersal of GM sorghum seeds lost during

harvest by ants or rodents (risk scenario 4). A draft licence condition requires that the planting areas and a 10 m buffer zone surrounding the outer edge of each planting area are subject to post-harvest inspection requirements.

187. The applicant proposes that post-harvest trial sites would be cultivated, using shallow cultivation, and irrigated, if rainfall is insufficient, to promote germination of volunteers and reduce persistence of GM seed (risk scenario 3). The parental cultivar of the GM sorghum, RTx430, germinates poorly at soil temperatures lower than 16°C (Franks et al. 2006) and generally sorghum crops in southern Queensland are planted in October or later to avoid cold conditions. A draft licence condition requires the post-harvest planting areas to be cultivated and irrigated once in October or November.

188. The applicant proposes that field trial sites would be located at least 100 m away from natural waterways. This is intended to manage the possibility of dispersal of GM sorghum seeds by flooding (risk scenario 4). Sorghum is in general more tolerant to flooding than other cereal crops excluding rice (Hadebe et al. 2016), and a study of flood tolerance of sorghum seed found that on average, over 40% of sorghum seed survived and germinated after 6 days immersion in water (Thseng & Hou 1993), indicating that long distance dispersal of sorghum seeds by flooding is feasible. One of the proposed local government areas where field trials may occur is Brisbane City. An inspection of the Brisbane City Plan: Flood – creek and waterway overlay suggested that some areas categorised as "very likely" to flood extend more than 50 m from waterways, but far fewer extend more than 100 m from waterways. Therefore, the proposal that field trial sites be located at least 100 m from waterways would minimise the likelihood of seed dispersal by flooding. Another consideration is that sorghum seed could be locally dispersed by high winds or heavy runoff in the event of a severe storm at seed maturity (risk scenario 4). A standard licence condition requires notification of any extreme weather condition affecting trial sites while GMOs are growing and until sites are signed off to allow assessment and management of any risks.

189. The applicant proposes that all equipment used with the GMOs would be cleaned before use for other purposes or removal from a trial site. The applicant also proposes to transport and store GMOs in accordance with the Regulator's *Guidelines for the Transport, Storage and Disposal of GMOs*. These controls would restrict the potential for dispersal of GMOs by people (risk scenario 4).

190. The applicant proposes that rodents in the trial sites would be controlled by baiting. This would restrict the potential for dispersal of GM seed by rodents (risk scenario 4). A draft licence condition requires implementation of measures including rodent baits and/or traps to control rodents within the trial sites.

191. The applicant proposes that some trial sites would be enclosed in bird-proof netting that is expected to exclude birds and non-burrowing animals. This would minimise the potential for dispersal of GM seeds from the planting areas by birds or animals (risk scenario 4) as well as the exposure of native animals or birds to the GMOs by consumption (risk scenario 2). Risk scenario 4 found that in sites lacking bird netting, or equally effective controls, endozoochory by large animals, or possibly by birds, would be a plausible route for dispersal of GM seeds. Therefore, a draft licence condition requires that all field trial sites must be either enclosed in bird netting that is capable of excluding birds and livestock and other large animals, or surrounded by a fence that is capable of excluding livestock and other large animals and equipped with bird scarers that are expected to deter the main seed-eating bird species present in the vicinity of the trial site.

192. Dispersal of viable seeds by rodents, birds or large animals could occur at planting, while mature seeds are present on the GM plants, or while seeds lost during harvest or threshing are present on the soil surface but have not yet germinated or decomposed. Therefore, the draft licence conditions regarding rodent, bird and animal controls require these measures to be in place from before planting until 60 days after harvest.

193. The applicant proposes, as one option to manage pollen flow from the GM sorghum, to bag the GM sorghum panicles during flowering and to surround each trial site with a 100 m monitoring zone

which will be inspected while the GM sorghum is flowering to destroy any plants that are sexually compatible with sorghum. The proposed pollination bags are resistant to weather and birds. These control measures would minimise outcrossing between the GM sorghum and sexually compatible plants outside the trial sites (risk scenarios 5 and 6), as well as minimising exposure of people to the GM pollen (risk scenario 1).

194. The other option proposed by the applicant to manage pollen flow was to surround each trial site with a 7.5 m pollen trap, a 200 m monitoring zone, and a further 100 m zone where no sorghum crops would flower simultaneously with the GMOs. This option was considered unlikely to fully control outcrossing between the GM sorghum and sexually compatible plants outside the trial site (risk scenarios 5 and 6). However, it might not be feasible for the applicant to bag GM sorghum plants in all proposed trial sites. Pollen flow could also be managed by sufficient isolation between the GMOs and related non-GM plants. The international standard for varietal certification of sorghum seed requires that sorghum or Sudan grass crops grown to produce high-purity basic seed must be not less than 400 m from any source of contaminating pollen (OECD 2016b). The United States regulatory agency for GM field trials, APHIS, recommended that unbagged GM sorghum plants should be isolated from cultivated sorghum by at least 805 m (USDA risk assessment presentation 2008). However, this guidance may be conservative due to uncertainty, as it dates from before publication of some relevant papers addressing sorghum gene flow (Rabbi et al. 2011; Schmidt et al. 2013). Based on currently available information, an exclusion distance of 600 m between the GM sorghum and any other grain sorghum or forage sorghum/Sudan grass crop would be expected to minimise pollen flow from the GM sorghum to the non-GM crop.

195. When considering pollen flow from the GM sorghum to sexually compatible weeds, one consideration is that weeds would be present at a much lower density than crops, which would reduce the overall outcrossing potential. However, a comparison of outcrossing data at a distance of 100 m suggests a higher outcrossing rate from cultivated sorghum to individual Johnson grass plants than to individual sorghum plants (Arriola & Ellstrand 1996; Rabbi et al. 2011; Schmidt & Bothma 2006). Also, the potential harms resulting from outcrossing to weeds (risk scenario 6) may be more serious than the potential harms resulting from outcrossing to cultivated sorghum (risk scenario 5). Balancing these factors, it is considered appropriate to separate sexually compatible weeds from the GM sorghum by the same exclusion distance used for non-GM sorghum crops.

196. Sorghum is self-pollinated and wind pollinated; there is some uncertainty about whether it may also be insect pollinated (see risk scenario 5). For GM crops that are insect pollinated, previous licences issued by the Regulator have often imposed a requirement for a pollen trap of non-GM plants of the same species. Apple is a crop that is solely insect pollinated, with no self-pollination or wind pollination. A recent study modelling insect pollination in apples found that an isolation distance of 183 m between a GM orchard and a non-GM orchard was sufficient to ensure that less than 0.2% of apple seed produced in the non-GM orchard had a GM parent (Vallaeys et al. 2017). Insect pollination in sorghum, if it occurs at all, would only be a small fraction of total pollination. Therefore, an isolation distance of 600 m in sorghum is expected to ensure negligible insect-mediated outcrossing without need for a pollen trap.

197. A draft licence condition requires either bagging the GM sorghum panicles during flowering and surrounding the trial site with a 100 m monitoring zone which will be inspected while the GM sorghum is flowering to destroy any plants that are sexually compatible with sorghum, or only surrounding the trial site with a 600 m monitoring zone which will be inspected while the GM sorghum is flowering to destroy any plants that are sexually compatible with sorghum. This condition is expected to minimise outcrossing between the GM sorghum and sexually compatible plants outside the trial sites (risk scenarios 5 and 6).

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

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

- limit the duration of the release to between October 2017 and June 2020
- limit the size of the release in the first year to one trial site with an area of up to 1 ha, and in each of the second and third years to four trial sites with a combined area of up to 5 ha
- not allow GM plant material to be used for human food or animal feed, with the exception of a poultry feeding trial if approved by an Animal Ethics Committee
- treat non-GM sorghum grown in the trial sites the same as GM plants
- destroy all GM seed that is not required for analysis or future planting
- monitor the post-harvest trial sites at least every 35 days for a period of at least 12 months, and until the sites are free of sorghum volunteers for at least six consecutive months, and destroy any volunteers found
- cultivate and irrigate the post-harvest trial sites
- locate the trial sites at least 100 m away from waterways
- clean equipment after use with the GMOs
- transport and store GMOs in accordance with the Regulator's guidelines
- control rodents in the trial sites by baiting and/or trapping
- either enclose the trial site in netting to exclude birds and large animals or surround the trial site with a fence to exclude large animals and install bird scarers
- control pollen flow by either bagging GM sorghum flowers and surrounding the trial site with a 100 m monitoring zone where any sexually compatible plants are destroyed, or by surrounding the trial site with a 600 m monitoring zone where any sexually compatible plants are destroyed.

3.2 Other risk management considerations

199. 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 and
- access for the purpose of monitoring for compliance.

3.2.1 Applicant suitability

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

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

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

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

3.2.2 Contingency plan

203. If a licence were issued, UQ would be required to submit a contingency plan to the Regulator before planting the GMOs. This plan would detail measures to be undertaken in the event of any unintended presence of the GM sorghum outside permitted areas.

204. UQ would also be required to provide the Regulator with a method to reliably detect the GMOs or the presence of the genetic modifications in a recipient organism. This methodology would be required before planting the GMOs.

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

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

3.2.4 Reporting requirements

206. If issued, the licence would require the licence holder to immediately report any of the following to the Regulator:

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

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

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

3.2.5 Monitoring for compliance

208. 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 site.

209. 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.

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

Section 4 Issues to be addressed for future releases

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

- additional molecular and biochemical characterisation of the GM sorghum plants, particularly with respect to potential for increased toxicity or allergenicity
- additional phenotypic characterisation of the GM sorghum lines, particularly with respect to potential for increased invasiveness
- information regarding potential for dispersal of sorghum seed by birds in Australia.

Section 5 Conclusions of the consultation RARMP

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

213. If a licence were issued, conditions would be imposed to limit the release to the proposed size, locations and duration, and to restrict the spread and persistence of the GMOs and their genetic material in the environment, as these were important considerations in establishing the context for assessing the risks.

Chapter 4 Draft licence conditions

Section 1 Interpretations and definitions

1. In this licence:

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

(b) words importing a gender include any other gender;

(c) words in the singular include the plural and words in the plural include the singular;

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

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

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

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

2. In this licence:

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

'Clean' (or **'Cleaned'**) means the removal and/or Destruction of the GMOs, to the reasonable satisfaction of the Regulator.

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

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

(b) recover and/or Destroy the GMOs; and

(c) inspect for and Destroy any Volunteers that may exist as a result of the event.

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

(a) uprooting;

(b) treatment with herbicide;

(c) burning/incineration;

(d) root cutting and mulching;

(e) crushing or grinding of seed;

(f) autoclaving; or

(g) a method approved in writing by the Regulator.

Note: 'As the case requires' has the effect that, depending on the circumstances, one or more of these techniques may not be appropriate. For example, in the case of plants with mature seed heads still attached, treatment with herbicide would not be appropriate as it would not destroy viable seeds.

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

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

'GM' means genetically modified.

'GMOs' means the genetically modified organisms that are the subject of the dealings authorised by this licence. GMOs include live plants, root stock that is able to grow into live plants, and viable seed.

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

'Monitoring Zone' means an area of land extending outwards:

(a) at least 100 m in all directions from the outer edge of a Planting Area if all GM Sorghum is bagged while Flowering (Figure 1A); or

(b) at least 600 m in all directions from the outer edge of a Planting Area if GM Sorghum is not bagged while Flowering (Figure 1B).

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

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

(a) whether the information or opinion is true or not; and

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

'Planting Area' means an area of land where the GMOs and non-GM Sorghum are planted and grown pursuant to this licence.

'Plant Material' means any part of the GM or non-GM Sorghum plants grown at a Planting Area, whether viable or not, or any product of these plants.

'Post Harvest Buffer Zone' means an area of land extending outwards at least 10 m in all directions from the outer edge of a Planting Area after the Planting Area has been harvested (Figure 1C).

'Regulations' means the Gene Technology Regulations 2001(Commonwealth) or the corresponding State law under which this licence is issued.

'Regulator' means the Gene Technology Regulator.

'Related Species' means plants from the section *Eusorghum* of the genus *Sorghum* excluding Sorghum.

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

'Sorghum' means plants of the subspecies *Sorghum bicolor* (L.) Moench subsp. *bicolor.*

'Tillage' means the use of any technique to disturb the soil.

'Volunteers' means GM or non-GM Sorghum plants that have not been intentionally grown.

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

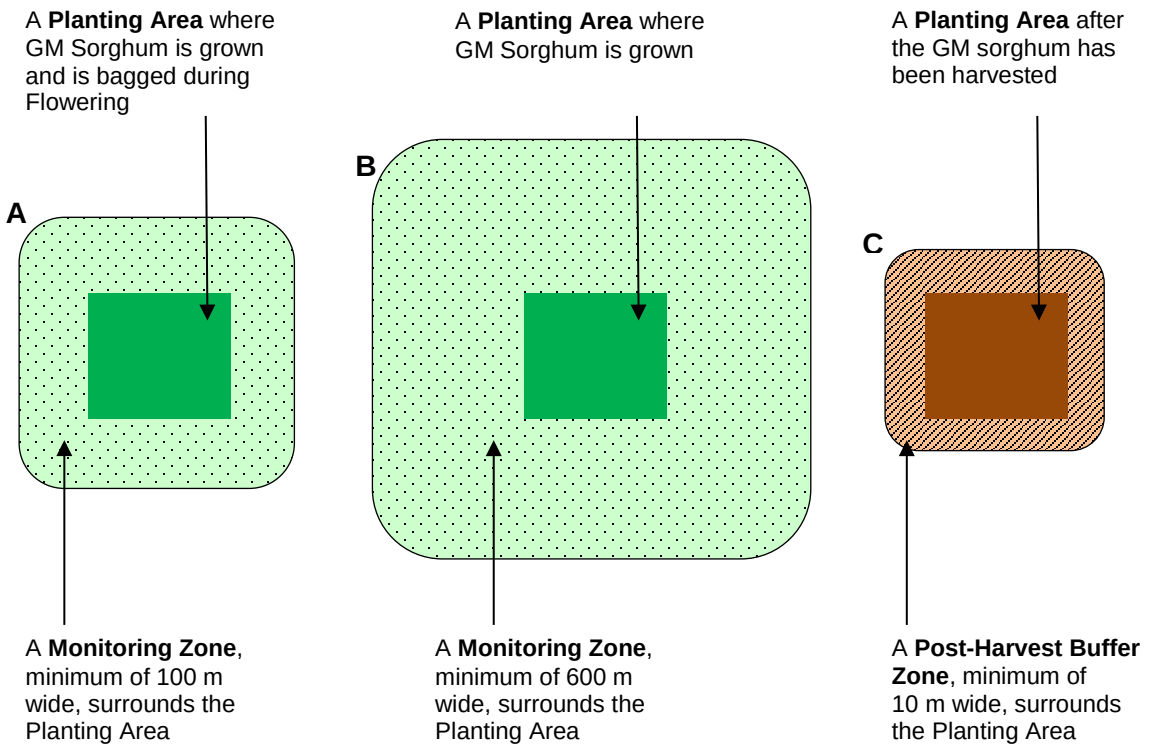

Figure 1. Diagrams (not to scale) showing the relationships between Planting Areas, Monitoring Zones and Post-Harvest Buffer Zones.

A: diagram where pollination bags are used while the GMOs are flowering;
B: diagram without pollination bags while the GMOs are flowering;
C: diagram after the GMOs are harvested.

Section 2 General conditions and obligations

3. This licence does not authorise dealings with GMOs that are otherwise prohibited as a result of the operation of State legislation declaring areas to be GM, GM free, or both, for marketing purposes.

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

5. The holder of this licence ('the licence holder') is the University of Queensland.

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

7. The dealings authorised by this licence are to conduct experiments with the GMOs, breed, propagate and grow the GMOs, use the GMOs in the course of manufacture of a thing that is not a GMO, transport and dispose of the GMOs, and possession, supply or use of the GMOs in the course of any of these dealings.

Obligations of the Licence Holder

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

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

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

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

10. The licence holder must:

(a) inform the Regulator immediately in writing, of:

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

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

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

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

11. The licence holder must be able to access and control the Planting Areas, Post-Harvest Buffer Zones, Monitoring Zones and approved facilities (if any) to the extent necessary to comply with this licence, for the duration of the licence.

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

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

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

Note: Examples of functions or positions are 'project supervisor', 'site manager', 'farm labourer' etc.

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

(c) detail of how the licence holder will access and control Planting Areas, Post-Harvest Buffer Zones, Monitoring Zones and approved facilities (if any) for the duration of the licence; and

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

(d) written methodology to reliably detect the GMOs or the presence of the genetic modifications in a recipient organism, and to distinguish between categories of GMOs approved for release; and

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

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

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

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

(b) the cancellation or suspension of the licence; and

(c) the surrender of the licence.

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

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

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

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

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

16. The licence holder must:

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

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

Provision of new information to the Regulator

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

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

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

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

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

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

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

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

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

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

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

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

Obligations of persons covered by the licence

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

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

Section 3 Limits and control measures

Limits on the release

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

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

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

(b) non-GM Sorghum plants; and

(c) plants approved in writing by the Regulator.

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

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

Period	Maximum number of Planting Areas	Maximum combined size of Planting Areas	Local Government Areas in which Planting Areas may be located
October 2017 – June 2018	1	1 ha	Brisbane City, Goondiwindi, Lockyer Valley, Redland City, Somerset, Southern Downs, South Burnett, Toowoomba
July 2018 – June 2019	4	5 ha	
July 2019 – June 2020	4	5 ha	

24. Subject to Condition 25, Plant Material must not be used, sold or otherwise disposed of for any purpose which would involve or result in its use as food for humans or feed for animals.

25. Non-viable products derived from the GMOs may be fed to poultry for experimental purposes, subject to those experiments being approved by an Animal Ethics Committee operating under *The Australian Code for the Care and Use of Animals for Scientific Purposes*.

Containment measures

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

Pollen and seed dispersal during cultivation

26. The outer edge of any Planting Area must be at least 100 m away from Waterways.

27. Any extreme weather event that is expected to affect or has already affected a Planting Area or associated areas, while the GMOs are growing or while the Planting Area is subject to inspection requirements, must be notified in writing to the Regulator as soon as practically and reasonably possible.

Note: The Contingency Plan must be implemented if the GMOs are detected outside areas under inspection (Condition 49).

28. Non-GM Sorghum plants grown in a Planting Area must be handled as if they were the GMOs.

29. Rodents within the Planting Area must be controlled by trapping and/or baiting from at least 7 days prior to planting the GMOs until at least 60 days after the GMOs are harvested or Destroyed.

30. For each Planting Area, one of the following measures to restrict seed dispersal by birds and animals must be adopted:

(a) enclose the Planting Area in bird netting that is capable of excluding birds and livestock and other large animals from prior to planting the GMOs until at least 60 days after the GMOs are harvested or Destroyed; or

(b) surround the Planting Area with a fence that is capable of excluding livestock and other large animals, and equip the Planting Area with bird scarers that are expected to deter the main seed-eating bird species present in the vicinity of the Planting Area, from prior to planting the GMOs until at least 60 days after the GMOs are harvested or Destroyed.

31. While bird netting or a fence are required under the immediately preceding condition, the bird netting or fence must be inspected for damage at least once every 35 days, and if damage is found, must be repaired as soon as practicable.

32. For each Planting Area, one of the following measures to restrict pollen flow must be adopted:

(a) enclose all GM Sorghum panicles in pollination bags that are impermeable to pollen and weather resistant from at least 10 days prior to the expected commencement of Flowering and until at least 10 days after the GMOs have finished Flowering, and surround the Planting Area with a Monitoring Zone of at least 100 m (Figure 1A); or

(b) surround the Planting Area with a Monitoring Zone of at least 600 m (Figure 1B).

Note: If pollination bags will not be used, there is an early notification requirement (Condition 51(a)).

33. Monitoring Zones must be maintained in a manner that enables identification of Sorghum or Related Species.

*Note: An example of an area that does **not** enable identification of Sorghum or Related Species is an area planted to a closed-canopy crop that grows simultaneously with the GMOs, and grows to a height that is comparable to, or taller than, Sorghum.*

34. While the GMOs are growing in a Planting Area, inspections must be conducted by people trained to recognise Sorghum and Related Species, and actions taken as follows:

Area	Period of inspection	Inspection frequency	Inspect for	Action
(a) Planting Area	First inspection must occur at least 10 days prior to the expected commencement of Flowering of any GMOs*, and inspections must continue until all GMOs in the Planting Area have finished Flowering	At least once every 14 days	Related Species	Destroy before Flowering or prevent from Flowering simultaneously with the GMOs
(b) Monitoring Zone	First inspection must occur at least 10 days prior to the expected commencement of Flowering of any GMOs*, and inspections must continue until all GMOs in the Planting Area have finished Flowering	At least once every 14 days	Sorghum and Related Species	Destroy before Flowering or prevent from Flowering simultaneously with the GMOs
(c) Pollination bags (if used)	While pollination bags are in place	At least once every 14 days	Damage that may permit pollen to escape	Repair or replace as soon as practicable

**Condition 51(b) requires the licence holder to provide information to the Regulator on the expected flowering period, however the inspection period should be based on the observed development of the GMOs, so that inspections commence prior to flowering of any GMOs.*

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

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

36. GMOs planted in a Planting Area must be harvested or Destroyed within 6 months of planting.

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

38. Harvested GM seed not required for experimentation or future planting must be Destroyed as soon as practicable.

Processing or experimentation with GMOs

39. If threshing or processing of GM seed is not conducted under a Notifiable Low Risk Dealings (NLRD) authorisation, such activities may only be undertaken within:

(a) a Planting Area; or

(b) a facility approved in writing by the Regulator.

Note: Dealings conducted under a NLRD authorisation must be assessed by an Institutional Biosafety Committee before commencement, must comply with the requirements of the Regulations, and are not subject to the conditions of this licence.

40. If experimentation or analysis with the GMOs is not conducted under a NLRD authorisation, such activities may only be undertaken within:

(a) a Planting Area prior to harvest or during harvest; or

(b) a facility approved in writing by the Regulator.

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

Transport or storage of the GMOs

42. If transport or storage of the GMOs is not conducted under a NLRD authorisation, such activities must:

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

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

(c) comply with all other conditions of this licence.

Note: Condition 15 requires signed statements for persons transporting or disposing of the GMOs.

43. Methods and procedures used to transport GMOs must be recorded, and must be provided to the Regulator, if requested.

Note: The Contingency Plan must be implemented if the GMOs are detected outside areas under inspection (Condition 49).

Persistence of the GMOs

44. After harvest of GMOs in a Planting Area, the Planting Area must be surrounded by a Post-Harvest Buffer Zone of at least 10 m.

45. After harvest of GMOs in a Planting Area, the Planting Area and associated areas of land must be inspected by people trained to recognise Sorghum. Inspections must cover the entirety of areas to be inspected. Actions must be taken as follows:

Area of land	Period of inspection	Inspection frequency	Inspect for	Action
(a) Planting Area (b) Post-Harvest Buffer Zone (c) Any other area where GMOs have dispersed during planting, growing or harvesting (d) Any other area used to Clean Equipment used in connection with the GMOs (e) Any other area used to Destroy GMOs	From the day of completion of harvest or Destruction of GMOs planted in the Planting Area, until: i. the area is replanted with the GMOs; or ii. the Regulator has issued a Sign-off for the area.	At least once every 35 days	Volunteers	Destroy before Flowering

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

(a) date of the inspections;

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

(c) details of the experience, training or qualification that enables the person(s) to recognise Sorghum and/or Related Species, if not already recorded in the logbook;

(d) details of areas inspected including current land use;

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

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

(g) for post-harvest areas, details of any post-harvest crops and any recent management practices applied (including Tillage events)

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

(h) details of any Volunteers observed during post-harvest inspections or land-management activities, including number, developmental stage and approximate position of the Volunteers within each area inspected ⌘;

(i) date(s) and method(s) of Destruction or of preventing Flowering simultaneously with the GMOs of any Sorghum, Related Species or Volunteers;

(j) details of any damage and any repairs to the bird netting or fence surrounding the Planting Area, while the bird netting or fence are required; and

(k) details of rodent control methods used and any evidence of rodent activity, while rodent control methods are required.

⌘ *Examples of acceptable ways to record the positional information for Volunteers in the Logbook include:*

- descriptive text

- marking on a diagram

- indicating grid references on corresponding map/sketch

Note: Details of Inspection activities must be provided to the Regulator (Condition 51(e)).

47. While post-harvest inspection requirements apply to a Planting Area, Post-Harvest Buffer Zone and any associated areas:

(a) the area must be maintained in a manner appropriate to allow identification of Volunteers;

(b) any Tillage of the area must be to a depth no greater than the depth of sowing of the GMOs;

(c) the area may not be grazed by livestock; and

(d) no plants may intentionally be grown in the area unless the plants are:

i. the GMOs or non-GM Sorghum, planted in accordance with the conditions of this licence; or

ii. agreed to in writing by the Regulator.

48. Prior to an application for Sign-off, a Planting Area must be Tilled and irrigated, with both the Tillage and the irrigation occurring in the October or November following harvest of the Planting Area.

Note: A period of natural rainfall may be taken as irrigation only with the agreement of the Regulator. Evidence (such as rainfall measurements, photos etc.) that the rainfall has been sufficient to promote germination should be provided.

Contingency plan

49. If any unintentional presence of the GMOs is detected outside the areas requiring inspection, the Contingency Plan must be implemented.

Section 4 Sign off

50. The licence holder may make written application to the Regulator that planting restrictions and inspection requirements no longer apply to a Planting Area and associated areas if:

(a) all post-harvest inspection activities have been conducted for at least 12 months on these areas;

(b) conditions have been conducive for germination and detection; and

(c) no Volunteers have occurred on these areas in the most recent six month inspection period.

Note: The Regulator will take into account the management and inspection history for the Planting Area and associated areas, including post-harvest crops planted (if any), Tillage, irrigation, rainfall, application of herbicide and occurrence of Volunteers, in deciding whether or not further inspections are required to manage persistence of the GMOs.

Section 5 Reporting and documentation

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

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

Notice	Content of notice	Timeframe
(a) Early Notification for planting where pollination bags will not be used	i. Details of the Planting Area including size, the local government area, GPS coordinates, a street address or other directions and a diagrammatical representation of the site (eg Google Maps) ii. Date on which the GMOs will be planted iii. Details on how inspections of the Monitoring Zone will be managed, including strategies for the detection and destruction of Sorghum or Related Species	At least 30 days prior to each planting where pollination bags will not be used (Condition 32(b) applies).
(b) Intention to Plant	i. Details of the Planting Area including size, the local government area, GPS coordinates, a street address or other directions and a diagrammatical representation of the site (eg Google Maps) ii. Identity of the GMOs to be planted at the Planting Area (eg lines or construct details) iii. Date on which the GMOs will be planted iv. Period when the GMOs are expected to Flower v. Period when harvesting is expected to commence vi. How all areas requiring post-harvest inspections are intended to be used until sign-off, including the proposed post-harvest crop(s), if any vii. Details on how inspection activities will be managed, including strategies for the detection and destruction of Volunteers, Sorghum or Related Species viii. History of how the site has been used for the previous two years	At least 7 days prior to each planting (to be updated immediately if the notified details change)
(c) Planting	i. Actual date(s) of planting the GMOs ii. Any changes to the details provided under part (b) of this condition.	Within 7 days of any planting
(d) Harvest	Actual date(s) of harvesting or Destroying the GMOs.	Within 7 days of commencement of any harvesting. If harvesting is ongoing when the notification is sent, another notification must be sent within 7 days of completion of harvesting.
(e) Inspection activities	Information recorded in a Logbook as per the inspection requirements (Conditions 31, 34, 45 and 46).	Within 35 days of inspection

Note: Other reports and documents that may need to be sent to the Regulator are described under Conditions 8, 10(a), 10(b), 12, 17 and 27.

References

ABARES (2016) Australian crop report No. 178, June 2016. Australian Bureau of Agricultural and Resources Economics and Sciences, Canberra.

Andersson, M.S., de Vicente, M.C. (2010) Chapter 19: Sorghum. In: *Gene Flow between Crops and Their Wild Relatives* The Johns Hopkins University Press. 443-462.

Arriola, P.E., 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., Ellstrand, N.C. (1997) Fitness of interspecific hybrids in the genus *Sorghum*: Persistence of crop genes in wild populations. *Ecological Applications* **7**: 512-518.

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

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

Baykal, U., Zhang, Z. (2010) Chapter 11: Small RNA-mediated gene silencing for plant biotechnology. In: *Gene silencing: Theory, techniques and applications*, Catalano, A.J., ed . Nova Science Publishers, Inc. New York. 255-269.

Belton, P.S., Delgadillo, I., Halford, N.G., Shewry, P.R. (2006) Kafirin structure and functionality. *Journal of Cereal Science* **44**: 272-286.

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

Cuevas, H.E., Zhou, C., Tang, H., Khadke, P.P., Das, S., Lin, Y.R. et al. (2016) The Evolution of Photoperiod-Insensitive Flowering in Sorghum, A Genomic Model for Panicoid Grasses. *Molecular Biology and Evolution* **33**: 2417-2428.

Cummings, J.L., Handley, L.W., MacBryde, B., Tupper, S.K., Werner, S.J., Byram, Z.J. (2008) Dispersal of viable row-crop seeds of commercial agriculture by farmland birds: implication for genetically modified crops. *Environmental Biosafety Research* **7**: 241-252.

da Silva, L.S., Taylor, J., Taylor, J.R. (2011) Transgenic sorghum with altered kafirin synthesis: kafirin solubility, polymerization, and protein digestion. *J Agric Food Chem* **59**: 9265-9270.

Davies, J.M. (2014) Grass pollen allergens globally: the contribution of subtropical grasses to burden of allergic respiratory diseases. *Clinical & Experimental Allergy* **44**: 790-801.

Davies, J.M., Li, H., Green, M., Towers, M., Upham, J.W. (2012) Subtropical grass pollen allergens are important for allergic respiratory diseases in subtropical regions. *Clin Transl Allergy* **2**: 4.

Djè, Y., Heuertz, M., Ater, M., Lefèbvre, C., Vekemans, X. (2004) In situ estimation of outcrossing rate in sorghum landraces using microsatellite markers. *Euphytica* **138**: 205-212.

Doggett, H. (1988) *Sorghum.*, 2nd Edition. Longman Scientific and Technical, Essex, UK.

Duodu, K.G., Taylor, J.R.N., Belton, P.S., Hamaker, B.R. (2003) Factors affecting sorghum protein digestibility. *Journal of Cereal Science* **38**: 117-131.

EFSA (2009) Scientific opinion of the GMO and BIOHAZ Panels on the "Use of antibiotic resistance genes as marker genes in genetically modified plants". *European Food Safety Authority* **1034**: 1-82.

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

Fleming, J., McNee, T., Cook, T., and Manning, B. (2012) Weed control in summer crops 2012-13. NSW Department of Primary Industries.

Franks, C.D., Burow, G.B., Burke, J.J. (2006) A comparison of U.S. and Chinese sorghum germplasm for early season cold tolerance. *Crop Sci* **46**: 1371-1376.

FSANZ (2010) Final assessment report. Application A1029. Food derived from drought-tolerant corn line MON87460. Approval report.

Gambín, B.L., Borrás, L. (2011) Genotypic diversity in sorghum inbred lines for grain-filling patterns and other related agronomic traits. *Crop & Pasture Science* **62**: 1026-1036.

Gómez, C., Espadaler, X. (1998) Myrmecochorous dispersal distances: a world survey. *Journal of Biogeography* **25**: 573-580.

Gordon, C.K. (2016) State of the Australian grains industry 2016. Grain Growers Limited, Canberra.

GRDC (2011) Mouse Control Fact Sheet. Grains Research and Development Corporation, Canberra.

GRDC (2014) GRDC Grownotes: Sorghum. Grains Research and Development Corporation, Canberra.

Gritton, E.T., Atkins, R.E. (1963) Germination of sorghum seed as affected by dormancy. *Agronomy Journal* **55**: 169-174.

Groves, R.H., Hosking, J.R., Batianoff, G.N., Cooke, D.A., Cowie, I.D., Johnson, R.W. et al. (2003) *Weed categories for natural and agricultural ecosystem management.* Bureau of Rural Sciences, Canberra.

Hadebe, S.T., Modi, A.T., Mabhaudhi, T. (2016) Drought tolerance and water use of cereal crops: a focus on sorghum as a food security crop in sub-Saharan Africa. *J Agro Crop Sci* **In press**: 10.1111/jac.12191.

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

Herde, D.J., Ryley, M.J., Jordan, D.R., Henzell, R.G., Galea, V.J. (2005) Timing of anthesis in the sorghum hybrid MR Buster and the elite line 31945-2-2. *International Sorghum and Millets Newsletter* **46**: 20-22.

Hodnett, G.L., Burson, B.L., Rooney, W.L., Dillon, S.L., Price, H.J. (2005) Pollen-pistil interactions result in reproductive isolation between *Sorghum bicolor* and divergent *Sorghum* species. *Crop Science* **45**: 1403-1409.

Jacques, G.L., Vesecky, J.F., Feltner, K.C., 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., Smith, J. (2014) Applying a weed risk assessment approach to GM crops. *Transgenic Research* **23**: 957-969.

Kiotseridis, H., Cilio, C.M., Bjermer, L., Tunsater, A., Jacobsson, H., Dahl, A. (2013) Grass pollen allergy in children and adolescents-symptoms, health related quality of life and the value of pollen prognosis. *Clin Transl Allergy* **3**: 19.

Lansac, A.R., Sullivan, C.Y., Johnson, B.E., Lee, K.W. (1994) Viability and germination of the pollen of sorghum [*Sorghum bicolor* (L.) Moench]. *Annals of Botany* **74**: 27-33.

Magomere, T.O., Obukosia, S.D., Shibairo, S.I., Ngugi, E.K., Mutitu, E. (2015) Evaluation of relative competitive ability and fitness of *Sorghum bicolor×Sorghum halepense* and *Sorghum bicolor×Sorghum sudanense* F1 hybrids. *Journal of Biological Sciences* **15**: 1-15.

Morgan, J. (2013) A diet fit for a pig: seven basic rules. NSW Department of Primary Industries.

Morrell, P.L., Williams-Coplin, T.D., Lattu, A.L., Bowers, J.E., Chandler, J.M., Paterson, A.H. (2005) Crop-to-weed introgression has impacted allelic composition of johnsongrass populations with and without recent exposure to cultivated sorghum. *Molecular Ecology* **14**: 2143-2154.

Murty, D.S., Nicodemus, K.D. (1987) Interallelic relations among endosperm variants in sorghum. *Journal of Heredity* **78**: 391-394.

Myers, J.A., Vellend, M., Gardescu, S., Marks, P.L. (2004) Seed dispersal by white-tailed deer: implications for long-distance dispersal, invasion, and migration of plants in eastern North America. *Oecologia* **139**: 35-44.

Nguyen, C.T., Singh, V., van Oosterom, E.J., Chapman, S.C., Jordan, D.R., Hammer, G.L. (2013) Genetic variability in high temperature effects on seed-set in sorghum. *Funct Plant Biol* **40**: 439-448.

OECD (2016a) Consensus document on the biology of sorghum (*Sorghum bicolor* (L.) Moench). Report No: 62, Organisation for Economic Co-operation and Development, Paris.

OECD (2016b) OECD seed schemes 2016: OECD seed schemes for the varietal certification or the control of seed moving in international trade. The Organisation for Economic Co-operation and Development, Paris.

OGTR (2013) Risk Analysis Framework 2013. Australian Government Office of the Gene Technology Regulator, Canberra.

OGTR (2017) The biology of *Sorghum bicolor* (L.) Moench subsp. *bicolor* (Sorghum). Office of the Gene Technology Regulator, Canberra, Australia.

Page, D.S. (1981) *Principles of Biological Chemistry.*, 2nd Edition. Willard Grant Press, USA.

Pakeman, R.J., Digneffe, G., Small, J.L. (2002) Ecological correlates of endozoochory by herbivores. *Functional Ecology* **16**: 296-304.

Parsons, W.T., Cuthbertson, E.G. (2001) *Noxious Weeds of Australia.*, 2nd Edition. CSIRO Publishing, Collingwood, Victoria.

Pedersen, J.F., Toy, J.J., Johnson, B. (1998) Natural outcrossing of sorghum and sudangrass in the central grass plains. *Crop Science* **38**: 937-939.

Peterson, G.C., Schaefer, K., Pendleton, B.B. (2009) Registration of 16 sorghum germplasm lines. *J Plant Regist* **3**: 203-205.

Philp, T., Peake, A., McLean, G. (2010) Improving profitability of irrigated sorghum through partial irrigation of larger areas. In *Proceedings of the 1st Australian Summer Grains Conference*, Gold Coast, Australia.

Rabbi, I.Y., Parzies, H.K., Kiambi, D., Haussmann, B.I., Folkertsma, R., 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.

Radauer, C., Breiteneder, H. (2006) Pollen allergens are restricted to few protein families and show distinct patterns of species distribution. *J Allergy Clin Immunol* **117**: 141-147.

Rew, L. J., Medd, R. W., Van de Ven, R., Gavin, J. J., Robinson, G. R., Tuitee, M., Barnes, J., and Walker, S. (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., Shepherd, R.C.H. (2011) *Weeds of the South-East: an identification guide for Australia.*, 2nd Edition. R.G. and F.J. Richardson, Meredith, Victoria, Australia.

Robson, S. (2007a) Nitrate and nitrite poisoning in livestock. NSW Department of Primary Industries.

Robson, S. (2007b) Prussic acid poisoning in livestock. NSW Department of Primary Industries.

Rodgers, N., Choct, M., Hetland, H., Sundby, F., Svihus, B. (2005) Dietary roller-milled sorghum improves broiler efficiency and whole sorghum improves gut development. *Recent Advances in Animal Nutrition in Australia* **15**: 57-64.

Rooney, W.L., Odvody, G.N., Schaefer, K., Collins, S.D. (2011) Registration of Tx2935 through Tx2944 sorghum germplasm. *J Plant Regist* **5**: 1-5.

Schmidt, J.J., Pedersen, J.F., Bernards, M.L., Lindquist, J.L. (2013) Rate of shattercane x sorghum hybridization in situ. *Crop Science* **53**: 1677-1685.

Schmidt, M., 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.

Schmidt, M.R., Bothma, G. (2005) Indications of bee pollination in sorghum and its implications for transgenic biosafety. *International Sorghum and Millets Newsletter* **6**: 72-75.

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

Sidhu, P.K., Bedi, G.K., Meenakshi, Mahajan, V., Sharma, S., Sandhu, K.S. et al. (2011) Evaluation of factors contributing to excessive nitrate accumulation in fodder crops leading to ill-health in dairy animals. *Toxicol Int* **18**: 22-26.

Singh, F., Rai, K.N., Reddy, B.V.S., and Diwakar, B. (1997) Development of cultivars and seed production techniques in sorghum and pearl millet. ICRISAT, India.

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

Spenceley, J., Butler, G., Nicholas, A., Simpfendorfer, S., Holland, J., Kniepp, J. et al. (2005) Grain Sorghum. NSW Department of Primary Industries.

Standards Australia Ltd, Standards New Zealand, CRC for Australian Weed Management (2006) *HB294:2006 National Post-Border Weed Risk Management Protocol.* Available online.

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

Stephens, J. C. and Quinby, J. R. (1934) Anthesis, pollination, and fertilization in sorghum. *Journal of Agricultural Research* **49**: 123-136.

Tang, H., Cuevas, H.E., Das, S., Sezen, U.U., Zhou, C., Guo, H. et al. (2013) Seed shattering in a wild sorghum is conferred by a locus unrelated to domestication. *Proc Natl Acad Sci U S A* **110**: 15824-15829.

Thseng, F., Hou, F. (1993) Varietal differences and diallel analysis of pre-germination flooding tolerance of sorghum seed. *Japan J Breed* **43**: 23-28.

Vallaeys, V., Tyson, R.C., Lane, W.D., Deleersnijder, E., Hanert, E. (2017) A Levy-flight diffusion model to predict transgenic pollen dispersal. *J R Soc Interface* **14**: 20160889.

Warwick, S.I., Black, L.D. (1983) The biology of Canadian weeds. 61 *Sorghum halepense* (L.) PERS. *Journal of Plant Science* **63**: 997-1014.