Australian Government
Department of Health
Office of the Gene Technology Regulator

February 2017

Risk Assessment and Risk Management Plan for

DIR 150

Limited and controlled release of potato genetically modified for disease resistance

Applicant: Queensland University of Technology

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Summary of the Risk Assessment and Risk Management Plan
for
Licence Application No. DIR 150

Decision

The Gene Technology Regulator (the Regulator) has decided to issue a licence for this application for the limited and controlled release (field trial) 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 concludes 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 150
Applicant	Queensland University of Technology (QUT)
Project title	Limited and controlled release of potato genetically modified for disease resistance
Parent organism	Potato (*Solanum tuberosum* cv. "Russet Burbank")
Introduced genes and modified traits	The following disease resistance genes either singly or in combination: • *Rx* gene derived from *S. tuberosum* cv. "Cara" conferring resistance to Potato virus X (PVX) • *Rpi-blb1* and *Rpi-blb2* genes derived from *S. bulbocastanum* conferring resistance to late blight (*Phytophthora infestans*)
Proposed location	One site in Redland City, Queensland
Proposed release size	Up to 0.1 hectare (ha) in total
Proposed release dates	February 2017 – January 2019
Primary purpose	To assess the agronomic characteristics and PVX disease response of GM potato plants under field conditions

Risk assessment

The risk assessment concludes that there are negligible risks to the health and safety of people, or the environment, from the proposed release.

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), relevant previous approvals and advice received from a wide range of experts, agencies and authorities consulted on the RARMP. Both the short and long term impacts are considered.

Credible pathways to potential harm that were considered included exposure of people or animals to the GM plant material, potential for spread and persistence of the GMOs, and transfer of the introduced genetic material to sexually compatible plants. Potential harms associated with these

pathways included toxicity or allergenicity to people, toxicity to other desirable organisms, 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, the proposed limits and controls effectively contain the GMOs and their genetic material and minimise exposure; and the GM potato has limited ability to establish populations outside cultivation or transfer the introduced genetic material to other plants.

Risk management plan

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

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 or animal feed, to minimise dispersal of the GMOs from trial sites, to transport GMOs in accordance with the Regulator's guidelines, to destroy GMOs not required for testing or further planting, and to conduct post-harvest monitoring at trial sites to ensure all GMOs are destroyed.

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Abbreviations

Act	*Gene Technology Act 2000*
cm	centimetres
cv.	cultivar
DAF	Department of Agriculture and Fisheries
DIR	Dealings involving Intentional Release
DNA	deoxyribonucleic acid
FSANZ	Food Standards Australia New Zealand
GM	genetically modified
GMO	genetically modified organism
ha	hectare
HGT	horizontal gene transfer
km	kilometres
m	metres
mm	millimetres
NBS-LRR	nucleotide binding site-leucine rich repeat
NLRD	Notifiable Low Risk Dealing
OGTR	Office of the Gene Technology Regulator
PC2	Physical Containment level 2
PVX	Potato virus X
QUT	Queensland University of Technology
RARMP	Risk Assessment and Risk Management Plan
Regulations	Gene Technology Regulations 2001
Regulator	Gene Technology Regulator

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).

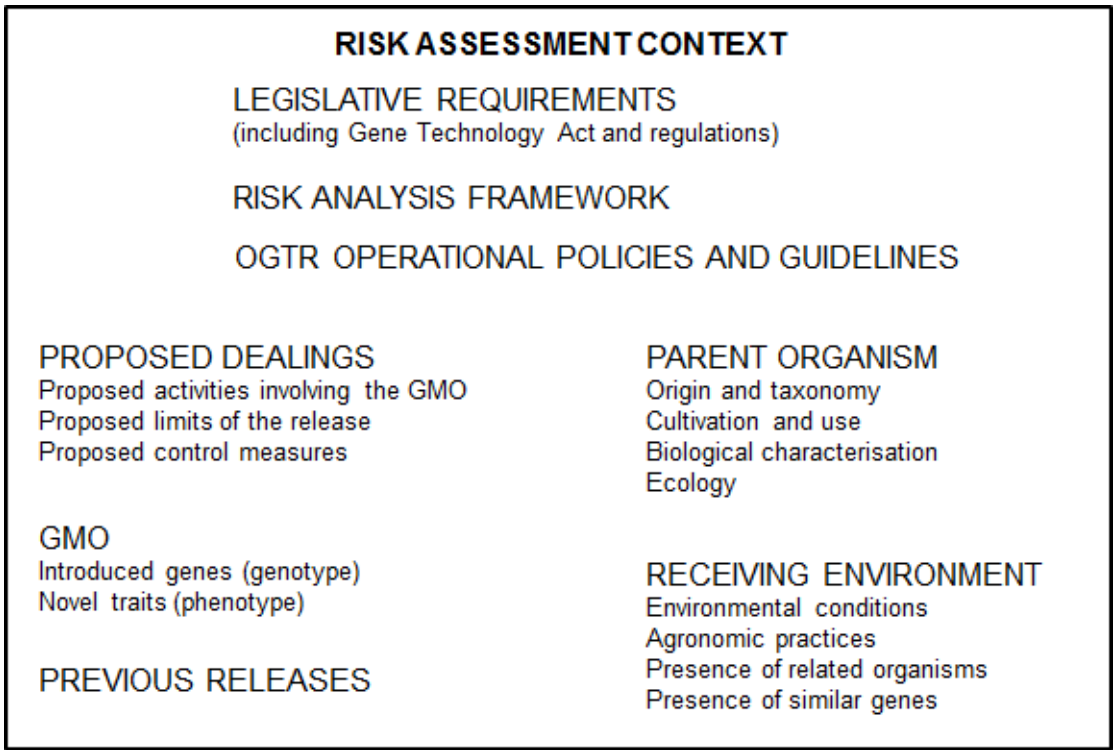

Figure 1. Summary of parameters used to establish the risk assessment context

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. The advice from the prescribed experts, agencies and authorities and how it was taken into account is summarised in Appendix A. No public submissions were received.

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

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

Section 3 The proposed dealings

9. The Queensland University of Technology (QUT) proposes to release up to 5000 lines of Russet Burbank potato genetically modified for disease resistance into the environment under limited and controlled conditions. The purpose of the release is to assess the Potato virus X disease response and agronomic characteristics of the GM potato plants 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 the purposes of, or in the course of, any of the above.

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

11. The release is proposed to take place on one site at the Queensland Department of Agriculture and Fisheries (DAF) Redlands Research Facility, in Redland City, Queensland, on a total area of 0.1 ha between February 2017 and January 2019.

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

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 potato and the introduced genetic material in the environment. These include:

- locating the field trial on flat land approximately 300 m from the nearest natural waterway
- restricting human and animal access by surrounding the trial site with a fence
- deflowering all potato plants grown at the trial site to prevent seed production

- destroying all GM plants and harvested tubers from the field trial that are not required for testing or future trials
- cleaning machinery prior to removing it from the trial site
- treating non-GM plants grown in the field trial the same as GM plants
- post-harvest monitoring of the trial site at least once every 60 days for at least two years and until the site is free of volunteer potato plants for at least one year, with any volunteer plants destroyed by herbicide treatment
- transporting and storing GM plant materials in accordance with the current Regulator's *Guidelines for the Transport, Storage and Disposal of GMOs*
- not allowing GM plant material to be used for human food or animal feed.

Section 4 The parent organism

4.1 Origin and cultivation

14. Cultivated potato, *Solanum tuberosum*, originated and was first domesticated in South America. Following export to Europe in the 16th century the crop was gradually distributed and adopted worldwide (CFIA 2015; Simon et al. 2010). Potatoes are now one of the world's top five food crops, with 368 million tonnes produced in 2013 (FAO 2015).

15. Potato is commercially grown in all states of Australia. It is the most important Australian vegetable crop, with nearly thirty thousand hectares commercially planted to potatoes in 2014-15 (ABS 2016). Potatoes are also grown as vegetables in domestic gardens. Potatoes are primarily grown as human food; however, potato by-products such as unmarketable tubers or processing waste may be used as stock feed (Freeman 1996).

4.2 Morphology and development

16. *Solanum tuberosum* is a herbaceous plant that grows to 0.4 – 1.4 m tall, depending on variety. It is a perennial but is typically cultivated as an annual. Tubers are borne at the end of underground stolons, and act as storage organs. Eyes on the tubers are buds that can sprout into new stems (CFIA 2015; OECD 1997).

17. Although potatoes can reproduce sexually, vegetative propagation is typically used in commercial cultivation (CFIA 2015). Potato crops are grown from seed potatoes, which are whole tubers or cut tuber pieces that contain at least one eye. In Queensland, potato plants emerge 2-5 weeks after planting, depending on variety, age of seed potato and soil temperature. Tubers reach maturity and are harvested 11-15 weeks after emergence. During the final 2-3 weeks of tuber maturation, the above-ground plants begin to yellow and die back (Jackson et al. 1997).

18. Potato plants typically flower 8-9 weeks (Gopal 1994; Plaisted 1980) after planting. The fruit of potato plants are green berries 1-4 cm in diameter (CFIA 2015). A minimum of six weeks of berry development after pollination is required to produce viable seed (Plaisted 1980).

4.3 Outcrossing

19. *Solanum tuberosum* is not sexually compatible in the field with plants other than tuber-bearing species from the genus *Solanum* section *Petota* (CFIA 2015). There are 181 *Solanum* species present in Australia (Atlas of Living Australia) but only one species, *S. tuberosum*, is from the section *Petota* (Spooner & Hijmans 2001).

20. A study of 676 potato cultivars found that 20% did not produce mature flowers as the buds dropped prematurely, and a further 18% were male-sterile (Gopal 1994). Male-fertile potato plants that set seed are 80 – 100% self-pollinated (Plaisted 1980). Outcrossing is mediated by insect

pollinators, particularly bumblebees (CFIA 2015), but also other bees (*Lonchopria* spp.) and pollen beetles (*Astylus* spp., *Meligethes aeneus*) (Petti et al. 2007; Scurrah et al. 2008). These pollinators are not present in mainland Australia (Atlas of Living Australia). Honey bees do not visit potatoes and the role of wind pollination is likely to be minor (CFIA 2015).

21. Studies of cross-pollination in fertile potato plants found that outcrossing primarily occurred between adjacent plants, with little or no outcrossing at distances greater than 4.5 m (CFIA 2015). An Irish study using a highly fertile cultivar as the pollen source and a male-sterile cultivar as the pollen recipient found that outcrossing occurred at the maximum distances tested, 20-21 m, with recipient potatoes at these distances producing an average of 0.6 germinable seeds per plant (Petti et al. 2007). A similar Argentinian study using a fertile cultivar as the pollen source and a male-sterile cultivar as the pollen recipient found that outcrossing also occurred at a distance of 35 m, although seed production rates were less than 0.1 seeds per plant (Capurro et al. 2014).

4.4 Weediness

22. Potatoes are not reported to be naturalised or a weed in Australia (Department of the Environment National Weeds Lists; Groves et al. 2003). Potatoes generally do not compete successfully outside of cultivated areas (Love 1994). Worldwide, *S. tuberosum* is only reported to be naturalised in two sites outside its native range; these sites are small areas in South Africa and Hawaii (Simon et al. 2010).

23. Commercial harvesting of potato crops leaves many small tubers in the soil, and the resultant potato volunteers can be a serious problem in subsequent crops (Beattie & Walker 2003; Rahman 1980; Steiner et al. 2005). Volunteer potatoes have been reported to reduce yield in subsequent row crops such as onions and carrots by up to 90%, and can affect yield even in competitive crops such as wheat. Volunteer potatoes can also harbour diseases or pests or contaminate harvests of rotation crops (Steiner et al. 2005).

24. A survey of farms in Ireland using standard management practices found an average of 29,000 potato volunteers per hectare in the first rotation cereal crop grown after potato, and an average of 3,700 volunteers per hectare in the second crop (Phelan et al. 2015). For comparison, the planting density of commercial potato crops ranges between 32,000 – 66,000 plants per hectare (Jackson et al. 1997; Steiner et al. 2005). If potato volunteers are not effectively controlled, soil tuber density can increase over a season (Steiner et al. 2005). In Tasmania, where most crops grown are not competitive with potato, potato volunteers have been recorded at 500 plants per hectare up to 9 years after harvest of a potato crop (Beattie & Walker 2003).

25. Potato tubers, in general, are inherently dormant for a period prior to the eyes sprouting. The average length of tuber dormancy for different commercial cultivars ranges from less than one month to over nine months after harvest (Suttle 2007). In some cultivars a small proportion of the tubers can remain dormant but viable for at least 18 months (Askew & Struik 2007). The period of dormancy is longer by several weeks for smaller (younger) tubers than for larger (older) tubers. Tubers will not sprout at all at temperatures less than 3°C, and the length of dormancy decreases as soil temperature increases between 3 - 25°C (Muthoni et al. 2014; Suttle 2007). Once dormancy ends, the time to emergence of volunteer potato shoots varies depending on depth of burial of the parent tuber (Rahman 1980).

26. Control of volunteer potatoes growing from tubers can be challenging due to the food reserves of the buried tubers. Cultivation or application of contact herbicide to a volunteer will only kill the above-ground parts of the plant, and the parent tuber is likely to re-sprout from another eye, so several sequential treatments would be required. Also, any daughter tubers produced by a volunteer can survive destruction of the above-ground plant and sprout after dormancy ends. Glyphosate is a systemic herbicide that will kill the above-ground plant and daughter tubers, but will not kill any unemerged sprouts on the parent tuber, so is most effective when applied after all sprouts have

emerged. Hand-weeding volunteer potatoes, although labour-intensive, provides effective control (Rahman 1980; Steiner et al. 2005).

27. Potato seeds are typically dormant for about 6 months (Plaisted 1980). However, a Scottish field study using highly fertile potato cultivars producing up to 1000 seed/m^2 found that seeds survived and produced volunteers for at least seven years (Lawson 1983). Potato plants grown from true seed are smaller and less vigorous than plants grown from tubers (Askew & Struik 2007).

28. There is little information available regarding dispersal of potato berries. However, potato berries have high levels of bitter and toxic glycoalkaloids (see Biochemistry section below), and in other *Solanum* berries glycoalkaloids are reported to deter herbivory by birds and small mammals (Cipollini & Levey 1997). Feral pigs and deer, which are both present in south-east Queensland, can dig up and eat potato tubers (DAFF 2013; Land Protection Council 2004). However, dispersal of tubers is most likely to occur through human activity, for instance post-harvest transport, use of unmarketable tubers as stock feed, or disposal of cull potatoes or potato waste.

4.5 Biochemistry

29. Potato plants naturally produce toxic glycoalkaloids, primarily the compounds α-solanine and α-chaconine, as a defence mechanism against pathogens and predators (Cardenas et al. 2016). Glycoalkaloids are synthesized in all parts of the plant with the highest levels found in sprouts, new leaves, flowers and berries (Friedman & McDonald 1997). The maximum safe level of glycoalkaloids in potato tubers is considered to be 200 mg/kg, and the levels of glycoalkaloids in commercial potatoes are about 75 mg/kg (Beier 1990; OECD 2002). However, glycoalkaloid synthesis in potatoes is increased by exposure of tubers to light, which also causes visible greening, or by mechanical damage to the tubers. Human consumption of green or sprouted potatoes can lead to illness or in rare cases death (Beier 1990; Friedman & McDonald 1997). The symptoms of mild glycoalkaloid poisoning include gastrointestinal disorders and headaches, and at higher doses hallucinations, delirium and coma (Beier 1990; Friedman & McDonald 1997; OECD 2002).

30. There are reports of allergic reactions to raw potato for adults and to cooked potato for young children. The main allergenic protein in potato is the storage protein patatin (OECD 2002; Zaheer & Akhtar 2016).

31. Potato products processed at high temperatures, such as French fries and potato chips, contain acrylamide generated by a reaction between asparagine and sugars. Acrylamide is classified by the International Agency for Research on Cancer as a probable carcinogen (Zaheer & Akhtar 2016).

4.6 Cultivars

32. The cultivar proposed to be genetically modified is Russet Burbank. This is the main potato variety processed for French fries in Australia (Wilson 2010) and worldwide (Bethke et al. 2014). Russet Burbank potato plants mature late and produce about 8-14 tubers per plant. The tubers have long dormancy, which improves their storability (Bethke et al. 2014; Wilson 2010). Russet Burbank potato plants are male-sterile (Bethke et al. 2014; USDA-APHIS 2015). They also have low female fertility due to few flowers (USDA-APHIS 2015; Wilson 2010) and ready loss of flowers due to premature abscission (McLean & Stevensen 1952).

33. The applicant proposes to grow the cultivar Ruby Lou as a non-GM control, as Ruby Lou potatoes are naturally resistant to Potato virus X. Ruby Lou is an Australian potato variety sold for the fresh market. The plant matures early, produces about 8 tubers per plant, and has short tuber dormancy (Dawson 2016). Ruby Lou potato plants are fertile and have been used as either female and male parents in breeding crosses (Dawson 2006).

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

5.1 Introduction to the GMOs

34. The applicant proposes to release GM Russet Burbank potatoes containing three introduced disease resistance genes (Table 1). One of the genes confers resistance to Potato virus X (PVX) and two genes confer resistance to the late blight pathogen *Phytophthora infestans*. The genes are present either singly or in combination, with a total of seven different gene combinations possible.

35. The introduced genes were derived from either a commercial potato cultivar or a wild potato species. Each introduced gene is controlled by its native promoter and terminator (Table 1).

Table 1 Genes introduced into the GM potato lines

Gene	Description	Promoter	Terminator	Source
Rx	PVX resistance gene	pRx	tRx	*Solanum tuberosum* cultivar "Cara"
Rpi-blb1	*P. infestans* resistance gene 1	pRpi-blb1	tRpi-blb1	*Solanum bulbocastanum*
Rpi-blb2	*P. infestans* resistance gene 2	pRpi-blb2	tRpi-blb2	*Solanum bulbocastanum*

36. The applicant proposes to release up to 5,000 lines of GM potato. The lines were produced using *Agrobacterium tumefaciens* mediated plant transformation. Information about this transformation method can be found in the document *Methods of plant genetic modification* available from the OGTR Risk Assessment References page.

37. When first generated, the GM potato lines contained the antibiotic resistance selectable marker gene *nptII* (neomycin phosphotransferase type II) from the common gut bacterium *Escherichia coli*. The *nptII* gene was used during initial development of the GMOs in the laboratory to select plant cells containing the introduced genes. However, prior to growing the GM potato plants, the *nptII* gene was excised using an inducible recombinase system (Righetti et al. 2014; Schaart et al. 2004), as described in the RARMP for DIR 146. The GM potato lines were screened using the polymerase chain reaction to confirm the absence of both *nptII* and sequences associated with the excision:recombination system. The applicant has indicated that following excision, only an 84 base pair non-coding sequence from a recombination site remains in the GM potato plants. Therefore, the only introduced genes present in the GM potatoes proposed for release are the genes listed in Table 1.

5.2 The introduced genes, encoded proteins and their associated effects

38. The three genes introduced into the GM potatoes encode resistance genes that are involved in defence against plant pathogens. An introduction to plant-pathogen interactions is found in the RARMP for DIR 146.

5.2.1 The Rx gene

39. The *Rx* gene is present in many commercial potato cultivars produced by conventional plant breeding (Nyalugwe et al. 2012; van der Voort et al. 1999). In some cultivars the *Rx* gene was introgressed from the wild potato species *Solanum acaule* (Bendahmane et al. 1999), and in other cultivars *Rx* was introgressed from the wild potato *Solanum tuberosum* subsp. *andigena* (van der Voort et al. 1999).

40. The protein encoded by the *Rx* gene is a member of the NBS-LRR (nucleotide binding site-leucine rich repeat) family, which is the largest class of plant resistance proteins (Bendahmane et al. 1999). The Rx protein is a receptor that recognises the presence of the Potato virus X coat protein (Bendahmane et al. 1995), or the coat proteins of other Potexviruses (Baures et al. 2008), and triggers a virus defence response. *Rx*-mediated resistance to PVX is unusual in that it is not associated with a

hypersensitive response and cell necrosis. Instead, *Rx*-mediated resistance rapidly suppresses PVX accumulation in the initially infected cells (Bendahmane et al. 1999).

5.2.2 The Rpi-blb1 and Rpi-blb2 genes

41. The *Rpi-blb1* (also known as *RB*) and *Rpi-blb2* genes are derived from the wild potato species *Solanum bulbocastanum*, which is native to Mexico and Guatemala (Song et al. 2003; van der Vossen et al. 2003; van der Vossen et al. 2005). *S. bulbocastrum* is highly resistant to all known races of the pathogen *Phytophthora infestans* that causes potato late blight (Song et al. 2003). *S. bulbocastanum* is not sexually compatible with cultivated potato (Song et al. 2003; van der Vossen et al. 2003). However, through a series of bridge crosses and over forty years of breeding, the *Rpi-blb2* gene was introgressed into the Bionica and Toluca late blight-resistant potato cultivars, which are currently grown in Europe (Haverkort et al. 2009).

42. The Rpi-blb1 and Rpi-blb2 proteins belong to the coiled coil subset of NBS-LRR plant resistance proteins. Both *Rpi-blb1* and *Rpi-blb2* confer broad-spectrum resistance to different late blight isolates (Song et al. 2003; van der Vossen et al. 2003; van der Vossen et al. 2005). In *Rpi-blb1*-mediated resistance a hypersensitive cell death response is triggered by the IPI-O protein secreted by *P. infestans.* In *Rpi-blb2*-mediated resistance the hypersensitive response is triggered by a separate family of effector proteins secreted by *P. infestans* (Oh et al. 2009).

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

43. The Rx protein is present in many commercial potato cultivars (Nyalugwe et al. 2012; van der Voort et al. 1999). It is regularly consumed by humans and livestock without adverse effects.

44. The applicant has previously generated GM potato plants containing the *Rx* gene for glasshouse trials. Staff who handled these GM potatoes did not report any health effects or allergic reactions.

45. The Rpi-blb2 protein is present in the potato cultivars Bionica and Toluca. These varieties have been grown in Europe for several years, particularly in organic farming, and have a history of safe use (VIB et al. 2015).

46. Most plant resistance genes have a low basal level of constitutive expression (Kramer et al. 2009). For instance, in a GM potato with an introduced *Rpi-blb1* gene controlled by its native regulatory sequences, the Rpi-blb1 protein was undetectable by the standard technique for measuring protein levels, and the protein concentration was estimated as less than 18 parts per trillion (Bushey et al. 2014).

47. Bioinformatic analysis may assist in the assessment process by predicting, on a purely theoretical basis, allergenic potential of a protein. The results of such analyses are not definitive and should be used only to identify those proteins requiring more rigorous testing. The applicant evaluated the degrees of similarity between each introduced protein product and allergenic proteins listed in the AllergenOnline database from the Food Allergy Research and Resource Program using the FASTA3 sequence alignment program (Pearson 2000). A match of at least 35% identity over a segment of at least 80 amino acids with a known allergen may indicate cross-reactivity (Codex Alimentarius Commission 2003). None of the three introduced proteins had such matches with any of the known allergens in the database.

5.4 Characterisation of the GMOs

48. The GM plants will be screened using the polymerase chain reaction to confirm that the intended introduced gene/s are present and that no unwanted vector sequence is present. The GM potatoes will also be screened by Southern hybridisation and only those containing single copies of the introduced gene/s would be grown in the field.

49. The applicant has not provided any quantitative expression analysis data.

50. The applicant has grown GM Russet Burbank potatoes containing the *Rx* gene under glasshouse conditions. No phenotypic changes or growth advantages over non-GM potatoes were observed.

Section 6 The receiving environment

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

6.1 Relevant abiotic factors

52. The release is proposed to take place at the DAF Redlands Research Facility near Brisbane. The proposed trial site is about 300 m from a stream and has never been known to flood. The site is flat and not prone to heavy runoff.

53. Potato leaves are damaged by air temperatures below 0°C (Jackson et al. 1997). Soil temperatures below -1.5°C injure buried tubers (Boydston et al. 2006). Since 1999, the lowest temperature recorded in Brisbane was 2.6°C (Bureau of Meteorology website), so potatoes are unlikely to suffer from frost damage.

54. The optimum temperature for potato growth is 21°C, and growth is severely restricted when the temperature is below 7°C or exceeds 30°C (Western Potato Council 2003). Mean climate records show that during summer in Brisbane 48% of days have maximum temperatures above 30°C (Bureau of Meteorology website), so potatoes could suffer from heat stress. The applicant is not proposing to grow potatoes during the summer.

55. Potatoes are shallow-rooted plants and are very sensitive to water stress (Jackson et al. 1997; Western Potato Council 2003). A crop of potatoes requires 400 – 500 mm of water, or more in hot weather, over a growth period of about four months (Western Potato Council 2003). The average rainfall in Brisbane is 85 mm per month (Bureau of Meteorology website), so rain-fed potatoes would be likely to suffer from water stress. The applicant proposes to irrigate the GM potatoes using overhead sprinklers or drip irrigation.

6.2 Relevant biotic factors

56. Potato plants are susceptible to a wide range of pests and diseases that can severely reduce tuber yield and quality. Potatoes must be rotated with other crops to prevent the build-up of insects and soil-borne diseases, and a four-year rotation is recommended (Western Potato Council 2003). In Queensland, common insect pests of potatoes include cutworms, aphids and potato tuber moth, and common diseases include early blight fungus, sclerotina rot fungus, leaf roll virus and bacterial wilt (Jackson et al. 1997).

57. The GM potatoes proposed for release are resistant to late blight and/or potato virus X diseases. Late blight, caused by the oomycete *Phytophthora infestans*, is the most severe potato disease worldwide, causing annual losses of approximately 16% of the global potato crop (Haverkort et al. 2009). Late blight is present in Australia but only as a less aggressive strain. This causes sporadic and localised disease outbreaks, primarily in Victoria and Tasmania. Global strains of late blight produce spores that can survive in soil for several years but the Australian strain can only survive on infected plants. Global strains of late blight are often resistant to commonly used fungicides but the Australian strain can still be effectively controlled by metalaxyl-based fungicides. Potential incursions of exotic strains of late blight into Australia are a concern for the potato industry (Edwards 2006).

58. The disease Potato virus X is widely distributed in Australia and worldwide. PVX typically causes mild mosaic symptoms or is symptomless. However, mixed infections of potato plants with PVX and other viruses (e.g. Potato virus Y) cause synergistic disease with more severe symptoms (Koenig &

Lesemann 1989; Nyalugwe et al. 2012). PVX is spread by mechanical contact, especially on agricultural equipment. The most effective means of protection is the use of potato cultivars that contain resistance genes (Koenig & Lesemann 1989).

6.3 Relevant agricultural practices

59. The applicant proposes that the GM planting material will be tubers harvested from tissue-cultured plants grown in a greenhouse. This is a standard means of producing Generation 1 seed potatoes in Australia (AUSVEG 2007). The applicant also intends to plant commercial non-GM Ruby Lou seed potatoes as comparators.

60. Potatoes do not grow well in compacted soil and the applicant proposes to use standard land preparation practices to produce a deep, loose seedbed at the time of planting (Jackson et al. 1997). The tubers would be planted by hand. The tubers would be planted with a row width of 75-90 cm, plant spacing of 20-30 cm, and planting depth of 10-15 cm, which all fall in the normal range for Queensland potato crops (Jackson et al. 1997).

61. Plants would be fertilized by periodic on-ground application of granular fertilizer. Weeds would be controlled by herbicides or manual hoeing. Pests and diseases would be controlled by spraying with appropriate chemicals as necessary.

62. The potato tubers would be harvested manually, using a shovel or mattock to dig deeply around each plant in order to dig up all tubers. Non-viable plant material would be left on the trial site to decompose. Any plants that are not harvested would be killed by a herbicide such as glyphosate.

63. GM potatoes would be planted several times over the course of the proposed field trial. In different seasons, potatoes would be planted on adjacent areas of the site rather than replanted on the same area, to avoid issues of volunteer potatoes growing in the crop.

6.4 Presence of related plants in the receiving environment

64. The only plants sexually compatible with potato in the Australian environment are other potato plants (Section 4.3). The proposed trial site is on an agricultural research station. The applicant reports that a plot of non-GM potato is currently growing on the research station approximately 300 m from the proposed trial site. There may also be potatoes growing in domestic gardens in the residential areas adjoining the research station. The nearest known potato farm is located approximately 2.5 km from the proposed trial site.

6.5 Presence of similar genes and encoded proteins in the environment

65. The *Rx* gene and its encoded protein are present in several commercial potato cultivars grown in Australia (Nyalugwe et al. 2012). These include Ruby Lou (Section 4.6) and Atlantic, which is the main potato variety processed for crisps in Australia (Wilson 2010) and is grown in Queensland (Jackson et al. 1997).

66. The *Rpi-blb1* and *Rpi-blb2* genes are derived from the wild potato *S. bulbocastanum*, which is not present in Australia. The commercial non-GM potato cultivars Bionica and Toluca contain the *Rpi-blb2* gene introduced by conventional cross-breeding (Haverkort et al. 2009), but these cultivars are not reported to be grown in Australia.

67. Genes homologous to *Rpi-blb1* and *Rpi-blb2* are present in the Australian environment. *Rpi-blb1* is 89% identical to the *SH20* plant resistance gene from cultivated potato (van der Vossen et al. 2003), and *Rpi-blb2* is 89% identical to the *Mi-1* plant resistance gene from tomato (van der Vossen et al. 2005). BLASTN searches conducted for both genes in January 2017 also found that *Rpi-blb2* has 88% identity to a *Mi* gene from *Capsicum annuum* (sweet and hot pepper) and 89% identity to a predicted resistance gene from potato. Potatoes, tomatoes and peppers are grown commercially and in domestic gardens in Australia.

Section 7 Relevant Australian and international approvals

7.1 Australian approvals

7.1.1 Approvals by the Regulator

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

69. The Regulator has not received any previous applications for release of GM potato. Six field trials of GM potato were conducted in Australia in the 1990s, including four trials of potatoes genetically modified for disease resistance. These trials were assessed by the Genetic Manipulation Advisory Committee under the former voluntary system in place prior to commencement of the Act.

7.1.2 Approvals by other government agencies

70. There are no approvals of these GM potato lines, including pending approvals, from other Australian authorities.

7.2 International approvals

71. None of the GM potato lines covered in this application have been approved for release in any other countries.

72. Fortuna GM potato, containing the two genes for late blight disease resistance included in this application, was approved for field trials in six countries of the European Union from 2006.

73. Innate™ Russet Burbank GM potato, containing a different gene for late blight disease resistance, was approved for commercial cultivation in the United States in 2015 (United States Department of Agriculture - Petitions).

Chapter 2 Risk assessment

Section 1 Introduction

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

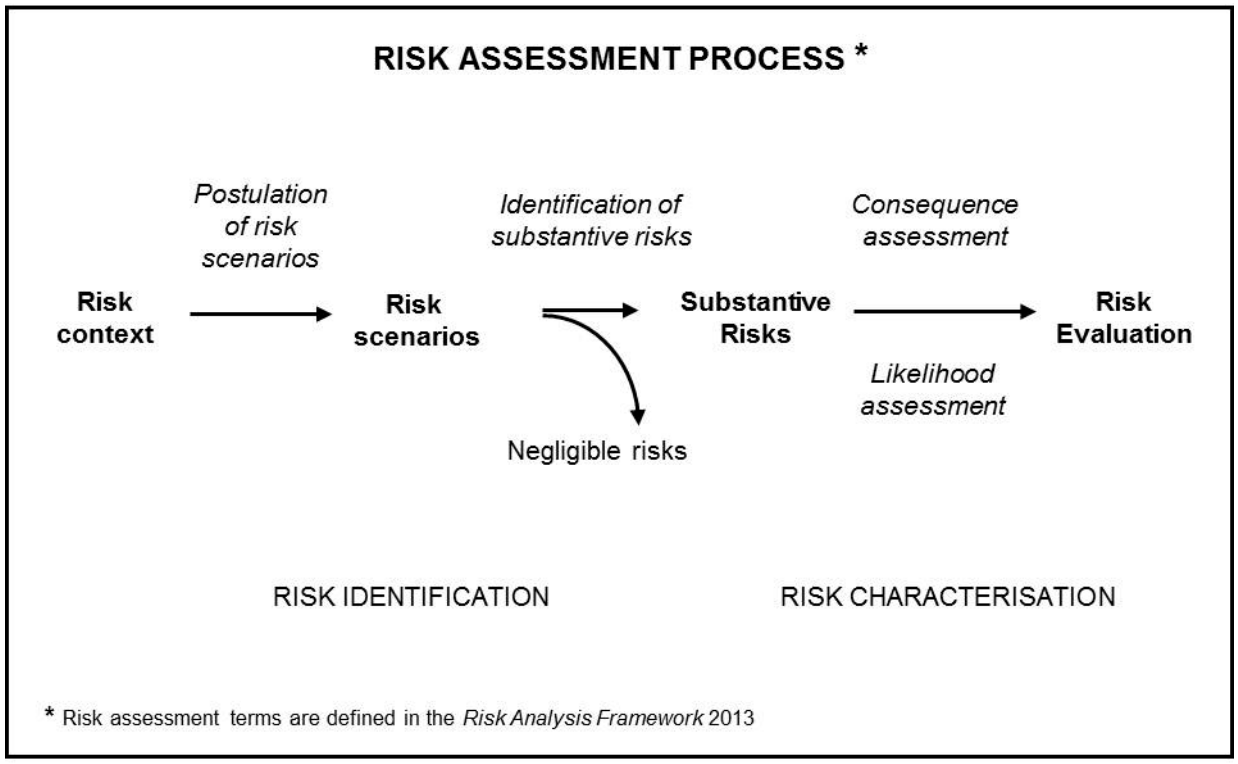

Figure 2. The risk assessment process

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

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

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

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

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

Section 2 Risk Identification

79. 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.

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

- the proposed dealings, which may be to conduct experiments, develop, produce, breed, propagate, grow, import, transport or dispose of the GMOs, use the GMOs in the course of manufacture of a thing that is not the GMO, and the possession, supply and use of the GMOs in the course of any of these dealings
- the proposed limits including the extent and scale of the proposed dealings
- the proposed controls to limit the spread and persistence of the GMO and
- the characteristics of the parent organism(s).

2.1 Risk source

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

82. As discussed in Chapter 1, the GM potato lines have been modified by the introduction of one or more of three genes derived from the potato species *S. tuberosum* or *S. bulbocastanum*. These introduced genes are considered further as potential sources of risk.

83. The introduced genes have been inserted together with their native regulatory sequences. Thus, the GM potatoes contain introduced regulatory sequences derived from *S. tuberosum* or *S. bulbocastanum.* 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, potential harms from the regulatory elements will not be considered further. However, the introduced regulatory sequences, especially the promoters, control gene expression and hence the distribution and concentration of the proteins derived from the introduced genes in the GM plants. The effects of protein levels, especially in relation to toxicity and allergenicity, will be considered below.

84. The use of an excisable marker gene system results in an 84 base pair non-coding sequence from the recombination site remaining in the GM potato lines (Chapter 1, Section 5.1). As this DNA is not expressed as a protein and dietary DNA has no toxicity (Society of Toxicology 2003), this sequence will not be further considered as a potential source of risk.

85. The genetic modifications have the potential to cause unintended effects in several ways including altered expression of endogenous genes by random insertion of introduced DNA in the genome, increased metabolic burden due to expression of the introduced proteins, novel traits arising out of interactions with non-target proteins and secondary effects arising from altered substrate or product levels in biochemical pathways. However, these types of effects also occur spontaneously and in plants generated by conventional breeding. Accepted conventional breeding techniques such as hybridisation, mutagenesis and somaclonal variation can have a much larger impact on the plant genome than genetic engineering (Schnell et al. 2015). Plants generated by conventional breeding

have a long history of safe use, and there are no documented cases where conventional breeding has resulted in the production of a novel toxin or allergen in a crop (Steiner et al. 2013). Therefore, the potential for the processes of genetic modification to result in unintended effects will not be considered further.

2.2 Causal pathway

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

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

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

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

89. 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

90. Potential harms from GM plants include:

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

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

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

2.4 Postulated risk scenarios

92. Three risk scenarios were postulated and screened to identify substantive risk. These scenarios are summarised in Table 2, and discussed individually below. Postulation of risk scenarios considers impacts of the GM potato or its products on people undertaking the dealings, as well as impacts on people and the environment if the GM plants or genetic material were to spread and/or persist.

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

Table 2 Summary of risk scenarios from the proposed dealings

Risk scenario	Risk source	Causal pathway	Potential harm/s	Substantive risk?	Reasons
1	Introduced disease resistance genes	Growing GM potato plants at the trial site ⬇ Expression of introduced genes in GM plants ⬇ Exposure of people who deal with the GM plant material or of other organisms that come into contact with the GM plant material in the trial site	Toxicity or allergenicity to people or toxicity to desirable organisms	No	• GM plant material would not be used in human food or animal feed. • The small scale of the trial and other proposed limits and controls would minimise exposure of people and other organisms to the GM plant material. • The introduced proteins are unlikely to be toxic or allergenic.
2	Introduced disease resistance genes	Growing GM potato plants at the trial site ⬇ Persistence of GM propagules after completion of the trial or dispersal of GM propagules outside the trial site ⬇ Establishment of volunteer GM plants in the environment ⬇ Expression of introduced genes in the volunteer plants	Toxicity or allergenicity to people or toxicity to desirable organisms OR Reduced establishment or yield of desirable plants	No	• The proposed limits and controls would minimise persistence or dispersal of the GM plants. • Potatoes have limited ability to survive outside cultivation. • The introduced proteins are not expected to increase the ability of the GM potato to become a weed.

Risk scenario	Risk source	Causal pathway	Potential harm/s	Substantive risk?	Reasons
3	Introduced disease resistance genes	Growing GM potato plants at the trial site ⬇ Pollen from GM plants fertilises sexually compatible plants outside the trial site ⬇ Establishment of volunteer plants that express the introduced genes in the environment	Toxicity or allergenicity to people or toxicity to desirable organisms OR Reduced establishment or yield of desirable plants	No	• The GM Russet Burbank potatoes do not produce viable pollen. • The proposed controls would minimise generation of hybrid plants that could produce viable GM pollen.

2.4.1 Risk scenario 1

Risk source	Introduced disease resistance genes
Causal pathway	⬇ Growing GM potato plants at the trial site ⬇ Expression of introduced genes in GM plants ⬇ Exposure of people who deal with the GM plant material or of other organisms that come into contact with the GM plant material in the trial site ⬇
Potential harm	Toxicity or allergenicity to people or toxicity to desirable organisms

Risk source

94. The source of potential harm for this postulated risk scenario is the introduced disease resistance genes.

Causal pathway

95. GM potatoes containing the introduced genes would be grown on the trial site. The introduced disease resistance genes are expected to be constitutively expressed at low levels in the plant tissues. People who are involved in cultivating, harvesting, transporting and analysing the GM potato could be exposed to the introduced proteins through skin contact with plants or by inadvertent inhalation or ingestion of small quantities of plant material.

96. Animals that are present in the trial site could feed on the GM plant material. However, potato plants produce bitter and toxic glycoalkaloids that would limit their palatability for most birds and mammals (see Chapter 1, Sections 4.4 and 4.5). As a number of insect pests feed on potato crops in Queensland (Jackson et al. 1997), it is expected that invertebrates would be exposed to the introduced proteins.

97. The proposed limits and controls of the trial would minimise the exposure of people or other organisms to GM plant material. The GM plant material would not be used for human food or animal feed. The site would only be accessed by authorised people and would be surrounded by a fence to exclude livestock and other large animals. As the proposed trial is limited to one site with a maximum cumulative planting area of 0.1 ha over two years, only a small number of people would deal with the GM plant material and a restricted number of organisms would be exposed to it.

Potential harm

98. 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).

99. The *Rx* gene is derived from a potato cultivar, and is present in many potato cultivars grown in Australia and worldwide (Nyalugwe et al. 2012; van der Voort et al. 1999). People and animals have widely consumed the Rx protein in potatoes for many years and it has a history of safe use. As the introduced *Rx* gene is controlled by its native regulatory sequences, expression levels in the GM potato would be similar to expression levels in potato cultivars that naturally contain the *Rx* gene. Thus, exposure to the Rx protein in the GM potatoes would not be expected to cause toxic or allergenic effects.

100. The *Rpi-blb2* gene, derived from the wild potato *S. bulbocastanum*, has been introgressed into potato germplasm by conventional breeding techniques. Two potato cultivars containing the Rpi-blb2 protein have been grown and consumed in Europe for several years, so the protein has some history of safe use (VIB et al. 2015). Rpi-blb2 is homologous to the Mi-1 protein from tomato (van der Vossen et al. 2005) which is widely consumed and not known to lead to toxic or allergenic effects. A bioinformatic comparison of the Rpi-blb2 protein to a database of known allergens did not identify any matches.

101. The Rpi-blb1 protein is homologous to the SH20 potato disease resistance protein (van der Vossen et al. 2003), which is widely consumed and not known to cause toxicity or allergenicity. In a different GM potato where the *Rpi-blb1* gene was introduced and controlled by its native regulatory sequences, the level of the Rpi-blb1 protein was undetectable and estimated to be extremely low (Bushey et al. 2014). Even if the Rpi-blb1 protein were inherently toxic, exposure to the protein at extremely low concentrations would be unlikely to elicit any toxic effects. A bioinformatic comparison of the Rpi-blb1 protein to a database of known allergens did not identify any matches.

102. Plant proteins that are toxic to humans or animals fall into eight main families (Dang & Van Damme 2015). The three introduced proteins in the GM potato are members of the NBS-LRR family of plant resistance proteins (Chapter 1, Section 5.2), which is not one of the families known to contain toxic proteins.

103. Potatoes naturally produce toxic glycoalkaloids as a defence against pathogens and predators (see Chapter 1, Section 4.5). The introduced disease resistance genes are not involved in biosynthesis of these toxins, but resistance proteins are also part of the plant defence system. Typically, activation of resistance proteins triggers a hypersensitive cell death response; however, it is possible that there would also be cross-talk with other plant defence mechanisms. A recent study found that in GM potato plants containing Rpi-blb1, challenge with *P. infestans* caused up-regulation of ethylene metabolism genes, which did not occur in control potato plants susceptible to late blight (Gao & Bradeen 2016). The genes regulating synthesis of glycoalkaloids in potato include ethylene responsive transcription factors (Cardenas et al. 2016). Although no direct evidence was found in the literature that activation of the introduced plant resistance proteins could induce increased production of glycoalkaloid toxins, this is an area of uncertainty.

104. The applicant is proposing to challenge GM potato plants with Potato virus X, which is expected to activate the introduced Rx protein. However, the Rx protein is present in a number of Australian potato cultivars and PVX is widespread in Australia (Nyalugwe et al. 2012), so even if activation of Rx does induce increased production of glycoalkaloids, this effect must occur frequently in Australian potato crops and would not increase glycoalkaloid concentration outside the normal range. The applicant is not proposing to challenge the GM potato plants with *P. infestans*, and late blight outbreaks are rare in Queensland (Edwards 2006), so it is unlikely that the introduced Rpi-blb1 or Rpi-blb2 proteins would be activated or would have any effect on glycoalkaloid levels.

105. ***Conclusion***: Risk scenario 1 is not identified as a substantive risk because the proposed limits and controls would minimise exposure of people and other organisms to the GM plant material and because the introduced proteins are unlikely to be toxic or allergenic to people or toxic to animals.

Therefore, this risk could not be greater than negligible and does not warrant further detailed assessment.

2.4.2 Risk scenario 2

Risk source	Introduced disease resistance genes
Causal pathway	⬇ Growing GM potato plants at the trial site ⬇ Persistence of GM propagules after completion of the trial or dispersal of GM propagules outside the trial site ⬇ Establishment of volunteer GM plants in the environment ⬇ Expression of introduced genes in the volunteer plants ⬇
Potential harm	Toxicity or allergenicity to people or toxicity to desirable organisms OR Reduced establishment or yield of desirable plants

Risk source

106. The source of potential harm for this postulated risk scenario is the introduced disease resistance genes.

Causal pathway

107. GM potatoes would be grown on the trial site and would produce propagules. Potatoes can propagate either vegetatively, through tubers, or sexually, through seed-bearing berries.

108. The GM potato cultivar is Russet Burbank, which produces about 8-14 tubers per plant (Wilson 2010). Commercial potato harvesting machinery leaves many small tubers in the field (Steiner et al. 2005), but the applicant proposes to harvest potato plants manually, which is expected to retrieve a higher proportion of the tubers. Tubers remaining in the soil are typically dormant for several months then sprout as volunteers in the next growing season; however, in some cultivars a proportion of tubers can lie dormant but viable for at least 18 months (Askew & Struik 2007). Potato volunteers begin initiation of daughter tubers 2-4 weeks after emergence (Jackson et al. 1997). The applicant proposes post-harvest inspections of the trial site every 60 days for at least two years and until the trial site has been free of volunteers for at least one year. Any potato volunteers found would be destroyed by application of a herbicide such as glyphosate, which is also expected to kill daughter tubers (Rahman 1980). These controls would minimise the likelihood of persistence of GM potato tubers on the trial site.

109. Transport of GM potato tubers to and from the trial site would be conducted in accordance with the Regulator's *Guidelines for the Transport, Storage and Disposal of GMOs.* The applicant proposes that agricultural machinery used in connection with the GMOs would be cleaned prior to removal from the site. These controls would minimise the likelihood of dispersal of GM potato tubers from the trial site by human activity. Although feral pigs or deer are able to dig up and feed on potato tubers (see Chapter 1, Section 4.4), the proposed trial site is surrounded by a fence that would exclude large animals. Some small animals may be able to burrow down to potato tubers, but are much more likely to feed *in situ* than to completely excavate and remove tubers. Thus, there is little opportunity for dispersal of GM potato tubers from the trial site by animal activity. Underground potato tubers could not plausibly be dispersed by wind or water, unless flooding caused severe erosion. The selection of a proposed trial site that is flat, 300 m from the nearest waterway, and has never been known to flood minimises the possibility of dispersal of GM potato tubers due to flooding.

110. The proposed controls of the trial would minimise the production of GM potato seed. Potato plants grown on the trial site during the trial would be deflowered prior to formation of viable seed. Post-harvest, the site would be inspected for at least two years and until the trial site has been free of volunteers for at least one year, and any potato volunteers found would be destroyed prior to production of viable seed. These measures would minimise the potential for persistence or dispersal of GM potato seed.

Potential harm

111. As discussed in Risk Scenario 1, the GM potato plants are not expected to be more toxic or allergenic than non-GM potato plants. This would apply even if the GM potato plants established beyond the trial limits.

112. GM potato plants established beyond the trial limits could potentially reduce the establishment or yield of desirable plants through competition. Outside of cultivated areas, potatoes generally do not compete successfully (Love 1994). Although potatoes have been grown in Australia since the early days of European settlement, potato plants have not naturalised anywhere in Australia (Groves et al. 2003; Simon et al. 2010). In cultivated areas, volunteers emerging after a potato crop can be problematic weeds in subsequent crops and lead to significant yield loss (see Chapter 1, Section 4.4). However, this is attributed to the high density of potato tubers left in the field after commercial harvesting, which a recent field survey measured as between 39,000 – 210,000 tubers per hectare (Phelan et al. 2015). Even if GM potato propagules dispersed into cultivated areas beyond the trial limits, they would be present at very low density in comparative terms, and would be unlikely to cause yield loss.

113. The introduced genes in the GM potato confer either resistance to potato virus X or resistance to late blight. PVX typically causes mild mosaic symptoms or is symptomless (Koenig & Lesemann 1989; Nyalugwe et al. 2012) and late blight outbreaks are rare in Queensland (Edwards 2006); neither PVX nor late blight are listed among the main diseases that affect Queensland potato crops (Jackson et al. 1997; Queensland Department of Agriculture and Fisheries website). Therefore, the genetic modifications would have a minimal effect on the ability of GM potato volunteers to survive disease pressure in the environment. The genetic modifications are not expected to alter the reproductive or dispersal characteristics of the GM plants, to increase the ability of the GM plants to establish in competition with other plants, or to increase the ability of the GM plants to survive standard weed management practices. Thus, the GM potato is not considered to have higher weediness potential than non-GM potato.

Conclusion: Risk scenario 2 is not identified as a substantive risk because the proposed limits and controls would minimise persistence or dispersal of the GM potato, potato has limited ability to survive outside cultivation, and the genetic modifications would not increase the ability of the GM potato to become a weed. Therefore, this risk could not be greater than negligible and does not warrant further detailed assessment.

2.4.3 Risk scenario 3

Risk source	Introduced disease resistance genes
Causal pathway	⬇ Growing GM potato plants at the trial site ⬇ Pollen from GM plants fertilises sexually compatible plants outside the trial site ⬇ Establishment of volunteer plants that express the introduced genes in the environment ⬇
Potential harms	Toxicity or allergenicity to people or toxicity to desirable organisms OR Reduced establishment or yield of desirable plants

Risk source

114. The source of potential harm for this postulated risk scenario is the introduced disease resistance genes.

Causal Pathway

115. GM potatoes of cultivar Russet Burbank would be grown on the trial site. Russet Burbank potato plants do not produce viable pollen (Bethke et al. 2014; USDA-APHIS 2015). Therefore, there could not be pollen flow from GM potato plants deliberately grown on the trial site to sexually compatible plants outside the trial site.

116. The applicant proposes to grow non-GM potatoes of cultivar Ruby Lou on the trial site. If Ruby Lou potatoes pollinated the GM Russet Burbank potatoes, the hybrid seed could grow into volunteer potatoes that both contain the introduced genes and produce viable pollen. While potatoes are being grown on the trial site, the applicant proposes to deflower the potato plants prior to formation of viable seed. Post-harvest, the site would be inspected for at least two years and until the trial site has been free of volunteers for at least one year, and any potato volunteers found would be destroyed prior to production of viable seed. These controls would minimise production of hybrid seed, and thus the potential for pollen flow from hybrid GM potato volunteers to sexually compatible plants outside the trial site.

117. Potatoes are not sexually compatible with any plant species found in Australia except other potatoes (see Chapter 1, Section 4.3). Even if the GM potatoes pollinated a commercial potato crop, this would not lead to a GM product entering food. The part of the potato plant which is eaten by humans or livestock is the tuber, part of the root system, whereas pollination only affects the seeds. Similarly, even if the GM potatoes pollinated a seed potato crop, the seed potatoes used for further planting are tubers and are not affected by pollination.

Potential harms

118. As discussed in Risk Scenario 1, the GM potato plants are not expected to be more toxic or allergenic than non-GM potato plants. As discussed in Risk scenario 2, the GM potato plants are not expected to have higher weediness potential than non-GM potato plants. These findings would also apply to GM plants growing outside the trial limits as a result of pollen flow.

Conclusion: Risk scenario 3 is not identified as a substantive risk because the GM Russet Burbank potatoes do not have viable pollen, and the proposed controls minimise production of hybrid GM volunteers that could have viable pollen. Therefore, this risk could not be greater than negligible and does not warrant further detailed assessment.

Section 3 Uncertainty

119. Uncertainty is an intrinsic property of risk analysis and is present in all aspects of risk analysis[1].

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

- uncertainty about facts:
  - knowledge – data gaps, errors, small sample size, use of surrogate data
  - variability – inherent fluctuations or differences over time, space or group, associated with diversity and heterogeneity
- uncertainty about ideas:

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

  - description – expression of ideas with symbols, language or models can be subject to vagueness, ambiguity, context dependence, indeterminacy or under-specificity
  - perception – processing and interpreting risk is shaped by our mental processes and social/cultural circumstances, which vary between individuals and over time.

121. 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.

122. 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.

123. For DIR 150, uncertainty is noted particularly in relation to:

- Potential for altered levels of natural potato toxins as a result of the genetic modifications
- Potential for cross-pollination of potato under Australian conditions
- Potential for dispersal or persistence of potato seed under Australian conditions.

124. 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.

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

Section 4 Risk Evaluation

126. 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.

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

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

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

- none of the GM plant material would enter human food or animal feed
- the introduced proteins are unlikely to be toxic or allergenic
- potatoes have limited ability to survive outside cultivation
- the introduced genes are unlikely to increase the ability of the GM potatoes to become a weed
- the GM potatoes do not produce viable pollen
- limits on the size, location and duration of the release proposed by QUT
- suitability of controls proposed by QUT to restrict the spread and persistence of the GM potato plants and their genetic material.

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

Chapter 3 Risk management plan

Section 1 Background

130. 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.

131. 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.

132. 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.

133. 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

134. The risk assessment of risk scenarios listed in Chapter 2 concluded that there are negligible risks to people and the environment from the proposed field trial of GM potato. These risk scenarios were considered in the context of the scale of the proposed release (Chapter 1, Section 3.1), the proposed containment measures (Chapter 1, Section 3.2), and the receiving environment (Chapter 1, Section 6), and considering both the short and the long term. The risk evaluation concluded that no additional 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

135. 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 QUT

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

137. The applicant proposes that the duration of the field trial would be limited to two years. The trial would be limited to a single site with a maximum cumulative planting area of 0.1 ha. The small size and duration of the trial would limit the potential exposure of humans and other organisms to the GMOs (risk scenario 1).

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

139. The applicant proposes that the trial site would be surrounded by a fence that would exclude large animals. This would restrict exposure of desirable organisms to the GMOs (risk scenario 1) and minimise the potential for dispersal of GMOs by large animals (risk scenario 2).

140. The proposed field trial site is approximately 300 m away from the nearest natural waterway. A standard licence condition requires that trial sites be located at least 50 m from waterways. This control would restrict the dispersal of viable GM plant material in the event of flooding (risk scenario 2). A related standard licence condition requires notification of any extreme weather condition affecting the site during the release to allow assessment and management of any risks.

141. The applicant proposes that any non-GM potatoes grown in the trial site would be treated as if they were GMOs. In the event of any uncertainty whether particular plants are GM or non-GM, this standard control would ensure that all GMOs are handled appropriately.

142. The applicant proposes that the GM potato plants would be deflowered prior to production of seed. This control would minimise persistence or dispersal of GM potato seed (risk scenario 2) and pollen flow from hybrid GM potatoes grown from seed (risk scenario 3). Potato flowers grow in groups on inflorescences. The flowers on an inflorescence open over a period of several days, with each flower remaining open for 2-4 days (Plaisted 1980), so an inflorescence would usually contain conspicuous open flowers for a week or more. Russet Burbank potato crops can flower for a period of at least three weeks (Martin et al. 1992). A licence condition requires inspections at least every 7 days during flowering of the GMOs, and that any flower buds, flowers or developing berries found must be removed from the potato plants.

143. The applicant proposes that the GM potatoes would be harvested manually by digging up the plants. As commercial potato harvesting machinery is known to leave many small tubers in the field (Steiner et al. 2005), harvesting manually instead would restrict persistence of GMOs on the trial site (risk scenario 2). An additional licence condition requires that any potato plants that are grown to maturity on the trial site must be harvested manually, rather than destroyed, to ensure removal of viable tubers from the soil.

144. The applicant proposes that machinery used in connection with the GMOs would be cleaned prior to removal from the site. A standard licence condition requires that all equipment used in connection with the GMOs be cleaned as soon as practicable and before use for any other purpose. This control would restrict the potential for dispersal of GMOs by people (risk scenario 2).

145. In order to restrict persistence of GM potato at the trial site (risk scenario 2), the applicant has proposed post-harvest monitoring of the trial site at least once every 60 days for at least two years and until the site is free of volunteer potato plants for at least one year. Any volunteer potato plants found would be destroyed by treatment with a herbicide such as glyphosate.

146. Glyphosate will kill both the above-ground plant and daughter tubers of potato volunteers (Rahman 1980). Similarly, other systemic herbicides may be translocated to and effective in killing daughter tubers during the tuber initiation and bulking stages of volunteer potato growth. However, during the tuber maturation stage, a potato plant is no longer actively growing and frequently the above-ground plant starts dying off (Jackson et al. 1997), so foliage-applied herbicide would not be translocated within the plant. Licence conditions should ensure that post-harvest inspections would

be sufficiently frequent to detect and destroy any potato volunteers prior to the end of the tuber bulking stage.

147. In Queensland, the period between potato plant emergence and the end of tuber bulking is generally 9-12 weeks (Jackson et al. 1997). Russet Burbank is a late-maturing variety (Wilson 2010), so the period between emergence and the end of tuber bulking for the GM plants is estimated as 11-12 weeks. However, these figures apply to irrigated crops; a New Zealand study found that a non-irrigated and severely water stressed Russet Burbank plot reached maturity in approximately 77% of the time required for irrigated plots (Martin et al. 1992). This suggests that under dry conditions in Queensland volunteer potatoes could complete active growth within as few as 59 days, and the proposed post-harvest inspections at least every 60 days may not be sufficiently frequent. Licence conditions require that post-harvest inspections must occur at least every 45 days and that if volunteers are detected, measures to destroy the volunteers must be applied within 7 days. This frequency of inspection and destruction of volunteers would also prevent maturation of seeds on volunteer plants, as earliest production of viable potato seeds occurs approximately 100 days after planting (Plaisted 1980), or at least 65 days after emergence.

148. According to the scientific literature, potato tubers left in the field after harvest usually sprout as volunteers in the following spring, but in some cultivars a small proportion of tubers can lie dormant but viable for at least 18 months (Askew & Struik 2007). Most of the scientific literature on potatoes is from potato growing areas of Europe or North America, which generally have colder climates than the proposed trial site in Queensland. The length of tuber dormancy decreases with increasing soil temperature (Suttle 2007), so tuber dormancy is likely to be shorter in Queensland. The proposed post-harvest inspection period of at least two years, and until the site is free of volunteers for at least one year, is considered appropriate to control persistence of volunteers emerging from potato tubers (risk scenario 2).

149. Potato tubers grow at the end of horizontal stolons that are occasionally as long as 60 cm (Hoyle 1964). As volunteers may emerge at some distance from the parent plant, a licence condition requires that a 1 m buffer zone surrounding the outer edge of a planting area is also subject to post-harvest inspection requirements.

150. Many licences issued by the Regulator for field trials of GM crops require post-harvest tillage and/or irrigation of the trial site to promote germination of dormant seed. However, in the case of potatoes, the period of tuber dormancy is an inherent physiological characteristic and no specific environmental cues are required for dormancy exit (Suttle 2007). The tubers are fully hydrated and contain sufficient energy reserves to sustain a developing plant for twenty or more days (Steiner et al. 2005). Therefore, the licence does not require post-harvest tillage or irrigation of the trial site.

151. The applicant proposes to destroy any GMOs not required for experimentation or future planting. GMOs that are transported to or from the trial site would be transported and stored according to the Regulator's *Guidelines for the transport, storage and disposal of GMOs*. These controls would restrict exposure of people and other organisms to the GMOs (risk scenario 1), and dispersal of GMOs into the environment (risk scenario 2).

152. The applicant does not propose to use GM plant material for human or animal consumption. In addition, FSANZ conducts mandatory premarket assessments of GM products in human foods and the GM potatoes have not been assessed by FSANZ. A condition in the licence prohibits plant material from the trial being used for human food or animal feed. This control would restrict exposure of humans and desirable organisms to the GMOs (risk scenario 1).

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

153. 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 release to one trial site at the DAF Redlands Research Facility in Redland City, Queensland, with a maximum cumulative planting area of 0.1 ha

- limit the duration of the release to between February 2017 and January 2019
- surround the trial site with a fence to exclude large animals
- locate the trial site at least 50 m away from waterways
- treat non-GM potatoes grown on the trial site as if they are GMOs
- deflower the potatoes
- clean equipment after use
- monitor the trial site at least once every 45 days for at least two years after harvest, and destroy any potato plants that may grow, until no volunteers are detected for a continuous one year period
- destroy all GMOs not required for further analysis or future trials
- transport and store GMOs in accordance with the Regulator's guidelines
- not allow GM plant material to be used for human food or animal feed.

3.2 Other risk management considerations

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

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

3.2.1 Applicant suitability

155. 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.

156. On the basis of information submitted by the applicant and records held by the OGTR, the Regulator considers QUT suitable to hold a licence. The licence includes a requirement for the licence holder to inform the Regulator of any information that would affect their suitability.

157. 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

158. QUT is required to submit a contingency plan to the Regulator before planting the GMOs. This plan will detail measures to be undertaken in the event of any unintended presence of the GM potato outside permitted areas.

159. QUT is also required to provide the Regulator with a method to reliably detect the GMOs or the presence of the genetic modifications in a recipient organism. This methodology is required before planting the GMOs.

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

160. The persons covered by the licence are the licence holder and employees, agents or contractors of the licence holder and other persons who are, or have been, engaged or otherwise authorised by the licence holder to undertake any activity in connection with the dealings authorised by the licence. Prior to growing the GMOs, QUT is 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

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

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

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

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

3.2.5 Monitoring for compliance

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

164. 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.

165. 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

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

- biochemical characterisation of the GM potato plants, particularly with respect to the levels of natural toxins
- information regarding the extent of cross-pollination in potato plants under Australian conditions

- information regarding pathways of dispersal and duration of dormancy for potato seeds, particularly under Australian conditions.

Section 5 Conclusions of the RARMP

167. The RARMP concludes that the proposed limited and controlled release of GM potato 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.

168. However, 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, 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[2]

Advice received by the Regulator from prescribed experts, agencies and authorities on the consultation RARMP is summarised below. 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.

Abbreviations: DIR: Dealing involving Intentional Release; **GM**: genetically modified; **RARMP**: Risk Assessment and Risk Management Plan

Sub. No.	Summary of issues raised	Comment
1	Notes that the licence will prohibit the use of the GM plant material in human food or animal feed. Does not have any further comments on the licence application at this stage.	Noted.
2	Supportive of the application as the consultation RARMP indicates that the proposed release poses negligible risks to people or the environment. It is understood that a range of licence conditions would ensure that there is ongoing oversight of the release.	Noted.
3	Agrees with the conclusion of the consultation RARMP that the risk of the proposed limited and controlled release is negligible.	Noted.
	Agrees that the introduced proteins are unlikely to be toxic, as stated in Table 2. Presumably this statement applies to humans and all animals, an issue that needs to be clarified in the RARMP. Discussion of toxicity could be strengthened by noting that only a small number of plant proteins have been associated with toxicity in people, and likely therefore higher organisms such as native animals; none of which are resistance proteins. Agrees that there is uncertainty with respect to altered levels of potato toxins resulting from genetic modification. The altered levels of potato toxins may need to be considered in the risk assessment of any future application for commercial release.	Text has been added to the conclusion of Risk Scenario 1, in Chapter 2 of the RARMP, clarifying that the introduced proteins are unlikely to be toxic or allergenic to people or toxic to animals. Text has been added to the discussion of toxicity in Risk Scenario 1 in Chapter 2, noting that the introduced resistance proteins belong to a plant protein family that is not known to contain members that are toxic to humans or animals. Section 4 of Chapter 3 identifies additional information that may be required to assess any future application for commercial release. This includes characterisation of levels of natural toxins in the GM potatoes.

[2] Prescribed experts, agencies and authorities include the Gene Technology Technical Advisory Committee, State and Territory Governments, relevant local governments, Australian Government agencies and the Minister for the Environment.

Sub. No.	Summary of issues raised	Comment
	Agrees that the genetic modifications are unlikely to lead to weediness in the GM potato lines in Queensland. A future application for commercial release may also need to consider the growing conditions in other Australian states, in particular the ability of the genetic modifications to enhance spread and persistence under different environmental conditions.	Noted. In the event of a future application for commercial release, the Regulator's risk assessment would consider the potential for the GM potatoes to spread and persist in any area of Australia.
	Notes that there is a section in the RARMP for DIR 146 that summarises plant pathogen interactions. For consistency and the provision of the background to disease resistance in plants, the RARMP for DIR 150 would benefit by including a section on plant pathogen interactions.	Text has been added to Section 5.2 of Chapter 1, referring the reader to the introduction to plant-pathogen interactions found in the RARMP for DIR 146.
	Agrees that the likelihood of gene flow to other plants is negligible.	Noted.
4	Supported the Office of the Gene Technology Regulator's conclusion that the dealing DIR 150 poses negligible risk of harm to human health and safety and the environment.	Noted.
5	Agrees with the overall conclusions of the RARMP.	Noted.
	The Regulator should consider clarifying whether a recent search for homologous genes has been undertaken.	Text has been added to Section 6.5 of Chapter 1, describing a search for homologous genes undertaken in January 2017.
	The Regulator should consider clarifying whether any expression analysis has been performed in the glasshouse.	Text has been added to Section 5.4 of Chapter 1 to indicate that the GM plants are screened using the polymerase chain reaction and Southern hybridisation to confirm that single copies of the introduced genes are present, but that the applicant has not provided any quantitative expression analysis data.
	It is unclear why Ruby Lou potatoes are being used as a control.	Text has been added to Section 4.6 of Chapter 1 to indicate that the cultivar Ruby Lou will be used as a non-GM control because these potatoes are naturally resistant to Potato virus X.
	The RARMP highlights that the closest potato farm is approximately 2.5 km from the proposed trial site, but does not consider domestically grown potatoes that may be located closer.	Text has been added to Section 6.4 of Chapter 1, noting that potatoes may be growing in domestic gardens in the residential areas adjoining the research station.
	Suggests clarifying whether the applicant intends to conduct breeding of the GMO.	References to breeding have been removed from Section 3 of Chapter 1 of the RARMP and from Condition 7 of the licence.
	Suggests that dot points 5 and 6 in the summary of licence conditions in Section 3.1.2 of Chapter 3 of the RARMP could appear inconsistent. Point 5 refers to GM and non-GM potatoes, but point 6 refers to GM potatoes only.	The term GM has been removed from dot point 6.

Sub. No.	Summary of issues raised	Comment
	Queries whether the list of reports to be sent to the Regulator in Condition 48 of the draft licence is complete.	Attachment B has been added to the licence. This is a checklist of all documents that must be sent to the Regulator. A note at the end of Condition 48 refers the reader to Attachment B.
6	Has no objection to the issue of a licence for DIR 150.	Noted.