



Australian Government
Department of Health
Office of the Gene Technology Regulator

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Risk Assessment and Risk Management Plan

for

DIR 162

Limited and controlled release of bread wheat
and durum wheat genetically modified for
enhanced rust disease resistance

Applicant: CSIRO

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Summary of the Risk Assessment and Risk Management Plan

for

Licence Application No. DIR 162

Decision

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

The application

Application number	DIR 162
Applicant	CSIRO
Project Title	Limited and controlled release of bread wheat and durum wheat genetically modified for enhanced rust disease resistance ¹
Parent Organism	Bread wheat (<i>Triticum aestivum</i>) Durum wheat (<i>Triticum turgidum</i> subsp. <i>durum</i>)
Introduced genes and modified traits	<ul style="list-style-type: none"> • Eight genes involved in stem rust disease resistance • Three genes involved in multi-pathogen (stem rust, leaf rust, stripe rust and powdery mildew) resistance GM lines will contain between one and eight disease resistance genes <ul style="list-style-type: none"> • Three selectable marker genes will be used across all lines
Proposed location	Ginninderra Experiment Station (ACT) and Boorowa Agricultural Research Station ² , Shire of Boorowa (NSW)
Proposed release size	Up to 1 ha per year ³
Proposed release dates	September 2018 - September 2023
Primary purpose	To evaluate agronomic performance of the GM bread wheat and durum wheat lines under field conditions

¹ The original title for the application was: Limited and controlled release of *Triticum aestivum* and *Triticum turgidum* subsp. *durum* genetically modified for enhanced rust disease resistance

² This site was previously named Boorowa Experiment Station.

³ The applicant requested a total area of 40m² per season, but revised the request to one hectare per season following release of the consultation RARMP. The revised area has been considered in this final version of the RARMP.

Risk assessment

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

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

Credible pathways to potential harm that were considered included exposure of people or other desirable organisms to the GM plant material, exposure of people and other desirable organisms to hybrids between different GMOs, potential for persistence or dispersal of the GMOs, transfer of the introduced genetic material to non-GM bread wheat and durum wheat plants and transfer of the introduced genetic material to plants of related species. 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 and that the imposed limits and controls will effectively contain the GMOs and their genetic material and minimise exposure.

Risk management

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.

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

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Abbreviations

ACT	Australian Capital Territory
Act	<i>Gene Technology Act 2000</i>
APR genes	Adult plant resistance genes
APVMA	Australian Pesticides and Veterinary Medicines Authority
Avr	Avirulence
<i>bar</i>	Bialaphos resistance (phosphinothricin N-acetyltransferase) gene
CaMV	Cauliflower mosaic virus
CSIRO	Commonwealth Scientific and Industrial Research Organisation
DIR	Dealings involving Intentional Release
DNA	deoxyribonucleic acid
FSANZ	Food Standards Australia New Zealand
GM	genetically modified
GMO	genetically modified organism
Ha	Hectare
<i>hptII</i>	Hygromycin phosphotransferase II gene
HR	Hypersensitive response
LGA	Local Government Area
m	metres
NB-LRR	nucleotide binding site-leucine rich repeat
NLRD	Notifiable Low Risk Dealing
<i>nptII</i>	Neomycin phosphotransferase II
NSW	New South Wales
NT	Northern Territory
OGTR	Office of the Gene Technology Regulator
PAT	phosphinothricin N-acetyltransferase
PC2	Physical Containment level 2
Qld	Queensland
R gene	Gene conferring resistance to a specific pathogen
RARMP	Risk Assessment and Risk Management Plan
Regulations	Gene Technology Regulations 2001
Regulator	Gene Technology Regulator
SA	South Australia
Tas.	Tasmania
USDA	United States Department of Agriculture
Vic.	Victoria

Chapter 1 Risk assessment context

Section 1 Background

1. An application has been made under the *Gene Technology Act 2000* (the Act) for Dealings involving the Intentional Release (DIR) of genetically modified organisms (GMOs) into the Australian environment.
2. The Act in conjunction with the Gene Technology Regulations 2001 (the Regulations), an inter-governmental agreement and corresponding legislation in States and Territories, comprise Australia's national regulatory system for gene technology. Its objective is to protect the health and safety of people, and to protect the environment, by identifying risks posed by or as a result of gene technology, and by managing those risks through regulating certain dealings with GMOs.
3. This chapter describes the parameters within which 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).

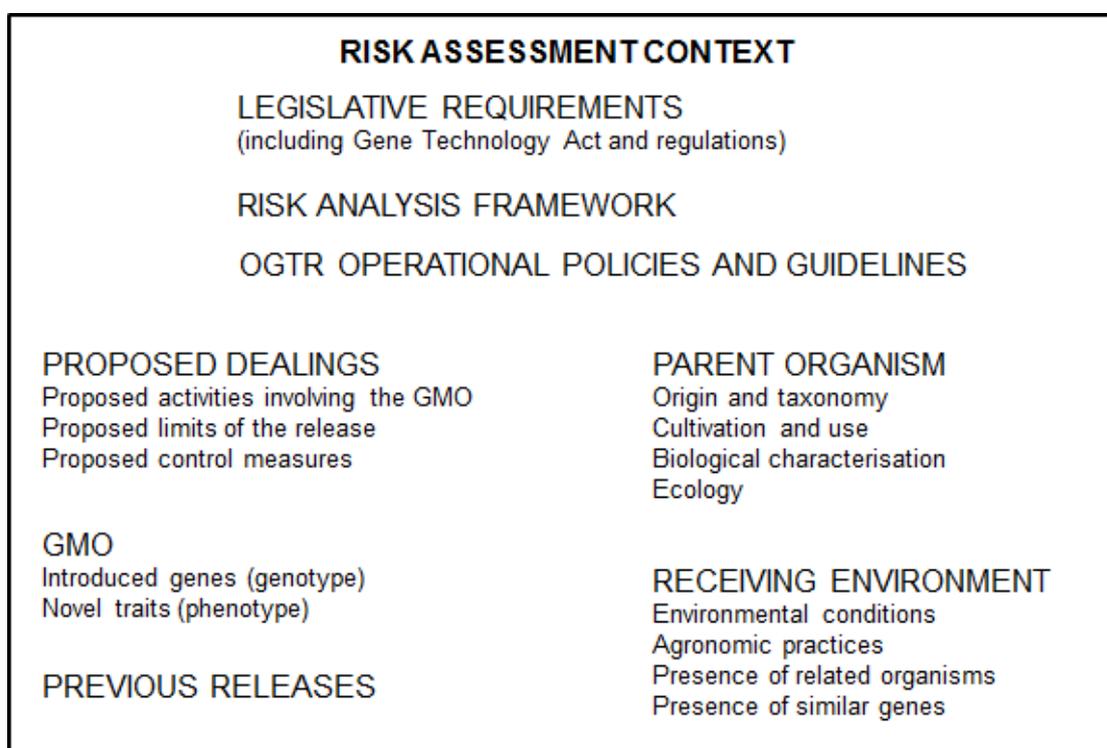


Figure 1 Summary of parameters used to establish the risk assessment context

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 (APVMA), 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 CSIRO proposes to release up to 600 lines of bread wheat and up to 60 lines of durum wheat genetically modified for enhanced rust disease resistance. The purpose of the release is to evaluate the agronomic performance of GM bread wheat and durum wheat lines under field conditions.
10. The dealings involved in the proposed intentional release are:
 - conducting experiments with the GMOs
 - propagating the GMOs
 - growing the GMOs
 - transporting the GMOs
 - disposing of the GMOs

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

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

11. The release is proposed to take place for up to five growing seasons, from the issue of the licence until September 2023. GM bread wheat and GM durum wheat⁴ would be grown on two trial sites with an area of up to 1 ha per season⁵ across both sites. The trial sites would be located in Ginninderra, ACT and in Boorowa, in the local government area of Hilltops Council in NSW.
12. Only trained and authorised staff would be permitted to deal with the GM bread wheat and durum wheat.

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 bread wheat and durum wheat and the introduced genetic material in the environment. These include:
 - locating the proposed trial sites at least 50 m away from the nearest natural waterway
 - surrounding the trial site with a 2 m buffer zone, a 10 m monitoring zone and a 190 m isolation zone in which no sexually compatible plants will be grown

⁴ For this document, the term 'wheat' will be used to include both bread wheat and durum wheat where possible. Where reference is made to either species separately they will be identified as bread wheat (*T. aestivum*) or durum wheat (*T. turgidum* subsp. *durum*).

⁵ The applicant requested a total area of 40m² per season, but revised the request to one hectare per season following release of the consultation RARMP. The revised area has been considered in this final version of the RARMP.

- only permitting trained and authorised staff to access the trial sites
- restricting human and animal access by surrounding the trial sites with livestock proof fences with lockable gates
- treating non-GM plants used in the trial as if they were GM
- inspecting all equipment after use for GM seeds and cleaning as required
- transporting and storing GM plant material in accordance with the current Regulator's Guidelines for the Transport, Storage and Disposal of GMOs
- destroying all plant material from the trial not required for testing or future trials
- post-harvest monitoring of the trial site at least once every 35 days for at least two years and until the site is free of volunteer plants for six months, with any bread wheat or durum wheat volunteers destroyed prior to flowering
- three irrigation events and one tillage to seed depth in the planting area and 2 m buffer zone during the two years of monitoring
- not allowing the GM plant materials or products to be used in commercial human food or animal feed.

Section 4 The parent organisms

14. The parent organisms are *Triticum aestivum* L. (bread wheat) and *Triticum turgidum* subsp. *durum* (Desf.) Husn. (durum wheat).

15. Detailed information about bread wheat is contained in the reference document *The Biology of Triticum aestivum* L. (*bread wheat*) (OGTR, 2017), which was produced to inform the risk analysis for licence applications involving GM bread wheat. Baseline information from this document will be used and referred to throughout the RARMP. Information on durum wheat morphology, development and physiology can be found in a review by Bozzini (1988). Information on durum wheat classification, breeding and compatible species can be found in chapters from Royo et al. (2005a, 2005b). A summary of durum wheat information is included in this RARMP document.

16. The great majority of commercially cultivated wheat in Australia is *T. aestivum*. Commercial bread wheat cultivation occurs in the wheat belt from south-eastern Queensland (Qld) through New South Wales (NSW), Victoria (Vic.), southern South Australia (SA) and southern Western Australia (WA). The 5-year average production in Australia is 25.8 Mt from 12.4 million ha, with an average yield of 2.1 t/ha. Of this approximately 34% is produced in WA, 30 % in NSW, 18 % in SA, 13% in Vic., 5 % in Qld and less than 1% in Tasmania (Tas.) (ABARES, 2017).

17. *Triticum turgidum* subsp. *durum* (durum wheat) is a closely related species and is the second *Triticum* species cultivated commercially in Australia. It generally accounts for less than 5 % of commercially-cultivated wheat (Kneipp, 2008; ABS, 2013). It is produced as a high-quality product for production of pasta and sold as a premium product in export markets, which account for around 50% of production (Kneipp, 2008). A number of characteristics of durum wheat and the flour produced from it, including kernel weight, protein content and gluten strength, make it suitable for pasta and semolina products (Feldman, 1976, 2001; Elias and Manthey, 2005). The importance of end products – for example pasta, couscous, flatbreads, bulgur and freekeh - varies across different regions. However, grain quality affects milling characteristics that are vital to the quality of all end-products (Elias and Manthey, 2005).

18. Durum wheat is cultivated in smaller areas within the wheat belt, mainly southern Queensland, northern New South Wales, western Victoria and south-eastern South Australia. Australian production is generally approximately 500,000 t annually (Kneipp, 2008; Ranieri, 2015). There are currently 15 cultivars listed on the [Wheat Variety Master List](#) for 2017/18, with three new varieties currently being tested ([NVT Online New varieties](#)). More detailed information on durum wheat varieties and cultivation practices can be found in industry publications (Hare, 2006; Kneipp, 2008; GRDC, 2016a, 2017a, b; WQA, 2017).

19. Worldwide, durum wheat makes up approximately 5 % of the world wheat production (Ranieri, 2015; Taylor and Koo, 2015), with world production of 38 MT in 2013/14 (Ranieri, 2015). In the US, durum wheat prices are higher than those for all classes of bread wheat (Taylor and Koo, 2015). Durum wheat is the most

widely cultivated tetraploid wheat (Mac Key, 2005; Matsuoka, 2011) and is generally grown under relatively dry conditions (Feldman, 1976, 2001; Palamarchuk, 2005; Matsuoka, 2011), including very cold dry conditions (Palamarchuk, 2005). Domesticated tetraploid wheat such as durum wheat, with large seeds and many seminal roots, are likely to have descended from wild ecotypes adapted to very low rainfall conditions where deep-rooted plants can maximise water use (Mac Key, 2005). It is likely that it originated from southwest Asia with a secondary centre of genetic diversity in Ethiopia (Palamarchuk, 2005). It is a free-threshing wheat with soft glumes and non-hulled seeds (Matsuoka, 2011) with large hard grains (Feldman, 1976, 2001). Over 80 % of durum wheat cultivars are described as spring wheats, with a smaller percentage being winter or facultative types (Royo et al., 2009). The characteristics of the latter are probably related to long-term adaptation and selection in colder, drier climates in their areas of cultivation, mainly around the Black and Red Seas (Palamarchuk, 2005).

20. There are a number of factors, both biotic and abiotic, that limit the growth and survival of bread wheat and durum wheat, with both species grown in similar areas and conditions. These include abiotic stresses - water stress (drought or waterlogging), heat and cold stress, nutrient deficiencies, salinity - and biotic stresses including pests and diseases. For bread wheat these are detailed in the biology document (OGTR, 2017). Although durum wheat is a separate species, it is closely related to bread wheat and many of the cultivation requirements and interactions with abiotic and biotic factors in the growing environment are similar to those for bread wheat. Whilst details of these may vary slightly, the overall requirements for, and limitations to, durum production are similar to those of bread wheat. More details of these can be found in a number of industry publications (Hare, 2006; Kneipp, 2008; QDAF, 2012a, b; GRDC, 2016a, b, c, 2017a, b; SARDI, 2017).

21. Neither bread wheat nor durum wheat is regarded as a weed of national significance ([National Weeds List](#)). Bread wheat is regarded as naturalised non-native species present in all Australian states and territories with the exception of the Northern Territory (NT), while durum wheat is not listed in any naturalised or weedy category (Groves et al. 2003). The weed risk assessment included in the [biology document](#) concludes that bread wheat possesses few attributes that would make it weedy and this is supported by the observation that there are very few weedy populations of bread wheat or durum wheat in the Australian environment.

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

5.1 Introduction to the GMOs

22. The applicant proposes to release up to 600 lines of GM bread wheat and up to 60 lines of GM durum wheat. The GMOs can be assigned to four groups, based on the genetic modifications (Table 1).

Table 1: The GM bread wheat and durum wheat lines proposed for release

Group	Modified trait	Genes	Modified Species	# Lines
A	Stem rust and multi-pathogen resistance ^a , single plasmid	9 ^b	Bread wheat	340
B	Stem rust and multi-pathogen resistance ^a , two plasmids	8	Bread wheat	100
C	Stem rust resistance, single plasmid	7	Bread wheat	140
D	Multi-pathogen resistance, single plasmid	3	Bread wheat, durum wheat	80

^a Lines in this group may contain combinations of genes for rust resistance or combinations of genes for rust resistance with a gene for multi-pathogen resistance.

^b Genes in Group A are also used in other Groups.

23. The GM wheat lines were produced using *Agrobacterium*-mediated transformation. Information about the *Agrobacterium*-mediated transformation method can be found in the document [Methods of plant genetic modification](#) available from the [OGTR Risk Assessment References page](#).

24. Lines in Groups A, C and D contain constructs consisting of up to eight genes. In these groups, each construct has been introduced by transformation with a single plasmid. Lines in Group B contain constructs consisting of six to eight genes. These constructs have been introduced by co-transformation with two

plasmids. The five constructs used in Group B contain one plasmid used in a line from Group A co-transformed with a second plasmid containing a single gene. Constructs introduced to lines in Group A and B contain multiple genes, while constructs introduced to lines in Group C and D each contain a single gene. There may be up to 20 lines containing each construct.

25. The introduced genes are derived from rye (1), bread wheat (4) or relatives of bread wheat - *Aegilops tauschii* (4), *Triticum monococcum* subsp. *aegilopoides*⁶ (1), or *Triticum monococcum* (1). Candidate genes are shown in Table 2.

26. Short regulatory sequences that control expression of the genes are also present in the GM wheat lines (Table 2). The regulatory sequences are derived from plants (potato) or microorganisms (Cauliflower mosaic virus or *Agrobacterium tumefaciens*).

27. The GM wheat plants also contain selectable marker genes (Table 2) that confer resistance to different classes of antibiotics or to herbicide. Selectable markers are used in the laboratory to select transformed GM plants or plasmids during early stages of development. The selectable marker genes are *hptII*, which codes for hygromycin phosphotransferase (HPH or HPT) enzymes; *nptII* (neomycin phosphotransferase II) which encodes an aminoglycoside 3'-phosphotransferase II enzyme that is also known as neomycin phosphotransferase II (NPTII) and the *bar* gene which encodes the phosphinothricin N-acetyltransferase (PAT) protein involved in glufosinate herbicide tolerance. The *hptII* (Zalacain et al., 1986) and *bar* (Thompson et al., 1987) genes are derived from *Streptomyces hygroscopicus*, a common saprophytic, soil-borne microorganism that is not considered to be a pathogen of plants, humans, or other animals (OECD, 1999). The *nptII* gene is derived from *Escherichia coli* (*E. coli*) strain K12. The *E. coli* bacterium is a common gut bacterium that is widespread in human and animal digestive systems and in the environment. More information on marker genes may be found in the document [Marker Genes in GM Plants](#).

5.2 The introduced genes, encoded proteins and associated effects

28. The genes and their encoded proteins are summarised in Table 2, with a description of their potential function in the GM bread wheat and durum wheat lines. All the GMOs contain disease resistance genes, (either for stem rust resistance or for multi-pathogen resistance) derived from bread wheat, rye or bread wheat relatives. The lines have been grouped according to the combinations of genes inserted (Groups A and B), transformation using a single plasmid (Groups A, C, D) or co-transformation with two plasmids (Group B) and use of single genes (Groups C and D).

29. For wheat, there are a number of pests and diseases of concern, including a number of important fungal pathogens broadly grouped as necrotrophic leaf fungi, biotrophic leaf fungi and root and crown fungi (Murray and Brennan, 2009). The rust of interest in the current application is stem rust (*Puccinia graminis* f. sp. *tritici*), with the multi-pathogen resistance genes also providing resistance to leaf rust (*Puccinia triticina*), stripe rust (or yellow rust – *Puccinia striiformis*) and powdery mildew (*Blumeria graminis* f. sp. *tritici*).

30. Two classes of resistance genes to rust diseases have been described in wheat: pathogen race specific resistance genes (R genes) and race nonspecific resistance genes, referred to as adult plant resistance genes (APR genes). Both R and APR wheat rust resistance genes are designated Lr, Sr, and Yr for leaf, stem and yellow rust (stripe rust) respectively (Ellis et al., 2014).

⁶ Also designated *Triticum boeoticum* (and referred to as such in the application document). *Triticum monococcum* subsp. *aegilopoides* is the accepted name listed in the [World Checklist of Selected Plant Species](#) and the [USDA Germplasm Resources Information Network](#) (USDA GRIN) taxonomy searches (accessed February 2018).

Table 2: Genes and regulatory elements introduced to GM bread wheat and durum wheat lines

Genetic element	Gene Source	Description	Function
<i>Disease Resistance Genes</i>			
<i>Sr50</i>	<i>Secale cereale</i>	Nucleotide binding leucine rich repeat sequence	Stem rust resistance
<i>Sr45</i>	<i>Aegilops tauschii</i>	Nucleotide binding leucine rich repeat sequence	Stem rust resistance
<i>Sr22</i>	<i>Triticum monococcum</i> subsp. <i>aegilopoides</i>	Nucleotide binding leucine rich repeat sequence	Stem rust resistance
<i>Sr35</i>	<i>Triticum monococcum</i>	Nucleotide binding leucine rich repeat sequence	Stem rust resistance
<i>Sr46</i>	<i>Aegilops tauschii</i> ^a	Nucleotide binding leucine rich repeat sequence	Stem rust resistance
<i>Sr26</i>	<i>Triticum aestivum</i>	Nucleotide binding leucine rich repeat sequence	Stem rust resistance
<i>Sr33</i>	<i>Aegilops tauschii</i>	Nucleotide binding leucine rich repeat sequence	Stem rust resistance
<i>Sr33m</i>	<i>Aegilops tauschii</i>	Nucleotide binding leucine rich repeat sequence	Stem rust resistance
<i>Lr67</i>	<i>Triticum aestivum</i>	Sugar transporter gene variant	Multi-pathogen resistance
<i>Lr34</i>	<i>Triticum aestivum</i>	ABC transporter variant	Multi-pathogen resistance
<i>Lr34B</i>	<i>Triticum aestivum</i>	Homologue of <i>Lr34</i>	Multi-pathogen resistance
<i>Promoters</i>			
<i>35S</i>	Cauliflower mosaic virus	Promoter for resistance markers	
<i>pSr50</i>	<i>Secale cereale</i>	Native promoter from the <i>Sr50</i> gene	
<i>pSr45</i>	<i>Aegilops tauschii</i>	Native promoter from the <i>Sr45</i> gene	
<i>pSr22</i>	<i>Triticum monococcum</i> subsp. <i>aegilopoides</i>	Native promoter from the <i>Sr22</i> gene	
<i>pSr35</i>	<i>Triticum monococcum</i>	Native promoter from the <i>Sr35</i> gene	
<i>pSr46</i>	<i>Aegilops tauschii</i> ^a	Native promoter from the <i>Sr46</i> gene	
<i>pSr26</i>	<i>Triticum aestivum</i>	Native promoter from the <i>Sr26</i> gene	
<i>pSr33</i>	<i>Aegilops tauschii</i>	Native promoter from the <i>Sr33</i> gene	
<i>pLr67</i>	<i>Triticum aestivum</i>	Native promoter from the <i>Lr67</i> gene	
<i>pLr34</i>	<i>Triticum aestivum</i>	Native promoter from the <i>Lr34</i> gene	
<i>Introns</i>			
<i>StIs1 I2</i>	<i>Solanum tuberosum</i>	Intron inserted in resistance marker sequence	
<i>Selectable Marker Genes</i>			
<i>hptII</i>	<i>Streptomyces hygrosopicus</i>	Plant selectable marker - hygromycin resistance	
<i>bar</i>	<i>Streptomyces hygrosopicus</i>	Plant selectable marker - glufosinate herbicide resistance	
<i>nptII</i>	<i>Escherichia coli</i> K12	Plasmid selectable marker - kanamycin resistance	
<i>Terminators</i>			
<i>CaMVpolyA</i>	Cauliflower mosaic virus	Terminator	
<i>OCS</i>	<i>Agrobacterium tumefaciens</i>	3' non-translated region of the octopine synthase gene	

^a The source for this gene is listed as *Triticum aestivum* in the application for DIR 162 as the gene has been previously introgressed into wheat, however the original source is *Aegilops tauschii*

5.2.1 *R genes*

31. The majority of the resistance genes in this application belong to the nucleotide binding leucine rich repeat (NB-LRR) class. R genes were the first class of resistance genes to be genetically defined and introgressed into commercial varieties through conventional wheat breeding; single genes were found to confer high levels of resistance and this made selection of plants simple and economical (Ellis et al., 2014). A number of R genes are derived from wheat, other cereal crops and their relatives. Race-specific R genes are associated with a hypersensitive reaction in the host, resulting in incompatible host-pathogen interactions, based on a gene-for-gene system. However, R gene-mediated resistance is described as generally non-durable due to the high evolution rate of pathogens, leading to new virulent strains overcoming single resistance genes (McDonald and Linde, 2002). This often occurs within a few years (McDonald and Linde, 2002; Ellis et al., 2014; Herrera-Foessel et al., 2014).
32. It has been suggested that long-term success in controlling rusts using R genes would result from the release of varieties containing combinations - 'stacks' or 'pyramids' - of several effective R genes to minimise selection for virulence in rust pathogens (Singh et al., 2008; Ellis et al., 2014).
33. A number of R genes for wheat stem rust resistance are proposed for release in this application – *Sr22*, *Sr26*, *Sr33*, modified *Sr33*, *Sr35*, *Sr45*, *Sr46* and *Sr50* – and will be examined in lines containing individual genes or as combinations of three to eight genes per line. Some of these lines also include the APR gene *Lr67*. These *Sr* genes are listed among 39 genes that are effective against the known Ug99 wheat stem rust races, although field effectiveness may vary under differing disease pressure (Singh et al., 2011; Singh et al., 2015). It has been suggested that combinations of some of these genes with one another and in plant backgrounds containing other R or APR genes may be valuable to provide durable stem rust resistance (Pariyannan et al., 2013; Saintenac et al., 2013; Mago et al., 2015; Steuernagel et al., 2016). The highly virulent Ug99 races are not present in Australia but have been detected in many other countries (Singh et al., 2011; Singh et al., 2015).

5.2.2 *APR genes*

34. APR genes are associated with partial rust resistance phenotypes, observed only in adult plants. The host-pathogen interaction is compatible, and resistance is characterised by less pathogen growth and slow disease development in the field, thus it may be described as 'slow rusting'. When several APR genes are accumulated, 'near immunity' can be achieved. APR gene-mediated resistance is described as broad and durable (Ellis et al., 2014; Herrera-Foessel et al., 2014; Mondal et al., 2016). APR genes may provide resistance to all isolates (or pathotypes) of a pathogen species or they may provide resistance to multiple pathogen species (Rinaldo et al., 2017). Functions of cloned APR genes are diverse, ranging from protein kinases, to transporters and transmembrane proteins (Ellis et al., 2014). There is also some evidence that the presence of some APR genes, including *Lr34* may interact with R genes to boost rust resistance, although the exact mechanisms of these interactions are not fully understood (Vanegas et al., 2007; Ellis et al., 2014). The *Lr34* and *Lr67* genes are described as foundation APR genes, increasing the impact of other resistance genes, including NB-LRR class genes (Ellis et al., 2014).
35. The multi-pathogen resistance genes proposed for release in this application are APR genes that provide resistance to wheat stem rust (*P. graminis* f.sp. *tritici*), wheat leaf rust (*P. triticina*), wheat stripe rust (*P. striiformis*) and powdery mildew (*B. graminis*) diseases (Krattinger et al., 2009; Moore et al., 2015).
36. The *Lr67* gene encodes a predicted hexose transporter protein that differs from the form of the protein produced by the susceptible allele by two amino acids that are conserved in orthologous hexose transporters. The resistant transporter protein functions to reduce glucose uptake (Moore et al., 2015).
37. The *Lr34* gene has two mutations that enable the transporter protein encoded by *Lr34* to confer resistance, while *Lr34B* does not (Krattinger et al., 2011). The *Lr34B* gene is a homologue of *Lr34*, located on a different chromosome. The two mutations present in *Lr34* have been engineered into the *Lr34B* gene. The applicant proposes to assess the ability of the *Lr34B* gene containing the mutation to confer disease resistance in GM durum wheat lines and to compare the lines containing the modified *Lr34B* gene to GM durum wheat lines containing the known *Lr34* gene. It has been suggested that given the phenotypic

similarities, *Lr34* and *Lr67* may encode similar proteins and that lines carrying genes encoding functionally redundant proteins may not perform better than single-gene lines (Spielmeyer et al., 2013). The *Lr34* gene is present in many bread wheat cultivars in Australia and in 2016 was effective against all known Australian stem rust pathotypes (Cuddy et al., 2016).

38. Each of the *Lr* genes will be examined in single gene GM lines (Group D) in bread wheat and durum wheat (*Lr67*) or in durum wheat only (*Lr34* and *Lr34B*). In addition, *Lr67* will be inserted in combination with *Sr* genes in lines of Groups A, B and C.

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

39. No toxicity or allergenicity studies have been performed on the GM wheat plants or purified proteins encoded by the genes, as the proposed trial is at preliminary research stage. However, a number of the genes are sourced from wheat or rye, which are routinely consumed by people and animals and the remaining genes are of the same classes as those sourced from these crop plants.

40. Non-GM wheat and durum wheat contain a number of anti-nutritional factors and allergens that, in extreme cases, may have a toxic effect (OGTR, 2017). However, the proteins encoded by the introduced genes are not expected to have any toxic or allergenic effects.

41. Three of the genes proposed for the current release - *Sr46*, *Lr34* and *Lr67* - have been previously approved under licence DIR 151, a limited and controlled release of GM wheat. No adverse effects have been reported for this release.

42. The *hptII* (*hph*) and *nptII* genes are the most commonly-used antibiotic resistance genes for selection of transformed plant cells (Breyer et al., 2014). There is no evidence that the *hptII* or *nptII* genes or the proteins they encode are toxic or allergenic (OGTR Risk Assessment documents and references therein). The *bar* gene and the protein it encodes (phosphinothricin N-acetyl transferase or PAT) has been assessed in other RARMPs most recently in DIR 120 and DIR 145, and in scientific literature. The environmental safety of the PAT protein present in biotechnology-derived crops, either alone or in combination with other GM traits, has also been extensively assessed by regulatory authorities worldwide (CERA, 2011). Crops containing these genes have been approved for release in a number of countries and for use in food and feed worldwide (Biosafety Clearing House website, ISAAA website, both accessed 27 February 2018). GM foods containing the *hptII*, *nptII* and *bar* genes have been assessed and approved for sale in Australia (FSANZ website, accessed 28 February 2018).

5.4 Characterisation of the GMOs

43. Although these lines are at an early stage of development, the applicant has provided preliminary information on expected phenotypes for some genes or groups of genes. Each of the *Sr* genes was introduced individually into wheat plants that were tested in the glasshouse and no effects other than rust disease resistance were observed. Transformed plants expressing the *Lr67* gene have also been tested in the glasshouse, with adult plants showing partial resistance to stem, leaf and stripe rusts and powdery mildew.

44. *Lr67* and *Lr34* are APR genes for rust resistance, providing resistance at the adult plant stage. However, the applicant has observed that elevated expression levels of *Lr34* can result in seedling resistance and suggest that this may also occur with *Lr67*, although they have not yet observed this effect in seedlings expressing *Lr67*. The applicant expects that the genes will provide rust disease resistance without associated pleiotropic effects, however high levels of resistance gene expression may result in dwarfed plants (Grant et al., 2003). The applicant has indicated that any transformed plants exhibiting this type of effect in the glasshouse would not be used in the field due to obvious pleiotropic effects.

Section 6 The receiving environment

45. The receiving environment forms part of the context in which the risks associated with dealings with 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).

46. Information relevant to the commercial cultivation and distribution of bread wheat in Australia, including key biotic and abiotic interactions in the wheat-growing environment, is presented in the [wheat biology document](#). Information relevant to the commercial cultivation and distribution of durum wheat in Australia is available in a number of industry publications (Hare, 2006; Kneipp, 2008; QDAF, 2012a, b; GRDC, 2016a, b, c, 2017a, b; SARDI, 2017), with key factors discussed below in Sections 6.1 to 6.3. Durum wheat is cultivated in areas within the ‘wheat belt’ and as such is cultivated in a subset of the same environments as bread wheat in Australia.

6.1 Relevant biotic factors

47. While durum wheat can compete well with weeds, high weed pressure can affect yields. Weed control by integrated weed management is recommended for durum wheat, as for bread wheat crops (GRDC, 2016a, 2017a, b), and weed species relevant to durum production are similar to those for bread wheat (OGTR, 2017).

48. Important insect pests of durum wheat in northern areas are cutworms (*Agrostis* spp.) aphids, army worms (*Leucania* spp., *Spodoptera mauritia*) mites, including red-legged earth mite (RLEM – *Halotydeus destructor*), blue oat mite (*Penthaleus* spp.) and brown wheat mite (*Petrobia latens*) and in some seasons *Helicoverpa armigera*. Thresholds for insect control depend on the timing and severity of infestations and options for insect control. At some stages biopesticides may be suitable for insect pest control and a number of predatory insect species are valuable for pest insect control (GRDC, 2016a). Integrated pest management strategies are recommended in durum wheat production as for other cereal crops (GRDC, 2016c). Further information about insect pests in durum wheat and winter cereals can be found in grain industry publications (GRDC, 2016a, b, c, 2017a, b).

49. A number of the nematode and other pathogen-related diseases of concern for bread wheat (OGTR, 2017) are also of concern for durum wheat. The root lesion nematodes (*Pratylenchus* spp.) have the potential to impact on durum wheat crops, with different species having greater or lesser importance in specific growing regions (GRDC, 2016a, 2017a, b). Durum wheat is generally more resistant to *P. thornei* than bread wheat varieties (QDAF, 2012a, b; GRDC, 2016a, 2017a, b). Resistance to and tolerance of nematodes varies between durum varieties, so variety selection, crop rotations and crop hygiene are important factors in managing nematodes in durum wheat (QDAF, 2012a, b; GRDC, 2016a, c, 2017a, b). The most important disease for durum wheat is crown rot (*Fusarium pseudograminearum*), which can cause significant losses. It is less prevalent in WA but incidence appears to be increasing (GRDC, 2017b). *Fusarium* head blight (mainly caused by *Fusarium graminearum*) is also important and may be associated with mycotoxin production which results in downgrading of grain. Durum wheat is more susceptible to this pathogen than bread wheat. Other diseases of concern are common root rot (*Bipolaris sorokiniana*) which is often associated with crown rot, as well as leaf rust (*Puccinia triticina*), stem rust (*Puccinia graminis* f. sp. *tritici*) and stripe rust (or yellow rust – *Puccinia striiformis*), as well as yellow leaf spot (*Pyrenophora tritici-repentis*) (GRDC, 2016a). In SA, *Septoria tritici* blotch and eyespot were reported in 2015 in wheat crops (GRDC, 2017a). Resistance to these diseases varies between durum varieties, however all varieties are listed as susceptible or very susceptible to crown rot (GRDC, 2016c). Careful management of crop rotations, removal of crop residues that harbour disease inoculum and varietal selection are key tools for disease management in durum wheat, fungicide applications can be used but there are many considerations to ensure effectiveness (GRDC, 2016a).

50. Crop rotation, including non-cereal crops in particular, is recommended in durum wheat production for disease pest and weed control, and to allow rotation of herbicides for weed control (Hare, 2006; Kneipp, 2008; GRDC, 2016a). This is also true for bread wheat production systems (OGTR, 2017).

6.2 Relevant abiotic factors

51. It is proposed that the GMOs will be grown at two locations. The release is proposed to take place at Ginninderra Experiment Station (GES), ACT and at Boorowa Agricultural Research Station (BARS), NSW, two

dedicated, fenced field trial sites. The GES site is approximately 2.3 ha and has been previously used for licenced field trials. The BARS site is a new proposed site, anticipated to be of approximately 2.3 ha. Both sites are on CSIRO controlled land. Access to the research stations is restricted to authorised staff and CSIRO has control over the management of the fields immediately surrounding the proposed trial sites.

52. The proposed sites are located at least 50 m away from the nearest natural waterways and the areas are not prone to flooding (information provided by the applicant).

53. Information regarding abiotic stresses for bread wheat can be found in the [biology document](#). Briefly, these fit within the categories of nutrient stress, drought, waterlogging, heat stress, salinity, acidic soils and mineral toxicity. For durum wheat more information can be found in industry publications, however, key information is provided below.

54. Heat stress is regarded as the key abiotic stress for durum wheat in all growing regions, affecting grain yield, productivity with potential losses from heat stresses equal to or greater than those from drought and frost. Frost is also potentially damaging to durum wheat, as for other cereal crops (Hare, 2006; GRDC, 2016a, 2017a). Frost tolerant varieties are not available, however crop management to spread the flowering time within the crop may mitigate some frost risk (Hare, 2006). Waterlogging, particularly after flooding events, can also affect durum productivity (GRDC, 2016a). Availability of water is also key for durum cultivation, with production in northern regions reliant on soil moisture from rainfall prior to the growing season, while in southern areas rainfall during the production season is vital for adequate moisture levels (Kneipp, 2008). The key limiting nutrient for durum production is nitrogen (N) (Hare, 2006; GRDC, 2016a) and in some situations zinc (Zn) can also be a limiting factor as low Zn can also limit the uptake of other nutrients (Hare, 2006).

6.3 Relevant agricultural practices

55. The limits and controls of the proposed release are outlined in Section 3.1 and Section 3.2 of this Chapter. It is anticipated that the agronomic practices for the cultivation of the GM bread wheat and durum wheat by the applicant will not differ significantly from industry best practices used in Australia.

56. The GM wheat would either be hand sown in rows with a spacing of approximately 30 cm between rows, or planted with a small plot cone seeder in plots, 2 m wide and up to 10 m long, and maintained as a dryland crop, but with irrigation available if required.

57. The crop will be maintained using similar practices to those used in commercial wheat crops for management of weeds and disease. As the GM wheat lines within this trial are planted to assess the impact of candidate genes on disease resistance, there will be some differences in management of diseases such as rust.

58. Harvesting of the seeds would occur either by hand or using a plot harvester that is dedicated to GM trials. After harvest the land would be left fallow or planted with a break crop if approved.

6.4 Presence of related plants in the receiving environment

59. Both bread and durum wheats are commonly grown in Australia and are widely cultivated in the surrounding regions of the proposed field trial sites. The paddocks adjoining the GES and BARS trial sites are on CSIRO land. Those surrounding the GES are routinely used for GM and non-GM wheat trials and it is likely that a similar situation will occur for BARS.

60. In addition, the applicant has proposed that planting for the current application occur on areas of land previously approved for field trials DIR 111 and DIR 151, so other GM wheats may also present in the receiving environment. Under DIR 151, planting and growing of the GM wheat is permitted at GES and BARS until May 2022 and GM wheat approved under other licences may be grown in the monitoring zone. Therefore, it is possible that the GM wheat proposed for release under the current application could be grown immediately adjacent to GM wheat lines planted under DIR 151. At the GES site, there are also three planting areas currently under postharvest monitoring (PHM) from DIR 111. While no further planting can take place under this licence, it is possible that there may be volunteers present.

61. Gene flow can occur between cultivated varieties of bread wheat, although pollen flow is limited, generally occurring at low frequency and/or over short distances (Gatford et al. 2006). Bread wheat is considered a low-risk crop for both intraspecific and interspecific gene flow (Eastham & Sweet 2002). Although durum wheat has not been examined as closely as bread wheat, it is a closely related species and it is likely that pollen flow is limited and that the risks of intra- and inter-specific gene flow would be considered low for durum wheat as well. *Triticum turgidum* wheats – of which durum wheat is one subspecies – are self-fertilising, although natural hybridisation and introgression have been important in their diversification (Matsuoka, 2011). In general, pollen from the Graminae has a limited fertility period (Eastham and Sweet, 2002 and references therein), thus it is likely that pollen from durum wheat would not be viable for long.

6.4.1 Bread Wheat

62. Bread wheat (*Triticum aestivum* L.) is sexually compatible with a number of species within the tribe Triticeae that occur in Australia, including other cereal crops. Hybridisation with durum wheat occurs readily (Wang et al., 2005), with field outcrossing between rates varying according a number of factors, including environmental conditions, particularly wind speed and direction (Matus-Cádiz et al., 2004; Loureiro et al., 2007), highlighting the need for testing in a range of environments (Loureiro et al., 2007). Field outcrossing from bread wheat to durum wheat in a smaller field trial was less than 1 % at a distance of 8 m (Loureiro et al., 2007). In a larger study in a semi-arid region, gene flow at 20 m was 0.01 to 0.02 %, with no pollen flow was recorded at or past 40 m. In the same study no long-distance pollen flow was recorded (340 – 580 m) (Matus-Cádiz et al., 2004).

63. Hybridisation of *T. aestivum* with rye (Meister, 1921; Leighty and Sando, 1928; Dorofeev, 1969) is rare, despite the use of this cross to generate Triticale (X *Triticosecale*) (Ammar et al., 2004) and generally requires intervention to produce fertile hybrids. Crossing between Triticale and wheat has been performed under laboratory conditions but rates of natural outcrossing are unknown (Kavanagh et al., 2010). In bread wheat x Triticale crosses using hand pollination and embryo rescue, hybrids were almost completely self-sterile, with severe hybrid necrosis also observed (Bizimungu et al., 1997).

64. Bread wheat readily hybridises with *Aegilops* species (goatgrasses). *Aegilops tauschii* is generally regarded as the donor for the D genome in hexaploid wheat, however, unlike bread wheat, durum wheat does not contain the D genome, thus could be regarded as being less closely related to *Aegilops* species than bread wheat (CFIA, 2006). However, no *Aegilops* species are considered to be naturalised in Australia. Any specimens of *Aegilops* that have been collected in Australia presumably originate from seed accidentally introduced amongst wheat seed, or straying from that brought in for breeding programs ([Weeds in Australia](#), accessed 28 February 2018).

65. There has been one report of natural hybridisation between bread wheat and *Hordeum marinum* in a European study. However, it is likely to be a rare event (Guadagnuolo et al., 2001) and it was not stated whether the hybrids were fertile. *H. marinum* is found in wheat growing areas of Australia, but there have been no reports of natural hybridisation between the two under Australian conditions.

6.4.2 Durum Wheat

66. Durum wheat is regarded as self-fertile, although outcrossing of up to 5 % has been recorded (Bozzini, 1988). Pollen flow for tetraploid wheat (*T. turgidum*) landraces has been recorded from 1.6 % to 4.3 %, varying across years and locations and depending on whether pure stands or mixed stands of landraces were examined (Tsegaye, 1996). Outcrossing of durum wheat with other *T. turgidum* species, with related crop species and with weedy relatives have also been examined. Sterility barriers have been observed between durum wheat and *T. turgidum* subsp. *armeniicum* (= *T. timopheevii*) and *T. turgidum* subsp. *dicoccoides* (Feldman, 2001). Crosses with rye, maize, or pearl millet have been achieved, but only in glasshouses with embryo rescue (Inagaki and Hash, 1998; Cherkaoui et al., 2000; Klindworth et al., 2003; Garcia-Llamas et al., 2004). Mujeeb-Kazi (2005) summarised work examining the potential for introgression of genes from relatives in the primary, secondary and tertiary gene pools for durum wheat (including diploid genome donor species, other tetraploids and hexaploids) and noted that the majority of crosses

require some form of intervention to produce fertile offspring. This indicates that natural hybridisation of durum wheat, even with close relatives, is unlikely.

67. There are reports of natural hybridisation of durum wheat with *Aegilops* species, however results were unconfirmed (CFIA, 2006). While crossing of durum wheat and *Aegilops* spp. has been documented, these crosses were generally achieved only under laboratory conditions (Jacot et al., 2004). Glasshouse crosses with non-cultivated or weedy relatives have been observed, including *Aegilops ovata* (Benavente et al., 2001), *Aegilops caudata* (Simeone et al., 1989) and *Thinopyrum bessarabicum* (Jauhar and Peterson, 2006), but these required embryo rescue. Glasshouse crosses with *Ae. tauschii* as the male parent have produced hybrids with durum wheat without embryo rescue. The crosses had a mean ‘crossability’ of 5.61 % across 15 crosses involving six durum lines, however 50 % of crosses yielded no hybrids (Zhang et al., 2008). This study provides some information about the potential location of the barriers to hybridisation between the two species on specific chromosomes of the durum parent. There are a number of weedy relatives of durum wheat present in cropping areas in North America, but no natural hybrids with weedy *Agropyron* spp. (wheatgrass), *Hordeum* spp. or *Elymus* spp. relatives have been reported (CFIA, 2006). Hybridisation between durum wheat and *Aegilops geniculata* (= *Ae. ovata*) have been observed in the field in Europe, but hybrids in the field were typically sterile, indicating sterility barriers between the two species (David et al., 2004). In addition, as previously noted, there are no naturalised populations of *Aegilops* species in Australia ([Weeds in Australia](#), accessed 28 February 2018).

68. There are four Australasian Triticeae genera, of which *Australopyrum* and *Anthosachne* (*Elymus*) have Australian species, while *Stenostachys* and *Connorochloa* occur only in New Zealand and/or New Guinea (Barkworth and Jacobs, 2011). A number of introduced Triticeae species are also present in Australia including *Elymus repens*⁷ (couch grass) and at least four *Thinopyrum* species (Bell et al., 2010), some of which are classified as weeds in particular regions (Barrett-Lennard, 2003; NYNRMB, 2011), but not as weeds of national significance ([Weeds in Australia](#)). There has been no concerted investigation on natural hybridisation of these native and introduced Triticeae species with wheat (bread or durum). Factors such as genome incompatibilities, the necessity for the parent plants to be in close proximity, concurrent flowering, and the ability of the hybrid progeny to set viable seed, combine to make it extremely unlikely that any of these Triticeae would ever naturally cross with bread or durum wheats.

6.5 Presence of similar genes and encoded proteins in the environment

69. The introduced genes for rust disease resistance were isolated from bread wheat (*Sr26*, *Lr34*, *Lr34B* and *Lr67*) or rye (*Sr50*), both of which are commonly consumed cereal crops, or from bread wheat relatives. The *Sr46*, *Sr45*, *Sr33* and *Sr33mod* genes are sourced from *Ae. tauschii*, which is regarded as the D genome donor for *T. aestivum* (OGTR, 2017 and references therein). The *Sr35* gene is sourced from *T. monococcum* (Saintenac et al., 2013), a cultivated diploid wheat that has been suggested as the A genome donor for bread wheat (Kimber and Sears, 1987). The *Sr22* gene has been sourced from *T. monococcum* subsp. *aegilopoides* (Steuernagel et al., 2016), an A genome relative of bread wheat (Kimber and Sears, 1987).

70. The wheat relative *Ae. tauschii* is not present in Australia ([Weeds in Australia](#)), however it has been widely used as a genetic resource for wheat germplasm improvement since the early 20th century (Krattinger et al., 2009). Neither *T. monococcum* nor *T. monococcum* subsp. *aegilopoides* are recorded as present in the natural environment in Australia ([Atlas of Living Australia](#); [The Australasian Virtual Herbarium](#); [Global Biodiversity Information Facility](#); accessed 12 February 2018).

71. The *Lr34* gene has been present in commercial bread wheat varieties for at least 50 years (Krattinger et al., 2011; Ellis et al., 2014) and was incorporated into over 50 % of commercial wheat varieties (Hoisington et al., 1999). In a review of rust resistance and rust genotypes in commercial cereal crops in Australia, 30 of the 87 bread wheat lines tested had the *Lr34* genotype (Cuddy et al., 2016), thus the *Lr34*

⁷ This species is listed in the [Atlas of living Australia](#) as *Elytrigia repens*, however in [USDA GRIN](#) and [WCSP](#) databases the accepted name is *Elymus repens*.

gene is likely to be common in the environment. The *Sr22* gene is present in the Australian commercially-released Schomburgk bread wheat cultivar (Khan et al., 2005). A number of other R genes and APR genes occur in wheat or have been introgressed into wheat from other crop plants or from wild relatives. Thus as well as the specific genes mentioned, the classes of genes and the classes of proteins encoded by the genes proposed for this application are common in the environment and humans and other beneficial organisms have a long history of exposure to these genes and their encoded proteins.

72. The *hptII*, *nptII* and *bar* genes are derived common bacteria that are widespread in human and animal digestive systems and/or in the environment. Both humans and animals are routinely exposed to these genes and their encoded proteins in the environment.

73. All promoters used to drive expression of the introduced genes are the native promoters for the inserted genes, which were derived from wheat or wheat relatives. Humans and animals have been safely consuming these plants for centuries. The CaMV35S promoter, derived from a common plant virus, is used to drive marker gene expression. Other regulatory sequences are from common organisms including Cauliflower mosaic virus, *A. tumefaciens* and potato.

Section 7 Relevant Australian and international approvals

7.1 Australian approvals

74. Wheat lines containing three of the genes – *Sr46*, *Lr34* and *Lr67* – have been approved for limited and controlled release under the licence for DIR 151.

75. There have been no approvals for the commercial release of GM bread wheat or durum wheat in Australia.

7.2 International approvals

76. Field trials of GM wheat have been approved in a number of countries including the United States, Canada, the United Kingdom and a number of European countries. These approvals are for a range of modified traits, including disease resistance, as well as agronomic characteristics, herbicide tolerance, insect resistance and altered product quality traits ([USDA APHIS Biotechnology Permits](#), [EU GM Register](#); accessed June 2018).

77. None of the lines in the current application have been approved for release in any other country.

Chapter 2 Risk assessment

Section 1 Introduction

78. 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).

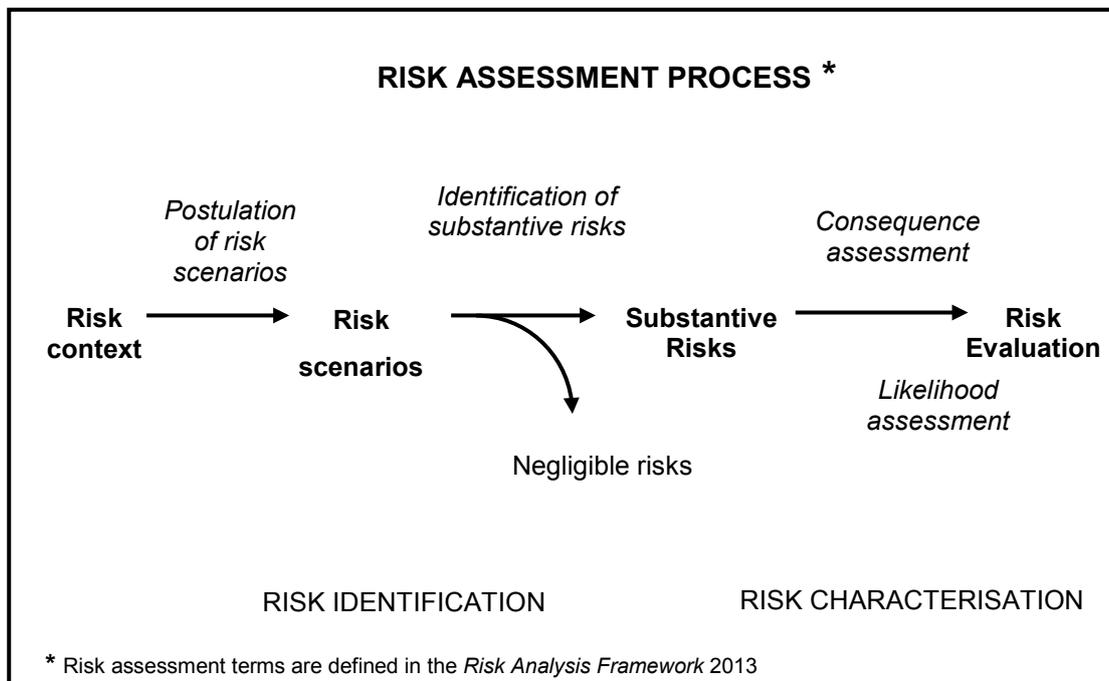


Figure 2 The risk assessment process

79. 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 (risk scenarios) in the short and long term.

80. Postulated risk scenarios are screened to identify substantive risks that warrant detailed characterisation. A substantive risk is only identified for further assessment when a risk scenario is 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.

81. 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. In particular, novel traits that may increase the potential of the GMO to spread and persist in the environment or increase the level of potential harm compared with the parental plant(s) are considered in postulating risk scenarios (Keese et al. 2014). In addition, risk scenarios postulated in previous RARMPs prepared for licence applications of the same and similar GMOs are also considered.

82. Substantive risks (i.e. those identified for further assessment) are characterised in terms of the potential seriousness of harm (Consequence assessment) and the likelihood of harm (Likelihood assessment). The level of risk is then estimated from a combination of the Consequence and Likelihood assessments. The level of risk, together with analysis of interactions between potential risks, is used to evaluate these risks to determine if risk treatment measures are required.

Section 2 Risk Identification

83. 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).
84. In addition, the following factors are taken into account when postulating relevant risk scenarios:
- 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 GMOs
 - the characteristics of the parent organism(s).

2.1 Risk source

85. The source 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.

The introduced genetic elements

86. As discussed in Chapter 1 (Table 1 and Table 2), the GM bread wheat lines have been modified by the introduction of between one and seven genes for stem rust resistance and/or one gene for multi-pathogen resistance. Each of the GM durum wheat lines has been modified by the introduction of one of three genes for multi-pathogen resistance. The introduced genes will be considered further as potential sources of risk.

87. The GM wheat and durum wheat lines also contain one or two marker genes selected from *hptII*, *nptII*, or *bar*. The *hptII* and *nptII* genes confer antibiotic resistance, while *bar* provides tolerance to phosphonitrilic-containing herbicides. These genes were used as selectable markers during development of the GM plants. The *hptII*, *nptII* and *bar* genes and their products 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 *hptII* and *nptII* is available in the document *Marker genes in GM plants* available from the [Risk Assessment References page](#) on the OGTR website. The *bar* gene and its protein product, PAT, have been assessed in other RARMPs as well as in scientific literature, as detailed in Chapter 1 (5.2). The environmental safety of the PAT protein present in biotechnology-derived crops has also been extensively assessed worldwide (CERA, 2011). As the marker genes have not been found to pose a substantive risk to either people or the environment, they will not be further considered for this application.

88. The introduced genes are controlled by introduced regulatory sequences. These are derived from a number of common sources including potato (*Solanum tuberosum*), a bacterium (*Agrobacterium tumefaciens*) and a plant virus (Cauliflower mosaic virus - CaMV). Each of the rust resistance or multi-pathogen resistance genes has a native promoter and terminator sequence, from the same source as the genes i.e. bread wheat and related species. Table 2 in Chapter 1 provides more information about the regulatory sequences. Regulatory sequences are naturally present in plants and the introduced elements are expected to operate in similar ways to endogenous elements. The regulatory sequences are DNA that is not expressed as a protein and dietary DNA has no toxicity (Society of Toxicology, 2003). Hence, risks from these regulatory sequences will not be further assessed for this application.

Unintended effects

89. The genetic modifications have the potential to cause unintended effects in several ways. These include altered expression of endogenous genes by random insertion of introduced DNA in the genome,

increased metabolic burden due to expression of the proteins encoded by the introduced genes, novel traits arising out of interactions with non-target proteins and secondary effects arising from altered substrate or product levels in biochemical pathways. However, the range of unintended effects produced by genetic modification is not likely to be greater than that from accepted traditional breeding techniques. Unintended effects also occur spontaneously and in plants generated by conventional breeding (Bradford et al., 2005; Ladics et al., 2015; Schnell et al., 2015). 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, unintended effects resulting from the process of genetic modification will not be considered further in this application.

2.2 Causal pathway

90. 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 effects of the introduced gene(s) and gene product(s) on the properties of the organism
- 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 GM plants (e.g. reproductive characteristics, dispersal pathways and establishment potential)
- tolerance to abiotic conditions (e.g. climate, soil and rainfall patterns)
- tolerance to biotic stressors (e.g. pest, pathogens and weeds)
- tolerance to cultivation management practices
- gene transfer to sexually compatible organism
- gene transfer by horizontal gene transfer
- unauthorised activities.

91. Although all of these factors are taken into account, some are not included in the risk scenarios below as they may have been considered in previous RARMPs and a plausible pathway to harm could not be identified.

92. 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: plant 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.

93. 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

94. Potential harms from GM plants include:

- harm to the health of people or desirable organisms, including toxicity/allergenicity,

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

95. These harms are based on those used to assess risk from weeds (Virtue, 2004; Keese et al., 2014). Judgements of what is considered harm depend on the management objectives of the land into which the GM plant is expected to spread and persist. 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

96. Four risk scenarios were postulated and screened to identify any substantive risks. These scenarios are summarised in Table 3 and examined in detail in Sections 2.4.1 – 2.4.4. Postulation of risk scenarios considers impacts of the GM bread wheat and GM durum wheat or their products on people undertaking the dealings, as well as impacts on people, other desirable organisms and the environment if the GM plants or genetic material were to spread and/or persist.

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

Table 3: Summary of risk scenarios from the proposed dealings with the GM bread wheat and durum wheat

Risk scenario	Risk source	Causal pathway	Potential harm	Substantive risk?	Reason
1	Introduced genes conferring enhanced rust disease resistance and multi-pathogen resistance	Growing GM wheat at the field trial sites ↓ Expression of the introduced genes in GM plants ↓ Exposure of humans and other desirable organisms by ingestion of, or contact with, the plant material	Increased toxicity or allergenicity for humans or increased toxicity to other desirable organisms	No	<ul style="list-style-type: none"> • The introduced genes are sourced from bread wheat, rye and wheat relatives that are routinely used for food or feed, or have been the source of genes introduced into wheat through conventional breeding • Encoded proteins and similar proteins occur naturally in the environment and are not known to be toxic or allergenic to people or other desirable organisms • GM plant material would not be used in food or feed • The small size and short duration of the proposed trial would minimise exposure of people and other desirable organisms to the GM plant material

Risk scenario	Risk source	Causal pathway	Potential harm	Substantive risk?	Reason
2	Introduced genes conferring enhanced rust disease resistance and multi-pathogen resistance	Growing GM wheat plants at the field trial sites ↓ Expression of the introduced genes in GM plants ↓ Pollen flow between GM wheat plants and other GM wheat plants growing at the sites ↓ Hybridisation of different GM wheat lines producing lines with additional introduced genes ↓ Exposure of humans and other desirable organisms at the trial sites by ingestion of, or contact with the hybrid GM plant material	Increased toxicity or allergenicity for humans or increased toxicity to other desirable organisms	No	<ul style="list-style-type: none"> • The source organisms for the introduced genes are routinely used for food and feed, or have been the source of genes introduced into wheat through conventional breeding • Encoded proteins and similar proteins occur naturally in the environment and are not known to be toxic or allergenic to people or other desirable organisms • No reason to expect that novel proteins would be expressed in hybrids nor that the expressed proteins would behave differently in a hybrid background • The small size and short duration of the proposed trial would minimise exposure of people and other desirable organisms to the GM plant material
3	Introduced genes conferring enhanced rust disease resistance and multi-pathogen resistance	Growing GM wheat at the field trial sites ↓ Dispersal of GM seed outside the trial limits ↓ GM seed germinates ↓ Establishment of GM wheat plants in nature reserves, roadside areas or intensive use areas	Increased toxicity or allergenicity for humans or increased toxicity to other desirable organisms OR Reduced establishment and yield of desirable plants	No	<ul style="list-style-type: none"> • The proposed limits and controls minimise the likelihood of seed distribution outside the trial site • There is no expectation the introduced gene constructs confer other characteristics to enhance the spread and persistence of the GM wheat lines • Bread wheat and durum wheat grains have limited dispersal by animals • Bread wheat and durum wheat have limited ability to survive outside agricultural settings • The GM wheat lines used in this trial are susceptible to standard weed control measures • Risk Scenarios 1 and 2 did not identify any increased risk of toxicity or allergenicity in the GM plants
4	Introduced genes conferring enhanced rust disease resistance and multi-pathogen resistance	Growing GM wheat at the field trial sites ↓ Fertilisation of sexually compatible plants outside the trial site by pollen from GM wheat plants ↓ Germination of GM hybrid seed ↓ Spread and persistence of GM hybrid plants in nature reserves, roadside areas or intensive use areas	Increased toxicity or allergenicity for humans or increased toxicity to other desirable organisms OR Reduced establishment and yield of desirable plants	No	<ul style="list-style-type: none"> • The proposed limits and controls minimise the likelihood of pollen flow from the trial site to sexually compatible plants • Bread wheat and durum wheat have limited ability to outcross • There is no indication that hybrid plants would have increased ability to survive outside agricultural settings • Risk scenarios 1, 2 and 3 did not identify toxicity, allergenicity or weediness of the GMOs as substantive risks.

2.4.1 Risk scenario 1

<i>Risk Source</i>	Introduced genes conferring enhanced rust disease resistance and multi-pathogen resistance
<i>Causal Pathway</i>	<p style="text-align: center;">↓</p> <p style="text-align: center;">Growing GM wheat plants at the field trial sites</p> <p style="text-align: center;">↓</p> <p style="text-align: center;">Expression of the introduced genes in GM plants</p> <p style="text-align: center;">↓</p> <p style="text-align: center;">Exposure of humans and other desirable organisms at the trial sites by ingestion of, or contact with the GM plant material</p> <p style="text-align: center;">↓</p>
<i>Potential Harm</i>	Increased toxicity or allergenicity for humans or increased toxicity to other desirable organisms

Risk source

98. The source of potential harm for this postulated risk scenario is the introduced genes for rust disease resistance and multi-pathogen disease resistance in GM wheat lines.

Causal pathway

99. GM wheat is planted at the trial sites and the genes for rust disease resistance and/or multi-pathogen resistance are expressed. The proteins encoded by these genes are expressed either at seedling and adult plant stages (R genes) or only at adult stages. The encoded proteins may be expressed in a range of tissues at all developmental stages.

100. People may be exposed to GM plant material and the expressed proteins, either by direct contact with the plant material or through inhalation of pollen. This is most likely at the trial site, but may also occur during transport and handling of GM plant material. Other organisms such as livestock, rodents, marsupials, birds or invertebrates may be exposed at the trial site through contact with, or ingestion of GM plant material. A range of birds, stock and wildlife may consume cereals (Hill et al., 1988; AGRI-FACTS, 2002; OGTR, 2017), thus, they may have direct contact with the GM plant material during ingestion.

101. Limits and controls are proposed for the trial that would minimise the exposure of people or animals to the GM plants and their products, including access to planting areas, duration and size of the trial. In addition, no material from this trial would be used for human food or animal feed. The trial sites would be located on land owned and controlled by CSIRO, and would only be accessed by authorised people.

102. The trial is proposed for a maximum of five growing seasons during the period from September 2018 until September 2023. The potential for exposure is limited to a short period when GMOs are present at the trial sites during these growing seasons. In addition, the areas proposed are small, thus further limiting exposure. The total area of the two sites is 4 ha, but of this a maximum planting area of 1 ha per season across both sites is proposed.

Potential harm

103. 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).

104. Potentially, people exposed to the proteins expressed by the introduced genes may show increased toxic reactions or increased allergenicity. Similarly, exposure to the proteins expressed by the introduced genes may lead to increased toxicity to other desirable organisms. From consideration of the causal pathway, including the proposed limits and controls, human exposure would be limited to staff involved in handling the GM wheat plants during the course of the field trial.

105. Although no toxicity or allergenicity studies have been performed on the GM plant material, the introduced genes were isolated from wheat, rye or relatives of wheat that have been the source of genes

introduced into wheat through conventional breeding (Chapter 1, Section 5.1). Thus, people and other beneficial organisms are exposed to the same or similar proteins through their diet and in the environment. The *Lr34* gene has been present in commercial bread wheat varieties for at least 50 years (Krattinger et al., 2011; Ellis et al., 2014). It was incorporated into over half of commercial wheat varieties worldwide (Hoisington et al., 1999), including Australian commercial bread wheat lines (Cuddy et al., 2016). Three genes proposed for the current release - *Lr34*, *Lr67* and *Sr46* - have been approved for planting under the licence for DIR 151. No adverse effects have been reported from this release and there is no information to suggest that the introduced genes or their products are toxic or allergenic to people or toxic to other desirable organisms.

106. Non-GM wheat is not regarded as toxic to humans or other desirable organisms. However, it can produce allergic and autoimmune responses in susceptible individuals by inhalation of flour (for example baker's asthma) or ingestion (coeliac disease) (OGTR, 2017). There is no reasonable expectation that any of the genes proposed for this trial would influence the pathways producing known allergens in wheat. Additionally, plant material from this trial may not be used for food or feed.

Conclusion

107. Risk scenario 1 is not identified as a substantive risk due to limited exposure and the lack of toxicity or allergenicity of the introduced genes and their encoded proteins to humans and lack of toxicity to other organisms. Therefore, this risk could not be considered greater than negligible and does not warrant further detailed assessment.

2.4.2 Risk scenario 2

<i>Risk Source</i>	Introduced genes conferring enhanced rust disease resistance and multi-pathogen resistance
<i>Causal Pathway</i>	<p style="text-align: center;">↓</p> <p style="text-align: center;">Growing GM wheat plants at the field trial sites</p> <p style="text-align: center;">↓</p> <p style="text-align: center;">Expression of the introduced genes in GM plants</p> <p style="text-align: center;">↓</p> <p style="text-align: center;">Pollen flow between GM wheat plants and other GM wheat plants growing at the sites</p> <p style="text-align: center;">↓</p> <p style="text-align: center;">Hybridisation of different GM wheat lines producing lines with additional introduced genes</p> <p style="text-align: center;">↓</p> <p style="text-align: center;">Exposure of humans and other desirable organisms at the trial sites by ingestion of, or contact with the hybrid GM plant material</p> <p style="text-align: center;">↓</p>
<i>Potential Harm</i>	Increased toxicity or allergenicity in humans or increased toxicity to other desirable organisms

Risk source

108. The source of potential harm for this postulated risk scenario is the introduced genes for rust disease resistance and multi-pathogen disease resistance in GM wheat lines.

Causal pathway

109. Due to the small size of the planting areas proposed for this field trial, different lines grown under DIR 162 would be planted in close proximity to one another. Given that different GM lines from both bread wheat and durum wheat are sexually compatible and that they may have similar flowering times, pollen flow between the GMOs is likely and could potentially result in hybrid plants containing additional genes.

110. In addition, as set out in Chapter 1, Section 6.4, the GM wheat grown at the proposed release sites may be grown immediately adjacent to GM wheat lines planted under the licence for DIR 151. Some of the rust resistance genes proposed for release under DIR 162 are the same as those approved for release in GM wheat approved under DIR 151. However, other GMOs licenced under DIR 151 contain different rust resistance or multi-pathogen resistance genes, or have been modified for other trait classes (enhanced drought tolerance, altered oil content and altered grain composition) with genes not included in the

current application. Thus, there is potential for the production of hybrid GM wheat plants containing additional introduced genes for these traits.

111. At the GES site, there is also one planting area from DIR 111 currently under postharvest monitoring (PHM). While no further planting can take place under this licence, the site is under post-harvest monitoring, so it is possible that there may be volunteers present at the site from this release. The introduced genes for DIR 111 conferred traits including altered grain composition, altered nutrient use efficiency, enhanced rust disease resistance or improved drought tolerance. The *Lr34* rust resistance gene proposed for the current application is also approved for DIR 111, however, other genes and traits are not included in the current application, so any volunteers could potentially create different stacked lines through hybridisation with plants released under DIR 162.

112. Wheat is largely self-pollinating, with less than one percent cross-pollination reported beyond distances of 0.5 to 20 m with results depending on the size and conditions of the reported studies (Matus-Cádiz et al., 2004; Gatford et al., 2006; Loureiro et al., 2007; Rieben et al., 2011). Nonetheless, under the licence conditions described above, adjacent plantings of sexually compatible GM plants are permitted, so pollen flow between planting areas may occur at low levels. This could lead to pollination and seed set, resulting in hybrid seeds produced in the DIR 111, 151 or 162 trial sites. However, existing licence conditions for DIRs 111 and 151 and proposed conditions for DIR 162 should effectively manage hybrid seeds or plants. The licence requirements for post-harvest monitoring of planting areas under the licence for DIR 111 require that any volunteers from this trial must be destroyed prior to flowering. Thus, the likelihood of any hybrids occurring between plants from this trial and those proposed for release under DIR 162 is minimal. If any hybrid seed was produced on plants grown under DIR151 and DIR162 it would be harvested with other trial material. Any hybrid seed that was dispersed onto the trial site during harvest and germinated would also be destroyed prior to flowering under the licence conditions for DIR 151 and proposed conditions for DIR162, minimising the likelihood of any further hybridisation and persistence. Thus, exposure of people or other desirable organisms to hybrids would be minimal.

Potential Harm

113. If hybrids between lines from DIR 162, or between lines from DIR 162 and DIR 151 or DIR 111 were to occur, such lines may contain additional proteins produced as a result of expression of the stacked introduced genes. People and other desirable organisms may thus be exposed to hybrid GM bread wheat and/or durum wheat plants containing proteins encoded by the stacked genes and these proteins may be toxic or allergenic to humans or toxic to other desirable organisms.

114. However, Risk Scenario 1 did not identify toxicity or allergenicity of any of the individual genes as a substantive risk. Likewise, the RARMPs for DIR 111 and DIR 151 concluded that there were no substantive risks associated with toxicity or allergenicity of the genes and their products, nor for potential hybrids of the lines in these releases. There is no evidence to suggest that combinations of genes from DIR 162 with those from either DIR 111 or DIR 151 would result in the production of novel proteins, or that their expression would be altered in a hybrid background, thus there is minimal likelihood of novel allergens or toxins. The genes are sourced from common organisms that are widely present in the environment, or from organisms that have been the source for genes for conventional wheat breeding, suggesting that humans and other desirable organisms have a long history of exposure to the genes and their products.

115. The licence for DIR 151 has a condition that prohibits the use of any seed from the trial for development of cultivars for commercial release if any other GMOs approved under a separate licence or any sexually compatible species have been planted at the site concurrently with the GMOs under DIR 151. Thus, if GMOs from DIR 151 and DIR 162 were planted adjacent to one another, any hybrid seed produced and harvested from DIR 151 could only be planted within a limited and controlled trial. DIR 151 has limits and controls to minimise the exposure of people and other desirable organisms to the genes and their expressed proteins and the spread of seed outside the trial site, as would any future trial that used seed from DIR 151.

116. Additionally, for reasons outlined in Risk scenario 1, the proposed limits and controls would minimise exposure of people and other organisms to the GM plant material.

Conclusion

117. Risk scenario 2 is not identified as a substantive risk due to limited exposure and the lack of toxicity or allergenicity to humans of the introduced genes and their encoded proteins or those from hybrid plants containing combinations of these proteins. These genes, or combinations of genes, and their encoded proteins also lack toxicity to other organisms. Therefore, this risk could not be considered greater than negligible and does not warrant further detailed assessment.

2.4.3 Risk scenario 3

<i>Risk Source</i>	Introduced genes conferring enhanced rust disease resistance and multi-pathogen resistance
<i>Causal Pathway</i>	<p style="text-align: center;">↓</p> <p style="text-align: center;">Growing GM wheat plants at the field trial sites</p> <p style="text-align: center;">↓</p> <p style="text-align: center;">Dispersal of GM seed outside the trial limits</p> <p style="text-align: center;">↓</p> <p style="text-align: center;">GM seed germinates</p> <p style="text-align: center;">↓</p> <p style="text-align: center;">Establishment of GM wheat plants in nature reserves, roadside areas or intensive use areas</p> <p style="text-align: center;">↓</p>
<i>Potential Harm</i>	<p style="text-align: center;">Increased toxicity or allergenicity for humans or increased toxicity to other desirable organisms</p> <p style="text-align: center;">OR</p> <p style="text-align: center;">Reduced establishment and yield of desirable plants</p>

Risk source

118. The source of potential harm for this postulated risk scenario is the introduced genes for rust disease resistance and multi-pathogen disease resistance in GM wheat lines.

Causal pathway

119. If GM wheat seed was dispersed outside the trial sites, or persisted at the trial sites after completion of the trial, this seed could germinate and give rise to plants expressing the introduced genes. These plants could spread and persist in the environment and establish populations of GM wheat, expressing genes for enhanced rust disease resistance and/or multi-pathogen resistance. This could increase the likelihood of exposure of people or other desirable organisms to the proteins expressed in the GM plants.

120. Similarly, if hybrids occurred at the trial site between different GM wheat lines, seed from such hybrids could also be spread outside the trial site. While it is unlikely that such progeny would survive to produce seed, due to the requirements to remove volunteer plants from the trial site prior to flowering, (discussed in Risk Scenario 2), there is a small possibility that such hybrid GM wheat seed could also be dispersed from the trial site.

121. Morphological and physiological characteristics of wheat would generally limit the likelihood of spread and persistence in the environment. These are summarised in Chapter 1, Section 4 and in the biology document for bread wheat. Both bread wheat and durum wheat have been selected during domestication for reduced shattering of seed heads - a mechanism for seed dispersal in ancestral wheat plants (Li and Gill, 2006). If the GM wheat persisted at trial sites through dormancy of seeds in the seed bank, the number of volunteers may be increased after the trial, providing seeds for spread to other areas. Bread wheat does not show a high degree of dormancy or a persistent seed bank under Australian conditions (OGTR, 2017). Although durum wheat has been noted as maintaining good germinability for three to five years or longer under very cold, dry, low oxygen conditions (Bozzini, 1988), it is unlikely that such a combination of conditions would occur in the Australian wheat-growing areas. While durum wheats are classed as hard wheats, studies examining preharvest sprouting susceptibility found that durum wheat varieties showed cultivar variability and that preharvest sprouting tolerance that was in the middle of the range for white coated wheats tested in the same study (McCaig and DePauw, 1992). This suggests that it is unlikely that durum wheat seeds would show greater dormancy than bread wheat seeds. Thus although a

range of factors in the environment can influence dormancy in both bread wheat and durum wheat, it is unlikely that either species would persist to provide significant seed banks in the Australian environment.

122. Dispersal of GMOs outside the limits of the trial sites is most likely to occur through the activity of people or animals and through extreme weather events.

Dispersal through human activity

123. Although human activity is generally one of the main mechanisms for seed dispersal from wheat crops (OGTR, 2017), the applicant has proposed limits and controls to prevent the spread of GM wheat seed from the trial site. Access to the site is restricted to authorised, trained staff. The applicant has proposed harvesting by hand or using dedicated small plot harvesters. All equipment used at the trial site would be cleaned in a designated clean-down area before leaving the site or being used for any other purpose. All GM plant material would be transported in accordance with the Regulator's Transport, Storage and Disposal of GMOs guidelines, which would minimise the opportunity for dispersal of GM material or of contact with any GM plant material during transport from the trial site to other facilities for analysis.

Dispersal by animals

124. The activity of animals such as rodents, herbivores and birds could lead to dispersal of the GMOs outside the limits of the trial sites. Animals can potentially spread seed by consumption and excretion of whole seeds, movement of seeds in hair, fur, feathers or on muddy feet, or by removing and hoarding seed.

125. Wheat seeds can be dispersed in sheep wool (Ryves, 1988), however wheat lacks seed dispersal characteristics such as stickiness, burrs and hooks (Howe and Smallwood, 1982). The intended introduced traits of the GM plants are not expected to alter these characteristics of seeds. Dispersal on animal hooves is probable but not well reported. Durum wheat seeds share many morphological characteristics with bread wheat seeds, including those that would influence the likelihood of transport by animals. Although studies are not available specifically for durum wheat, it is highly likely that durum wheat seeds have similar probability of spread in these ways by animals.

126. Reports on seed dispersal for wheat through ingestion are rare. Intact wheat seed may make up to 30% of dry matter in the faeces of cattle fed grain (Beauchemin et al., 1994), however the germination rates of this seed were not measured. Kangaroos, mice, rats and rabbits are known pests of wheat (Hill et al., 1988; AGRI-FACTS, 2002) and could potentially distribute viable seeds. Viable seeds have not been found in rabbit dung (Malo and Suárez, 1995). Seeds which survive chewing and digestion by animals are typically small and dormant (Malo and Suárez, 1995), unlike wheat seeds. Therefore rabbits are unlikely to disperse the GM wheat seeds.

127. Rodents are opportunistic feeders and their diet includes seeds and other plant material (Caughley et al., 1998). They may not only eat and destroy seed at the seed source, but may also hoard seeds (AGRI-FACTS, 2002), which increases the possibility of seed dispersal. However, the applicant proposes an area around the GM planting area, maintained in a manner that does not attract or harbour rodents and the implementation of rodent control measures if rodents are detected. These measures would minimise the potential for seed dispersal by rodents. Furthermore, if dispersal did inadvertently occur, the GM wheat lines are susceptible to standard weed control measures.

128. A variety of birds may feed on cereal crops, including wheat, however a search of the literature found little evidence of extensive spread of seed via birds. Birds such as cockatoos do most damage to wheat during germination (Temby and Marshall, 2003). While corellas and galahs can cause damage to cereal crops during germination and seed ripening, only a small proportion of intact wheat seed fed to these species under controlled conditions is excreted, with varying germination rates (Woodgate et al., 2011). Even under controlled laboratory conditions seed germination rates were very low: 0.8 % to 2 % of the seed consumed survived ingestion and excretion by birds and germinated (Woodgate et al., 2011). Under field conditions germination rates would be lower than those observed under optimised laboratory conditions. Emus may feed on wheat seed but generally prefer other foods (Davies, 1978). If emus did eat wheat seeds, it is likely that germination rates of seed after digestion would be low but experimental

evidence is sparse. Only one study of bird digestion of durum wheat was found. This study showed that durum seed is rapidly digested after feeding to mallard ducks, however it did not indicate whether any viable seed survived digestion (Clark and Gentle, 1990). Specific information on the survival and germination of bread wheat and durum wheat seeds after bird feeding in the Australian environment is sparse and it is likely that seed survival and viability would vary with different bird species and different overall diets. Despite a long history of cultivation in Australia, weedy populations of bread wheat and durum wheat are not found in the environment. While this does not preclude the occurrence of some viable seed spread by birds or other means, it does indicate that any such seed is unable to persist in the environment and thus does not cause harm through the presence of weedy populations.

129. Although dispersal by most insects is unlikely, ants may move wheat seeds short distances, but often bury such seeds at depths at which germination is highly unlikely and therefore have a limited role in dispersal of wheat seeds (OGTR, 2017).

130. The proposed trial sites are small and the period during which viable seed is available for animal consumption or for spread of viable seeds via animal fur, feathers or muddy feet is short (during sowing and immediately prior to harvest) thus limiting the opportunity for consumption or spread of viable seed. In addition to the proposed management of vegetation in the buffer zone and monitoring zone to allow detection of volunteers and assist in rodent control. The applicant proposes fencing the trial sites to minimise access by large animals, however the likelihood of spread via farm animals is minimal. The weed risk assessment for bread wheat considers a range of factors with respect to the spread of wheat seeds. The likelihood of dispersal of viable plant parts by land-based animals is rated as 'unlikely to occasional'. It is expected that a similar rating could be made for durum wheat, considering their similar characteristics. The limited size and duration of the current trial further limits the availability of viable seed for spread and there are also a number of factors which limit the survival of wheat plants outside cultivation if seeds were spread from the trial site (OGTR, 2017). Considering the similar requirements for durum wheat cultivation and survival (Hare, 2006; Kneipp, 2008; GRDC, 2016a, b, c, 2017a, b; SARDI, 2017), it is likely that the same factors would limit the survival of durum wheat seed spread outside the trial site.

Dispersal in extreme weather

131. Extreme weather events have the potential to spread plant material outside a trial, with the most likely means of spread through wind or water. It is possible that plant material such as leaves, stalks or indeed whole plants may be moved short distances by extreme winds, but it is not clear that this could move plant material outside the trial site. It is unlikely that either bread wheat or durum wheat seed would be spread by wind as they have non-shattering seed heads, seeds are heavy and they lack specific structures associated with wind transport. Dispersal by water is possible, but is unlikely as bread and durum wheat ears and seeds are heavy and not adapted for water dispersal. In addition, trial sites will be at least 50 m from any natural watercourse and in areas that are not prone to flooding.

Potential Harm

132. If GM plants were able to establish outside the trial site they could potentially cause increased toxicity or allergenicity to humans or increased toxicity to other desirable organisms through increased exposure. However, as discussed in Chapter 1 (section 5.3) and in Risk Scenarios 1 and 2, there is no reasonable expectation that the GM bread wheat and durum wheat and their products, alone or in combination through hybridisation, would be any more toxic or allergenic than non-GM bread wheat or durum wheat.

133. Establishment of GM wheat outside the trial site could potentially reduce the establishment and/or yield of desirable plants by a number of means. This could occur through reduced establishment or yield of desirable agricultural crops; reduced establishment of desirable native vegetation; reduced utility of roadsides, drains, channels and other intensive use areas; or by providing a reservoir for pathogens or pests.

134. Although both bread wheat and durum wheat have a long history of cultivation in Australia, neither is listed as a weed of national significance ([National Weeds List](#)), nor as a significant weed in Australian

ecosystems (Groves et al., 2003). Bread wheat is listed as a naturalised, non-native species present in agricultural ecosystems in all Australian states and territories except the Northern Territory (NT), while durum wheat is not listed as naturalised or weedy in agricultural ecosystems (Groves et al., 2003). Large weedy populations of bread wheat and durum wheat are not observed in the agricultural or natural environment. There is no reasonable expectation that any of the introduced genes will alter characteristics such as seed shattering, other seed dispersal characteristics or seed dormancy which would alter the GMOs' ability to persist, disperse and establish outside an agricultural setting.

135. The introduced genes may provide the GM plants an increased ability to survive under high disease pressures and under those conditions their competitive ability may be increased. However, in order to increase weediness, these characteristics would need to be coupled with other mechanisms that increase spread and persistence in the environment, through changes in dispersal, establishment and survival. These characteristics would not reasonably be expected to change as a result of the introduced genes, either in individual lines or in a hybrid background.

136. There is some suggestion that the introduced genes for rust disease or multi-pathogen resistance may have pleiotropic effects, as high levels of disease resistance gene expression may be associated with impaired plant growth (Grant et al., 2003) or have fitness costs (Tian et al., 2003). The applicant has stated that any plants that show such effects in the glasshouse would not be selected for testing in the field. In addition, if any such effects occurred in the field, they are likely to impair fitness of the GMOs rather than increasing the likelihood of spread and persistence in the environment.

137. None of the introduced traits are likely to change the susceptibility of the GM wheat lines to conventional weed controls. Thus, the GM wheat plants proposed in this trial could be controlled by standard weed control measures, such as cultivation or the use of herbicides, if required.

138. Risk Scenarios 1 and 2 did not identify toxicity or allergenicity of any of the individual genes or combinations of the introduced genes in a hybrid background, as a substantive risk. In addition, the limits and controls outlined in Risk Scenario 1 further limit the likelihood of exposure to GM plants. The limits and controls reduce the potential amount of seed available for dispersal outside the trial site, as well as the opportunities for spreading seeds.

Conclusion

139. Risk scenario 3 is not identified as a substantive risk due to the lack of toxicity or allergenicity of the introduced genes and their encoded proteins; the proposed limits and controls designed to restrict dispersal; the extremely limited ability of the GM bread wheat or durum wheat to spread and persist outside the trial site, and their susceptibility to standard weed control measures. Therefore, this risk could not be considered greater than negligible and does not warrant further detailed assessment.

2.4.4 Risk scenario 4

<i>Risk Source</i>	Introduced genes conferring enhanced rust disease resistance and multi-pathogen resistance
<i>Causal Pathway</i>	↓
	Growing GM wheat plants at the field trial sites
	↓
	Fertilisation of sexually compatible plants outside the trial site by pollen from GM wheat plants
	↓
	Germination of GM hybrid seed
	↓
	Spread and persistence of GM hybrid plants in nature reserves, roadside areas or intensive use areas
	↓
<i>Potential Harm</i>	Increased toxicity or allergenicity for humans or increased toxicity to other desirable organisms OR Reduced establishment and yield of desirable plants

Risk source

140. The source of potential harm for this postulated risk scenario is the introduced genes for rust disease resistance and multi-pathogen disease resistance in GM wheat lines.

Causal pathway

141. Pollen from GM wheat lines could be transferred outside the trial sites and fertilise sexually compatible plants, either non-GM wheat or plants from another sexually compatible species. Hybrid plants carrying the inserted genes could form the basis for spread and dispersal of these genes in other varieties of wheat, or other sexually compatible plant species.

142. It should be noted that vertical gene flow per se is not considered an adverse outcome, but may be a link in a chain of events that may lead to an adverse outcome. Baseline information on vertical gene transfer associated with non-GM bread wheat plants can be found in the bread wheat [biology document](#). This information is also summarised in Chapter 1, Section 6.4, together with information about durum wheat.

143. People and other desirable organisms could then be exposed to the proteins expressed by the introduced genes through ingestion, contact with plant material or inhalation of pollen from hybrid plants.

144. Bread wheat is mainly self-pollinating and where pollen dispersal does occur, the main method is wind. Cross-pollination rates are influenced by the genotype of the variety and by environmental conditions, such as wind direction and humidity. Bread wheat outcrossing is generally less than 1 %, but rates of up to 6 % or higher have been observed. Wheat pollen is heavy and short-lived, with most pollen falling within the first few metres. Durum wheat is also regarded as being largely self-pollinating, although as with bread wheat, outcrossing rates can reach up to 5 %, again influenced by cultivar and environmental conditions (Bozzini, 1988). Field trials conducted in ACT and SA investigating gene flow from GM lines to non-GM crops have shown a cross-pollination frequency of 0.012% to 0.055%, over a distance of less than 12 m (Gatford et al., 2006). Given the similarities between the two species, it is likely that outcrossing rates and pollen movement for GM durum wheat would be similar to that for GM bread wheat and the introduced genes for disease resistance are unlikely to increase the likelihood of wheat outcrossing.

145. Bread wheat and durum wheat are sexually compatible with one another and hybrids between the two have been observed in the field (Wang et al., 2005). Both species are sexually compatible with a number of other species within the tribe Triticeae that occur in Australia, including other cereal crops, however, such crosses are highly unlikely under field conditions. Hybrids with potentially compatible weedy species are very rare (see Chapter 1, section 6.4). For example, there have been no reports of hybrids between wheat and *H. maritimum* in Australia despite the presence of this species in the Australian wheat belt. Likewise, no hybrids with *H. maritimum* have been reported for durum wheat in Canada where both species are present (CFIA, 2006). *Aegilops* species (goatgrasses) are not considered to be naturalised in Australia.

146. There has been no concerted investigation of natural hybridisation of the native and introduced Triticeae with bread wheat or durum wheat. However, factors such as genome incompatibilities, the necessity for the parent plants to be in close proximity, concurrent flowering, and the ability of the hybrid progeny to set viable seed, combine to make it extremely unlikely that any of these Triticeae would ever naturally cross with wheat.

147. The proposed limits and controls for this trial would minimise the likelihood of pollen flow from the trial to related species outside the trial site. Under these conditions, no bread wheat, durum wheat or related species may be present within at least 200 m of a planting area while GM wheat lines are being cultivated and any related species must be controlled within this distance during flowering. This would greatly reduce the potential for pollen flow from the trial to related species planted outside the trial sites, including cultivated wheat. In addition to this, the applicant proposes postharvest monitoring of the sites for any volunteer GM wheat to prevent production of plants that could hybridise with related species through pollen flow.

Potential Harm

148. If pollen from GM wheat lines was dispersed, any resulting hybrid plants could spread and persist in the environment, leading to increased exposure and potentially toxicity to more people and/or other desirable organisms, or allergenicity to more people. Hybrids expressing the introduced genes could also reduce the establishment and yield of desired plants and subsequently reduce biodiversity.

149. The traits that have been introduced into the GM plants of this application could combine, via vertical gene transfer, with traits of other non-GM commercially cultivated wheat plants, or with sexually compatible species. Bread wheat and durum wheat are the only related species present in Australia with which the GM wheat lines can readily hybridise. However, there is no reason to believe that the resulting plants would possess a level of toxicity or allergenicity greater than that of either parent. Nor is it likely that such hybrids would possess a level of weediness greater than that of either parent.

150. As discussed in Risk scenario 1 and Risk scenario 2, the introduced gene products, or combinations of these, are not expected to be toxic to humans or other organisms. Properties of these genes and their products are not expected to differ in a hybrid background. Therefore, in the rare event of vertical transfer from the GM bread wheat or durum wheat lines to non-GM bread wheat or durum wheat plants or sexually compatible species, it is expected that the introduced genes in any subsequent hybrids would have the same properties as the GM parent.

151. As discussed in Risk scenario 3, the introduced genes are unlikely to make the GM wheat plants more weedy and the properties of the introduced genes are not expected to change in a hybrid background resulting from cross-pollination.

152. Additionally, as mentioned, the limits on access, total area and timeframe for this trial further restrict the likelihood of increased exposure of humans or other desirable organisms to the GM plants and their products or spread of the genes through seed dispersal or pollen flow.

Conclusion

153. Risk scenario 4 is not identified as a substantive risk due to the limited occurrence of long distance pollen flow for bread wheat and durum wheat and the very low likelihood of viable hybrids. In addition, Risk scenarios 1, 2 and 3 did not identify toxicity, allergenicity or weediness of the GMOs or their hybrids as substantive risks. Therefore, this risk could not be considered greater than negligible and does not warrant further detailed assessment.

Section 3 Uncertainty

154. Uncertainty is an intrinsic part of risk and is present in all aspects of risk analysis⁸.

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

- uncertainty about facts:
 - knowledge – data gaps, errors, small sample size, use of surrogate data
 - variability – inherent fluctuations or differences over time, space or group, associated with diversity and heterogeneity
- uncertainty about ideas:
 - description – expression of ideas with symbols, language or models can be subject to vagueness, ambiguity, context dependence, indeterminacy or under-specificity

⁸ A more detailed discussion is contained in the Regulator's *Risk Analysis Framework* available from the [OGTR website](#) or via Free call 1800 181 030.

- perception – processing and interpreting risk is shaped by our mental processes and social/cultural circumstances, which vary between individuals and over time.

156. 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.

157. 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.

158. For DIR 162, uncertainty is noted particularly in relation to:

- potential increases in toxicity or allergenicity as a result of the genetic modification
- potential for increased spread and persistence of the GMOs, including land uses outside agriculture

159. 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.

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

Section 4 Risk evaluation

161. 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.

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

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

163. Four risk scenarios were postulated whereby the proposed dealings might give rise to harm to people or the environment. In the context of the control measures 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 3 and include:

- the limits and controls of the trial are such that exposure of humans and other desirable organisms to the GM plants is minimal
- the risk of seed dispersal or pollen flow is minimised
- none of the GM plant material is to be used for human food or animal feed
- the introduced genes and their expressed proteins are unlikely to be toxic or allergenic
- the expressed genes would not reasonably be expected to behave differently in stacked lines or in a hybrid background, thus there would be no increased risk if hybrids were to occur
- the introduced genes are not involved in regulation of characteristics that facilitate the spread of seeds
- the expressed genes are unlikely to alter the establishment and persistence of GM plants outside cultivation, nor to change their susceptibility to conventional weed control measures

164. Therefore, risks to the health and safety of people, or the environment, from the proposed release of the GM wheat plants into the environment are considered negligible. The Risk Analysis Framework, 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 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.⁹

⁹ 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

165. 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.

166. 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.

167. 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.

168. 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

169. The risk assessment of risk scenarios listed in Chapter 2 concluded that there are negligible risks to people or the environment from the proposed field trial of GM bread wheat and durum wheat. These risk scenarios were considered in the context of the scale of the proposed release, the proposed containment measures, and the receiving environment, 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

170. 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 imposed to limit the release to the proposed size, location and duration, and to restrict the spread and persistence of the GMOs and their genetic material in the environment. The conditions are discussed and summarised in this Chapter and listed in full in the licence.

3.1 Licence conditions to limit and control the release

3.1.1 *Consideration of limits and controls proposed by CSIRO*

171. Sections 3.1 and 3.2 of Chapter 1 provide details of the limits and controls proposed by CSIRO in their application. Many of these are discussed in the four risk scenarios considered for the proposed release in Chapter 2. The appropriateness of these controls is considered further in the following sections.

172. The applicant proposes two sites for the release of GM wheat lines. These are located on research stations in the ACT (Ginninderra) and in NSW (Boorowa). CSIRO owns the land on which the trials are

proposed and the land surrounding the trial sites. For each site, more than one planting area may be used. The field trial would run for five years, which includes up to five planting seasons. The maximum area planted would be 1 ha per season across both sites.

173. While the revised total area requested for cultivation is significantly increased from the original request, it does not raise new risks, nor does it change the level of risk assessed in Chapter 2. The revised trial size is consistent with similar limited and controlled releases for wheat in these and other locations. The limits and controls imposed in the licence are suitable to manage the risk for this area of planting.

174. The applicant has proposed that the sites will have lockable gates and that only authorised personnel would be permitted to deal with the GMOs. Standard licence conditions have been included that require that only authorised people are permitted to undertake any activity authorised by the licence and that all people dealing with the GMOs must be informed of relevant licence conditions. These measures are considered appropriate to limit the potential exposure of humans to the GMOs (Risk Scenario 1).

175. These conditions would limit the potential exposure of humans and other desirable organisms to GM wheat (Risk scenarios 1 and 2) and would limit the opportunity for dispersal of seed and establishment of GM lines outside the trial site (Risk Scenarios 3 and 4).

176. As discussed in Risk Scenario 2, there is potential for gene stacking between DIR 162 lines within the trial, as well as the possibility of hybridisation with GMOs from DIR 151 planted at the sites, or volunteers from DIR 111 at GES. Pollen transfer between GMOs grown under individual licences for DIR 111, DIR 151, or DIR 162 has been considered for each licence separately, as has the possibility of gene flow between lines from DIR 111, DIR 151 and DIR 162 (Risk Scenarios 1 and 2).

177. There is no expectation that combinations of genes from DIR 162 with those from either DIR 111 or DIR 151 would result in the production of novel proteins, or that their expression would be altered in a hybrid background (Risk scenario 1). Nor is there expectation that the hybrid GMOs would possess increased weedy characteristics (Risk Scenario 2). Nonetheless, if seed from DIR 162 trial was used to develop future GM bread wheat or durum wheat lines, there is a possibility that other genes could be unintentionally present. Therefore, a licence condition has been included for DIR 162 to require that from trials where such gene flow and resulting hybrids could have occurred, the licence holder must report the details of all lines grown concurrently from DIR 162 and other licences to the Regulator. This would ensure that relevant genotypic information would be available for any seed produced from this trial, that may be used for future licence applications (Risk Scenarios 1 and 2). This would avoid the possibility that seed from unintended hybrids could be used to develop lines for future commercial release.

178. The applicant proposed the presence of a fence surrounding the field trial site to prevent livestock accessing the trial. A standard licence condition has been included that prohibits the use of plant material from this trial for food or feed, thus livestock cannot be allowed to feed on the GM wheat (Risk Scenarios 1, 2 and 3). As discussed in the RARMP for DIR 152, the requirement to exclude livestock may be achieved in a number of ways, including, but not limited to, the presence of a livestock-proof fence. Therefore, the licence is not prescriptive in this regard.

179. The potential for seed dispersal by other animals has also been discussed in Risk Scenario 3 and, for the reasons discussed there, it is considered unnecessary to impose additional measures to control large animals or measures to control access of birds to the planting areas (Risk Scenario 3). In addition, there is no evidence that the GM bread wheat and GM durum wheat lines or hybrid GM wheat lines would be more toxic to birds than the non-GM parental wheat lines. Hence, there is no requirement to control access of birds to the GM wheat lines with respect to Risk Scenario 1 and Risk Scenario 2.

180. Small animals including rodents may remove seed from the planting area, providing a potential means of dispersal (Risk Scenario 3). Although the applicant has not discussed the incidence of rodent activity at the sites, they have proposed rodent control by use of baits.

181. Recent licences for GM wheat or for GM wheat and barley include a condition stating that rodent control measures must be used within the planting area while the GMOs are being grown and until the planting areas have been cleaned. The measures include, but are not limited to, trapping or baiting. In

addition, these licences contain conditions requiring that the monitoring zone must be maintained in a manner that does not attract or harbour rodents while the GMOs are being grown and until the planting areas have been cleaned. Examples of this maintenance include keeping the monitoring zone either free of vegetation or planted with vegetation mown to a height of less than 10 cm. These conditions are included in the licence to minimise risk associated with rodent activity and to facilitate detection of GM plant material that has been dispersed during dealings with the GMOs (Risk Scenario 3). This is discussed later in Chapter 3.

182. The applicant has proposed containment measures for the GM wheat that include a monitoring zone surrounding the trial site with a 2 m buffer zone, a 10 m monitoring zone and a 190 m isolation zone in which no bread wheat, durum wheat or sexually compatible plants will be grown. The proposed monitoring and isolation zones provide a combined separation distance of 200 m between the GMOs and any other wheat. The potential for outcrossing in wheat has been discussed in detail in the [biology document](#) for bread wheat and in a number of RARMPs. The most recent detailed discussion is in DIR 112 and DIR 102 (wheat and barley), with summaries in DIR 152 (wheat and barley) and in DIR 151 (wheat). The potential for outcrossing of durum wheat is discussed in Chapter 1 and in Risk scenario 4.

183. Based on the evidence available, including scientific literature on gene flow, international containment measures for GM wheat trials and guidelines for producing basic and certified seed, an isolation distance of 200 m between the GMOs and any other intentionally planted crops of bread wheat, durum wheat or related species is considered suitable. Conditions in earlier licences specify that the entire 200 m isolation zone must be inspected during flowering of the GMOs for the presence of volunteers and related species. This condition was reviewed for DIR 152, a limited and controlled release of GM wheat and barley.

184. As discussed in the RARMP for DIR 152, a total of 60 m was considered sufficient to manage gene flow to volunteers or sexually related species outside the planting area. This was achieved by the requirement for a monitoring zone of at least 10 m from the outer edge of any planting area, surrounded by an inspection zone of at least 50 m extending from the outer edge of the Monitoring Zone. These zones have conditions restricting the presence of wheat and related species and requiring monitoring for and destruction of volunteers and related species. The 140 m extending from the outer edge of the inspection zone is the isolation zone in which no crop of wheat (barley) or related species could be present, but which does not require inspection during flowering of the GMOs. Thus an overall isolation distance of 200 m was achieved.

185. Many seed certification schemes do not distinguish between bread wheat and durum wheat - or indeed between different cereal crops - with respect to their requirements (California Crop Improvement Association, 2003; Seed Services Australia, 2013; OECD, 2016). The Canadian scheme does include conditions for individual cereal crop species with regard to the recent cropping history of land used to grow pedigreed seed crops, separation distances from other crops and weed control requirements. However, the requirements are the same for bread wheat and durum wheat (Canadian Seed Growers' Association, 2005). This information, when considered in addition to the scientific literature (Risk Scenario 4) and the similarities between bread wheat and durum wheat discussed in earlier sections, indicates the same isolation distance is suitable for both bread wheat and durum wheat.

186. Thus, the licence includes conditions requiring a 10 m monitoring zone and a 50 m inspection zone to manage any risk of gene flow from wheat as well as a 140 m isolation zone, thus providing an isolation distance of 200 m. The presence of a 2 m buffer zone surrounding the planting area¹⁰ proposed by the applicant has not been included as, based on the available evidence, there were no plausible risks that would warrant the use of this control measure. Other measures were deemed adequate to manage

¹⁰ The applicant used the term 'location' to indicate the area in which GMOs are planted at a field trial site.

potential risk associated with rodent activity or GMO dispersal and have been included as conditions in the licence.

187. The applicant has proposed the use of multiple planting areas at the trial sites. Under the conditions included in the licence, where more than one planting area is established at a field trial site, no planting area may be less than 10 m from the outer edge of the surrounding monitoring zone (See Figure 1, Chapter 4). Where multiple planting areas are established, any land between planting areas is included in the monitoring zone and must be maintained as such.

188. The applicant has proposed that all trial sites would be located at least 50 m from any natural waterway and in areas that are not prone to flooding. This would reduce the likelihood of plant material being washed away from the planting areas (Risk Scenario 3) and has been included as a licence condition. A condition has also been imposed requiring immediate notification of any extreme weather event affecting the properties during the release to allow assessment and management of any risks.

189. The applicant has proposed a number of measures to minimise the persistence of GM wheat plants and seeds in the seedbank at the field trials after harvest of the GM plants. These measures include tillage to the depth of seeding within the planting areas, three irrigations during the two years following harvest to encourage germination of any remaining seed and inspection of the planting areas and monitoring zone at least once every 35 days for at least two years after harvest, including a 6 month volunteer-free period before signoff.

190. Germination rates differ between buried grain and grain lying on the surface; grains remaining near the surface, e.g. following shallow tillage after harvest, can generally easily germinate and become established (Ogg and Parker, 2000). Shallow tillage after harvest, combined with irrigation, will germinate much of the seed lying on the surface (Ogg and Parker, 2000). However, deep cultivation in certain soil types can reduce seed viability, but can also encourage prolonged dormancy in seeds as a result of a cool, moist low oxygen environment (Pickett, 1989; Ogg and Parker, 2000).

191. The Regulator considers that under Australian conditions, a post-harvest monitoring period of at least two years, with monthly inspections, and with no volunteers detected for at least 6 months immediately prior to the end of the monitoring period, would effectively manage survival and persistence of viable wheat seeds in the soil. Therefore, the licence imposes conditions requiring that after harvest, the trial sites should receive at least three irrigations at intervals of at least 28 days, with the last required irrigation occurring at a time that would promote germination of volunteers within the final volunteer-free period. These measures would minimise the persistence of the GMOs in the environment (Risk Scenarios 3 and 4).

192. The applicant proposes that rainfall events of greater than 20 mm in a 24 h period would be deemed to be equivalent to an irrigation event. However, a condition in the licence states that a period of natural rainfall may be taken as irrigation only with the agreement of the Regulator. Evidence that the rainfall has been sufficient to promote germination (such as rainfall measurements, photos or records of other plants germinating at the site etc.) needs to be provided. Additionally, prior to the last irrigation, the area must be tilled to a depth no greater than the depth of sowing. These treatments would ensure that any remaining seeds are exposed to sufficient moisture and placed at an appropriate depth for germination, as well as encouraging the microbial decomposition of any residual seed (Risk Scenarios 3 and 4).

193. As noted earlier, a 2 m buffer zone surrounding each planting area is not a requirement in the licence. However, licence conditions require inspection of any areas where GM material has been dispersed (including during planting, growing or harvest) and that volunteers and related species must be destroyed or prevented from flowering. A further condition in the licence requires that harvest of GM wheat be conducted separately from other crops. These conditions are imposed to manage any potential for spread and persistence of the GMOs due to mechanical dispersal of grain during sowing and harvesting (Risk Scenario 3). The applicant has stated that seed from the GMOs will be harvested either by hand or by plot harvester and that all wheat planted at the trial sites, including non-GM control varieties, would be treated as GM. These measures would minimise the spread of GM seed from the trial site during harvest.

194. No information has been provided regarding the handling of seed following harvest, although the applicant proposes that seed may be used for experimental analysis in PC2 laboratories under appropriate NLRDs and may be used to plant further trials. Licence conditions specify that if seed harvested from the GMOs is threshed other than in accordance with Notifiable Low Risk Dealings (NLRD) requirements, it must be threshed separately from any other crop, and threshing must take place on a planting area or in a facility approved in writing by the Regulator.

195. The applicant has proposed that any GM plant material would be transported to approved facilities for analysis or destruction according to the Regulator's Guidelines for the Transport, Storage and Disposal of GMOs. Any grain remaining after analysis must be stored in an approved facility for subsequent use, or destroyed by autoclaving or another method approved by the Regulator. These are standard conditions in the licence relating to the handling of GMOs, to minimise exposure of people and other organisms to the GMOs (Risk Scenario 1 and 2), dispersal into the environment and gene flow (Risk Scenario 3 and 4).

196. The applicant has proposed that all equipment; including machinery, storage and transport equipment, tools, footwear and clothing; would be inspected for GM seeds and cleaned before removal from the site or use for any other purpose. Equipment would be cleaned at the planting area, then moved to a concrete inspection/cleaning pad located at the entrance to each site, inspected and re-cleaned if required. Any seeds would be collected from the concrete pad and returned to the planting area or transported to a PC2 facility for destruction using an approved method. They have proposed that areas used to clean equipment, that are not on the planting area or the inspection pad, would be monitored bimonthly for at least 12 months. If volunteers were identified in the final six months of monitoring, the length of monitoring would be extended such that no volunteers were identified in the last six months of monitoring. Conditions in the licence require that any area where GMOs have dispersed as a result of dealings under the licence, including any area used to clean equipment, must be cleaned as soon as practical and inspected at least every 35 days from the date of cleaning for a minimum of 24 months prior to sign-off. Any volunteers detected must be destroyed before flowering. These measures will minimise the persistence of the GMOs in the environment (Risk Scenarios 3 and 4).

197. The applicant has proposed that GM plants and other wheat within each planting area would be disposed of using one or more of the following methods: uprooting, tilling, treatment with herbicide, burning/incineration, autoclaving, crushing, milling, burial of seed or other plant material under 1m of soil in an area immediately adjacent to the trial site, or a method approved in writing by the Regulator. Autoclaving, crushing, milling and deep burial are considered effective methods for seed destruction as they render seed non-viable, therefore minimising the risk of germination and/or spread.

198. The applicant has proposed that areas used to bury seed would be monitored bimonthly for at least 12 months. If volunteers were identified in the final six months of monitoring, the length of monitoring would be extended such that no volunteers were identified in the last six months of monitoring. However, as burial is defined as a means of destroying the GMOs, the burial site is not considered an area that requires cleaning under the conditions of the licence. Wheat seeds planted in waterlogged soil do not germinate due to lack of oxygen and in very wet conditions it is thought that seeds burst as they run out of oxygen and die (NSW DPI, 2007). Therefore, licence conditions require that seeds should be irrigated at the time of burial to encourage decomposition. In addition, if wheat seed is planted at depth, the coleoptile will stop growing before reaching the soil surface, thus the first leaf emerges from the coleoptile below the soil surface and cannot break through the soil surface and plants die (NSW DPI, 2007). Thus, in deep burial any seeds that do germinate would be unable to emerge and would die. The licence conditions require that the burial site must not be intentionally disturbed for a period of at least 12 months from the time of burial. The licence holder is required to inspect the burial site for any disturbance and to notify the Regulator of any disturbance and any remedial action taken. If seed is dispersed during burial, this area would require cleaning as an area in which the GMOs have been dispersed in the course of dealings under the licence, and post-cleaning conditions would apply (see paragraph 195, above). Deep burial of GMOs was only requested, and is only permitted at the BARS site.

199. The applicant does not propose to use GM plant material from the field trial for animal feed or human food. Licence conditions have been imposed such that GM plant material may not be used as food for humans or feed for animals (Risk Scenarios 1 and 2).

200. After harvest the land will be left fallow or planted with a break crop if approved in writing by the Regulator. The location may be re-sown with GM wheat in the following season.

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

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

- limit the duration of the release to a maximum of five planting seasons, until September 2023
- limit the release to a maximum of two locations, in the ACT (Ginninderra - GES) and NSW (Boorowa – BARS)
- limit the release to a maximum area of 1 ha per season across both sites
- locate trial sites at least 50 m from any natural waterways
- surround the planting area(s) with a monitoring zone of at least 10 m, maintained in a manner that does not attract or harbour rodents, and in which related species must be prevented from flowering
- surround the monitoring zone with a 50 m inspection zone in which no bread wheat or durum wheat may be planted and which must be inspected for volunteers and related species during flowering
- surround the inspection zone with a 140 m isolation zone in which no crop of bread wheat, durum wheat or related species may be present
- implement measures including rodent baits and/or traps to control rodents within the planting areas
- harvest the GM wheat separately from other crops
- harvest the GM wheat by hand or with a dedicated plot harvester
- clean the areas after use including the planting area and any area in which seed has been dispersed
- clean any equipment used on site
- apply measures to promote the germination of any wheat seeds that may be present in the soil after harvest, including irrigation and shallow tillage
- monitor for at least 24 months after harvest and destroy any wheat plants that may grow, until no volunteers have been detected for a continuous six month period
- monitor burial sites for disturbance and report remedial action to the Regulator if disturbance occurs
- destroy all GMOs not required for further analysis or future trials
- transport and store the GMOs in accordance with the Regulator's guidelines
- not allow the GM plant material to be used for human food or animal feed

3.2 Other risk management considerations

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

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

3.2.1 Applicant suitability

203. 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.

204. 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.

205. 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

206. If a licence were issued, CSIRO 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 wheat outside permitted areas.

207. CSIRO 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

208. 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, CSIRO 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

209. 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.

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

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

3.2.5 Monitoring for compliance

211. The Act stipulates, as a condition of every licence, that a person who is authorised by the licence to deal with a GMO, and who is required to comply with a condition of the licence, must allow inspectors and other persons authorised by the Regulator to enter premises where a dealing is being undertaken for the

purpose of monitoring or auditing the dealing. Post-release monitoring continues until the Regulator is satisfied that all the GMOs resulting from the authorised dealings have been removed from the release sites.

212. 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.

213. 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

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

- additional molecular and biochemical characterisation of the GM bread wheat and durum wheat lines, particularly with respect to potential for increased toxicity and allergenicity
- additional phenotypic characterisation of the GM bread wheat and durum wheat lines, particularly with respect to traits that may contribute to weediness

Section 5 Conclusions of the consultation RARMP

215. The RARMP concludes that the proposed limited and controlled release of GM bread wheat and GM durum wheat 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.

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

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Appendix A: Summary of submissions from prescribed experts, agencies and authorities

The Regulator received a number of submissions from prescribed experts, agencies and authorities¹¹ on the consultation RARMP. All issues raised in submissions that related to risks to the health and safety of people and the environment were considered in the context of the currently available scientific evidence and were used in finalising the RARMP that formed the basis of the Regulator's decision to issue the licence. Advice received is summarised below.

Submission	Summary of issues raised	Comment
1	Notes no use for food or feed. No further comments.	Noted.
2	Negligible risks to the health and safety of people and the environment.	Noted.
3	<p>Agrees with the overall conclusions of the RARMP.</p> <p>Agrees with the conclusion that the risk of environmental harm resulting from seed dispersal is negligible, but requests more information regarding seed dispersal by birds.</p> <p>Agrees with the conclusion that the risk of environmental harm resulting from seed dispersal is negligible, but suggests further discussion of gene flow to weedy relatives</p>	<p>Noted.</p> <p>There is limited information in the literature regarding the dispersal of viable seeds from cereal crops, either by birds or animals. Previous RARMPs that discuss this in detail are referenced, along with other relevant references.</p> <p>Text has been amended to clarify the information available regarding ingestion, digestion and excretion of viable wheat seeds under Australian conditions. The discussion of seed coats and digestibility has also been amended.</p> <p>The likelihood of gene flow to related species has been discussed for bread wheat and durum wheat in Chapter 1. The absence or occurrence of weedy relatives in Australia was also detailed there; the very low potential for hybridisation with <i>Hordeum marinum</i> has been clarified.</p>
4	No concerns.	Noted.
5	Agrees with the conclusions of the RARMP.	Noted.
6	<p>Agrees with the overall conclusions of the RARMP.</p> <p>The Regulator should consider clarifying why rabbits are unlikely to disperse GM wheat seeds.</p>	<p>Noted.</p> <p>Discussion in Chapter 2 of the RARMP has been reworded for clarity.</p>

¹¹ Prescribed agencies include GTTAC, State and Territory Governments, relevant local governments, Australian Government agencies and the Minister for the Environment and Energy.

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

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

Submission	Summary of issues raised	Comment
1	Opposed to GM for any food crop	The Act requires the Regulator to identify and manage risks to human health and safety and the environment posed by or as a result of gene technology. This submission is outside the Regulator’s legislative responsibility.