Australian Government
Department of Health, Disability and Ageing
Office of the Gene Technology Regulator

Licence for dealings involving an intentional release of a GMO into the environment

Licence number: DIR 214

Licence holder: The University of Queensland

Trial of a genetically modified (GM) vaccine for the prevention of respiratory disease in horses

Issued: 4 June 2025

Office of the Gene Technology Regulator

Licence conditions

Section 1 Interpretations and Definitions

1. In this licence:

   (a) unless defined otherwise in this licence, words and phrases used in this licence have the same meaning as they do in the Act and the Gene Technology Regulations 2001;

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

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

   (d) expressions used to denote persons generally (such as “person”, “party”, “someone”, “anyone”, “no one”, “one”, “another” and “whoever”), include a body politic or corporate as well as an individual;

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

   (f) where a word or phrase is given a particular meaning, other grammatical forms of that word or phrase have corresponding meanings;

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

2. In this licence:

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

   ‘APVMA’ means the Australian Pesticides and Veterinary Medicines Authority.

   ‘Decontaminate’ (or ***‘Decontamination’***) means, as the case requires, kill the GMOs by one or more of the following methods:

   - chemical treatment;
   - autoclaving;
   - high-temperature incineration; or
     a method approved in writing by the Regulator.

   Note: 'As the case requires' has the effect that, depending on the circumstances, one or more of these techniques may not be appropriate.

   ‘External service provider’ means a person engaged by the licence holder solely in relation to transport, storage and/or disposal of the GMOs, and who is not undertaking any dealings with the GMOs that are not for those purposes.

   ‘GM’ means genetically modified.

   ‘*GMO’* means the genetically modified organisms that are the subject of the dealings authorised by this licence.

   ‘NLRD’ is a Notifiable low risk dealing. Dealings conducted as an NLRD must be assessed by an institutional biosafety committee (IBC) before commencement and must comply with the requirements of the Gene Technology Regulations 2001.

   ‘OGTR’ means the Office of the Gene Technology Regulator.

'Personal information' has the same meaning as in the *Privacy Act 1988*. Personal information means information or an opinion about an identified individual, or an individual who is reasonably identifiable:

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

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

'Primary facility' means an enclosed building within the Trial site which contains animal holding pens.

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

'Regulator' means the Gene Technology Regulator.

'Sample' means any biological material collected from a treated horses for analysis as part of the trial

'Secondary facility' means a fenced paddock within the Trial site.

'Trial site' means the Queensland Animal Biosciences Precinct at The University of Queensland Gatton Campus.

Section 2 General conditions and obligations

Holder of licence

3. The licence holder is The University of Queensland.

Remaining an Accredited Organisation

4. The licence holder must, at all times, remain an accredited organisation.

Validity of licence

5. This licence remains in force until it is suspended, cancelled or surrendered. No dealings with the GMO are authorised during any period of suspension, or after the licence has been cancelled or surrendered.

Note: Although this licence has no expiry date, the duration of preparation and administration of the GMOs is restricted in accordance with Condition 23.

Persons covered by this licence

6. The persons covered by this licence are:

   (a) the licence holder, and any employees, agents or External service providers engaged by the licence holder; and

   (b) the project supervisor(s); and

   (c) other persons who are, or have been, engaged or otherwise authorised by the licence holder or the project supervisor to conduct any of the dealings authorised by this licence.

7. The licence holder must keep a record of all persons covered by this licence, and must keep a record of the contact details of the project supervisor(s) for the licence.

Note: Where External service providers are used, it is sufficient to record the company name and the position or job title of the person(s) conducting the dealing.

8. The licence holder must provide information related to the persons covered by the licence when requested to do so in writing by the Regulator and must provide the information within a time period stipulated by the Regulator.

Description of GMOs covered

9. The licence authorises specified dealings in respect of the GMOs identified and described in **Attachment A**.

Dealings authorised by this licence

10. The licence holder and persons covered by this licence may conduct the following dealings with the GMOs:

    (a) conduct the following experiments with the GMOs:

        i) prepare the GMO for administration to horses;

        ii) administer the GMO to horses by intramuscular injection or intranasal instillation;

        iii) collect Samples from GMO administered horses;

        iv) prepare Samples described in 10(a)iii) for transport;

    (b) transport the GMOs;

    (c) dispose of the GMOs;

    and may possess, supply, use or store the GMO for the purposes of, or in the course of, any of these dealings.

11. Supply of the GMOs for the purposes of dealings by a person or organisation not covered by this licence is only authorised by this licence if the Regulator provides prior written approval to the licence holder.

    Note: For approval to be granted, the receiving person or organisation must have an appropriate authorisation to conduct dealings with the GMOs. This is likely to be a NLRD or a licence issued by the Regulator.

12. This licence does not apply to dealings with the GMOs conducted as an NLRD or pursuant to another authorisation under the Act.

Conditions imposed by the Act

Note: The Act mandates the following 3 conditions.

Informing people of licence conditions (section 63)

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

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

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

    (c) the surrender of the licence.

Monitoring and audits (section 64)

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

Additional information to be given to the Regulator (section 65)

15. The licence holder must immediately inform the Regulator, if they become aware of:

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

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

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

Note 1: For the purposes of this condition:

(a) The licence holder is taken to have become aware of additional information if they were reckless as to whether such information existed; and

(b) The licence holder is taken to have become aware of contraventions, or unintended effects, if they were reckless as to whether such contraventions had occurred, or such unintended effects existed.

Note 2: Contraventions of the licence may occur through the action or inaction of a person.

Note 3: Additional information includes any changes at a Trial site, which might increase the likelihood of unintentional exposure of people or release of the GMO into the environment.

Note 4: An example of informing immediately is contact made at the time of the incident via the OGTR free call phone number 1800 181 030 or OGTR.M&C@health.gov*.*

Informing the Regulator of any material changes of circumstance

16. The licence holder must immediately, by notice in writing, inform the Regulator of:

(a) any relevant conviction of the licence holder occurring after the commencement of this licence;

(b) any revocation or suspension after the commencement of this licence, of a licence or permit held by the licence holder under a law of the Commonwealth, a State or a foreign country, being a law relating to the health and safety of people or the environment;

(c) any event or circumstances occurring after the commencement of this licence that would affect the capacity of the licence holder to meet the conditions in it.

17. The licence holder must provide information related to the licence holder's ongoing suitability to hold a licence when requested to do so in writing by the Regulator, and must provide the information within a time period stipulated by the Regulator.

Further conditions with respect to informing persons covered by the licence

18. If a particular condition, including any variation of it, applies to an External service provider covered by this licence, the licence holder must not permit that person to conduct any dealings unless the person has been informed of the condition, including any variation of it.

Note: Information required under Condition 18 may be provided to External service providers who are engaged solely for storage and transport of the GMO through labelling of the outermost container of the GMOs in accordance with Condition 41(a).

19. If a particular condition, including any variation of it, applies to a person with respect to any dealing, other than to an External service provider, the licence holder must not permit a person covered by this licence to conduct that dealing unless:

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

i) has been informed by the licence holder of the condition and, when applicable, its variation; and

ii) has understood and agreed to be bound by the condition, or its variation; and

iii) has been trained in accordance with sub-condition 19(b) below; and

(b) the licence holder has trained that person in a manner which enables them to conduct the dealings in accordance with the conditions of this licence.

20. The licence holder must notify all persons covered by the licence, from whom Personal information relevant to the administration and/or enforcement of the licence is collected by the licence holder, that such Personal information may be disclosed to the Regulator.

21. The licence holder must ensure that a copy of the licence is readily available to all persons covered by the licence, other than External service providers, who are conducting dealings with the GMO.

Note: The licence may be made available electronically.

Section 3 Limits and control measures

Limits on trials conducted under this licence

22. The GMO may be administered to a maximum of 10 horses.

23. The preparation and administration of the GMO must be completed within 5 years from the date of issuing of the licence.

24. The licence holder must ensure that:

(a) administration of the GMO occurs within the Primary facility;

(b) horses remain in the Primary facility from the first administration of the GMO until at least 7 days after the last administration of the GMO; and

(c) horses have tested negative for the presence of the GMO via nasal swab PCR test before being moved from the Primary facility to the Secondary facility.

(d) a record of testing results must be kept for the duration of the licence and provided to the Regulator upon request.

Note: This licence condition aims to ensure that animals to be relocated do not contain residual episomes from the GMO.

Trial site

25. Access to the Trial site must be restricted to persons authorised by the Licence holder.

26. Signs indicating the presence of the GMO must be displayed at all entrances to the Trial site.

27. The Trial site must be surrounded by a secure fence

28. The Secondary facility must be surrounded by a fence capable of containing horses.

Preparation and administration of the GMOs

29. Administration of the GMO to horses must not commence prior to approval of an Animal Ethics Committee and the APVMA.

30. Preparation and administration of the GMO must be conducted by suitably qualified and trained staff.

31. Persons administering the GMO and collecting Samples must also be trained in horse handling.

32. The licence holder must ensure that horses are properly restrained (*e.g.* with a tether) during;

(a) administration of the GMO

(b) Sample collection which requires sharps

Conditions relating to the conduct of the dealings

33. The licence holder must ensure that each horse administered with the GMO is individually identifiable.

34. Following the first administration of the GMO and for at least 7 days after the last administration, animal excreta and other waste within the primary facility containing the GMO-inoculated animals must be removed from the holding pens daily and decontaminated.

35. Conditions that apply to dealings with GMOs do not apply to:

    (a) nasal swabs collected from horses at least 2 weeks after administration of the GMO;

    (b) blood Samples collected from horses at least 7 days after administration of the GMO; and

    (c) other Samples, materials and waste, that are reasonably expected not to contain the GMO. Upon request from the Regulator, the licence holder must provide a written justification for this expectation.

36. The licence holder must ensure that dealings are only conducted in a manner which:

    (a) does not compromise the health and safety of people; and

    (b) minimises the exposure of persons conducting the dealings to the GMO.

37. The licence holder must ensure that procedures are in place to account for the GMO and GMO inoculated horses from generation to destruction. Records must be made available to the Regulator on request.

38. The licence holder must ensure that GMO-inoculated horses are not used, sold or otherwise disposed of for any purpose which would involve or result in its use as food for humans or feed for animals.

Work practices at Trial sites

39. For the purposes of Condition 36, work practices and behaviours within a Trial site must include, but are not limited to, the following:

    (a) persons preparing or administering the GMO, or collecting blood, or nasal swab Samples that are reasonably expected to contain the GMO must wear personal protective equipment (PPE), including but not limited to overalls, gloves, boots, eye protection and, at a minimum, a surgical face mask

    (b) all work surfaces must be Decontaminated after they have been used for conducting dealings authorised by this licence;

    (c) the Primary facility must be Decontaminated following the final removal of GMO-inoculated horses;

    (d) equipment used for dealings with the GMOs must be Decontaminated after use;

Transport, storage and disposal of the GMOs

40. Unless covered by an NLRD, the licence holder must ensure that transport of the GMOs is conducted only for the purposes of, or in the course of, another dealing permitted by this licence, or for supply in accordance with Condition 11.

41. The licence holder must ensure that transport of the GMO, and storage of the GMO within the trial site, follows these sub-conditions:

    (a) GMOs must be contained within sealed, unbreakable primary and secondary container(s), with the outer packaging labelled to indicate at least:

        i) that it contains GMOs; and

        ii) that it contains biohazardous material as designated by a biohazard label; and

iii) the contact details for the licence holder; and

iv) instructions to notify the licence holder in case of loss or spill of the GMOs; and

(b) the external surface of the primary and secondary container must be Decontaminated prior to and after transport; and

(c) procedures must be in place to ensure that GMOs can be accounted for and that a loss of GMOs during transport or storage or failure of delivery can be detected; and

(d) access to the GMOs is restricted to authorised persons for whom Condition 18 or Condition 19 has been met (i.e. the GMOs are within a locked unit or an area which has restricted access). This includes situations where containers are left for collection in a holding area, or left unattended prior to Decontamination; and

Note: All stored GMOs remain the responsibility of the licence holder.

(e) if the GMO is being transported or stored with a coolant (e.g. dry ice, liquid nitrogen or any other coolant) which will release a gas, a mechanism to allow the escape of the gas must be included. If water ice is used as a coolant then the outer packaging should be constructed so as to prevent any leakage. All containers must be able to withstand the temperatures to which they will be subjected; and

Note: When transporting and storing with coolants, it is preferable for coolants to be used outside of the secondary container.

(f) a consolidated record of all GMOs being stored under this condition is maintained and made available to the Regulator upon request; and

(g) for the purposes of transport entirely within a building, where the GMOs are accompanied by an authorised person for whom Condition 19 has been met, Conditions 41(a)iii), 41(a)iv) and 41(c) do not apply.

Note: This condition does not apply to transport of the GMO to and from the trial site conducted as an NLRD

42. The licence holder must ensure that all GMOs and waste reasonably expected to contain the GMOs are Decontaminated:

(a) prior to disposal, unless the method of disposal is also a method of Decontamination; and

(b) before or upon suspension, cancellation or surrender of the licence, unless covered by another authorisation under the Act, or exported; and

(c) by autoclaving, chemical treatment, high-temperature incineration or any other method approved in writing by the Regulator.

Note: This condition does not apply to dealings conducted as an NLRD (see Condition 40)

43. Where transport is conducted by External service providers for the purpose of destruction, the licence holder must ensure that the GMO, or waste reasonably expected to contain the GMO, enters the clinical waste stream for Decontamination via autoclaving or high-temperature incineration.

Note: 1: This condition does not apply to dealings conducted as an NLRD (see Condition 40)

Note 2: In the event of a spill during transport by an External service provider, compliance with relevant State or Territory legislation and regulations to manage clinical or biohazardous spills is sufficient.

Contingency plans

44. The licence holder must ensure that any person exposed to the GMOs is offered prompt medical attention. The clinician must be provided with any relevant information about the GMO.

45. If there is a spill or an unintentional release of the GMOs at the Trial site, the following measures must be implemented:

    (a) the GMOs must be contained to prevent further dispersal; and

    (b) persons cleaning up the GMO must wear appropriate PPE as specified in condition 39(a); and

    (c) the exposed area must be Decontaminated with an appropriate chemical disinfectant effective against the GMO; and

    (d) any material used to clean up the spill or PPE worn during clean-up of the spill must be Decontaminated; and

    (e) the licence holder must be notified as soon as reasonably practicable.

46. If there is an unintentional release of the GMOs, the licence holder must ensure that the following persons are notified as soon as reasonably possible:

    (a) the relevant IBC; and

    (b) the Regulator.

47. If a GMO-inoculated horse escapes its containment, the animal must be captured and returned to the appropriate facility within the Trial site, and the licence holder must notify the Regulator immediately.

Section 4 Reporting and Documentation

Note: The following licence conditions are imposed to demonstrate compliance with other conditions and facilitate monitoring of compliance by staff of the OGTR. Notices and reports may be emailed to OGTR.M&C@health.gov.au. A summary of notification and reporting requirements is provided at ***Attachment B****.*

48. At least 14 days prior to first administering the GMO at the Trial site, or a timeframe agreed to in writing by the Regulator, the licence holder must notify the Regulator, in writing, of:

    (a) the commencement of the trial; and

    (b) the proposed reporting structure for the trial at the site and how the reporting structure enables the licence holder to become aware of all reportable events including but not limited to Conditions 15, 16, 49 and 50;

    (c) details of how the persons covered by the licence (for that type of dealing) will be informed of licence conditions applicable to them and how they will be trained to safely conduct the dealings;

    (d) the expected date of first administration;

Note: For the purpose of finding out whether the Act has been complied with, an OGTR inspector may, if entry is at a reasonable time, enter a facility occupied by the licence holder or a person covered by the licence and exercise monitoring powers.

49. The licence holder must notify the Regulator, in writing, of the end of the trial, no later than 30 days after:

    (a) the final dose being administered; or

    (b) the decision that no further horses will be administered with the GMO.

50. The licence holder must inform the Regulator as soon as reasonably possible:

    (a) in the event of a loss or spill of the GMO;

    (b) in the event of the exposure of a person, or animals other than the horses being administered, to the GMO.

51. Upon request from the Regulator, the licence holder must provide any signed records or documentation collected under a condition of this licence, within a time period stipulated by the Regulator

ATTACHMENT A

DIR No: 214

Title: Trial of a genetically modified (GM) vaccine for the prevention of respiratory disease in horses

GMO Description

GMOs covered by this licence

The GM vaccine contains a replication defective Human Adenovirus serotype 5 modified by the deletion or introduction of the genes or genetic elements listed in Table 1 below.

Parent Organism

Common Name: Human Adenovirus

Scientific Name: Human Adenovirus C, serotype 5

Modified traits

Category: Veterinary

Description: The GMO has deletions of the E1 and E3 regions of its genome which prevent replication and immune evasion respectively. It includes an insertion of the virulence-associated protein A (VapA) gene from *Rhodococcus equi* under the CMVie promoter.

Table 1. Nucleic acid responsible for conferring the modified traits

Genetic modifications	
Source, identity, nature of modification	**Modified trait description**
• Deletion of viral early-transcribed region 1 (E1)	to render virus replication incompetent.
• Deletion of viral early-transcribed region 3 (E3)	to render the virus unable to evade the host immune system.
• Insertion of VapA gene from *R. equi*	to express VapA protein

Route of administration of the GMOs

Intramuscular injection or via intranasal instillation to horses.

Attachment B – Summary of reporting requirements*

Prior to the commencement of the trial	**Condition**	**Timeframe for reporting**
The commencement of the trial	48(a)	At least 14 days prior to the first administration of the GMO at each trial site.
Details of how the persons covered by the licence will be informed of licence conditions applicable to them and how they will be trained to safely conduct the dealings	48(c)	
Expected date of first administration at trial site	48(d)	
The proposed reporting structure for the trial	48(b)	
Information to be provided at any time during the trial	**Condition**	**Timeframe for reporting**
Any additional information related to the health and safety of people and the environment associated with the dealings covered by the licence, or any unintended effects of the dealings authorised by the licence	15(a),(c)	As soon as the licence holder becomes aware
Information related to any contravention of the licence by a person covered by the licence	15(b)	As soon as the licence holder becomes aware
Any relevant conviction of the licence holder	16(a)	Immediately
Any revocation or suspension of a licence or permit held by the licence holder under a law of the Commonwealth, a State or a foreign country	16(b)	Immediately
Any event or circumstances that would impact the licence holder capacity to meet the licence conditions	16(c)	Immediately
Any unintentional release of the GMO via escaped horses.	46	As soon as reasonably possible after becoming aware of the event
In the event of exposure of a person or animal other than the horses in the trial to the GMO	50(b)	Immediately
In the event of loss or spill of the GMO	50(a)	Immediately
Provide notification to the Regulator, in writing, of the final GMO administration.	49(a)	Within 30 days of the decision to cease GMO administration at that particular trial site.
Information to be provided on request by the Regulator		
Information related to the persons covered by the licence	7	Within a timeframe stipulated by the Regulator
Information related to the licence holder's ongoing suitability to hold a licence	17	Within a timeframe stipulated by the Regulator
Copies of signed and dated statements and training records	19	Within a timeframe stipulated by the Regulator
A consolidated record of all GMOs being stored	41(f)	Within a timeframe stipulated by the Regulator
Any signed records or documentation collected under a condition of this licence	51	Within a timeframe stipulated by the Regulator

***** Notifications and documents to be sent to OGTR.M&C@health.gov